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|  |  |
| --- | --- |
| **InxMed (Shanghai) Co., Ltd.  Protocol No. IN10018-602** |  |

**Table 14.1.1.3 Subject Disposition - Phase II part 2 - CRC (All Subjects Screened)**

|  | Treatment Group n (%) | Control Group n (%) |
| --- | --- | --- |
| Enrolled | 5 | 5 |
|  | | |
| Subject Who Received at Least One Dose of Study Intervention | 5 (100) | 5 (100) |
|  | | |
| Treatment Discontinuation | 0 | 1 (20.0) |
| Disease Progression defined by RECIST 1.1 | 0 | 1 (20.0) |
|  | | |
| Study completion/withdrawal | 0 | 1 (20.0) |
| Death | 0 | 1 (20.0) |
|  | | |
| Full Analysis Set (FAS) | 5 (100) | 5 (100) |
| Safety Analysis Set (SAS) | 5 (100) | 5 (100) |
| Response Evaluation Set (RES) | 2 (40.0) | 3 (60.0) |

FAS: The FAS will include all subjects who had been assigned/ initiated study intervention.

ITT: The ITT will include all randomized subjects regardless of receiving the assigned study treatment or not.

SAS: The SAS will include all subjects who received at least 1 dose of investigational drug (including D-1553 or IN10018).

RES: The RES will include all subjects who started treatment cycle 1 and had adequate baseline tumor assessment and at least 1 follow-up tumor assessment which is considered evaluable for anti-tumor efficacy based on RECIST v1.1.

Percentages are based on the number of the subjects enrolled in each respective group.

Source Data: Listing 16.2.1.1, 16.2.1.2, 16.2.3.1

|  |  |  |
| --- | --- | --- |
| Program: t-disp.sas | DCO: 27APR2024 | Executed: 07JUL2024 20:34 |

|  |  |
| --- | --- |
| **InxMed (Shanghai) Co., Ltd.  Protocol No. IN10018-602** |  |

**Table 14.1.2.3 Demographics - Phase II part 2 - CRC (Full Analysis Set)**

|  | Treatment Group (N = 5) | Control Group (N = 5) |
| --- | --- | --- |
| Age (years) |  |  |
| n | 5 | 5 |
| Mean (STD) | 50.2 (16.35) | 66.6 (5.94) |
| Median (Q1, Q3) | 54.0 (48.0, 57.0) | 63.0 (63.0, 72.0) |
| Min, Max | 24, 68 | 61, 74 |
|  | | |
| Sex, n (%) |  |  |
| Male | 1 (20.0) | 1 (20.0) |
| Female | 4 (80.0) | 4 (80.0) |
|  | | |
| Ethnicity, n (%) |  |  |
| Ethnic Han | 5 (100) | 4 (80.0) |
| Other | 0 | 1 (20.0) |
|  | | |
| Race, n (%) |  |  |
| American Indian or Alaska Native | 0 | 0 |
| Asian | 5 (100) | 5 (100) |
| Black or African American | 0 | 0 |
| Native Hawaiians or Other Pacific Islanders | 0 | 0 |
| White | 0 | 0 |
| Other | 0 | 0 |
|  | | |
| Height (cm) |  |  |
| n | 4 | 5 |
| Mean (STD) | 160.38 (4.644) | 157.50 (12.000) |
| Median (Q1, Q3) | 161.50 (157.00, 163.75) | 153.00 (148.00, 164.50) |
| Min, Max | 154.0, 164.5 | 147.0, 175.0 |
|  | | |
| Weight at Baseline (kg) |  |  |
| n | 4 | 5 |
| Mean (STD) | 60.68 (7.013) | 63.28 (11.873) |
| Median (Q1, Q3) | 57.80 (56.65, 64.70) | 64.60 (59.70, 72.10) |
| Min, Max | 56.0, 71.1 | 45.0, 75.0 |
|  | | |
| BMI at Baseline (kg/m2) |  |  |
| n | 4 | 5 |
| Mean (STD) | 23.598 (2.5697) | 25.520 (4.1412) |
| Median (Q1, Q3) | 23.229 (21.525, 25.672) | 27.627 (23.543, 27.716) |
| Min, Max | 21.17, 26.76 | 19.22, 29.49 |

BMI at Baseline (kg/m2) = Weight at Baseline (kg) / [Height (cm)/100]2.

Percentages are based on the number of subjects of each respective group in the Full Analysis Set.

Source Data: Listing 16.2.4.1

|  |  |  |
| --- | --- | --- |
| Program: t-demo.sas | DCO: 27APR2024 | Executed: 07JUL2024 20:34 |

|  |  |
| --- | --- |
| **InxMed (Shanghai) Co., Ltd.  Protocol No. IN10018-602** |  |

**Table 14.1.3.3 Baseline Disease Characteristics - Phase II part 2 - CRC (Full Analysis Set)**

|  | Treatment Group (N = 5) | Control Group (N = 5) |
| --- | --- | --- |
| Clinical Diagnosis, n (%) |  |  |
| Colorectal cancer | 5 (100) | 5 (100) |
| Other | 0 | 0 |
|  | | |
| CRC Primary Tumor Location, n (%) |  |  |
| Ileocecum | 0 | 0 |
| Ascending Colon | 1 (20.0) | 1 (20.0) |
| Transverse Colon | 0 | 0 |
| Descending Colon | 1 (20.0) | 1 (20.0) |
| Sigmoid Colon | 1 (20.0) | 0 |
| Rectum | 2 (40.0) | 2 (40.0) |
| Anus | 0 | 0 |
| Other | 0 | 1 (20.0) |
|  | | |
| Time from Initial Clinical Diagnosis to ICF (months) |  |  |
| n | 5 | 5 |
| Mean (STD) | 16.01 (10.400) | 15.85 (5.376) |
| Median (Q1, Q3) | 12.32 (8.90, 26.71) | 13.44 (13.11, 21.03) |
| Min, Max | 4.8, 27.3 | 9.7, 22.0 |
|  | | |
| Histological Type, n (%) |  |  |
| Adenocarcinoma | 5 (100) | 5 (100) |
| Squamous Carcinoma | 0 | 0 |
| Neuroendocrine Carcinoma | 0 | 0 |
| Large Cell Carcinoma | 0 | 0 |
| Adenosquamous Carcinoma | 0 | 0 |
| Sarcomatoid Carcinoma | 0 | 0 |
| Unclassified cancer | 0 | 0 |
| Other | 0 | 0 |
|  | | |
| Histological Grade, n (%) |  |  |
| Highly differentiated | 0 | 0 |
| Moderately differentiated | 0 | 4 (80.0) |
| Poorly differentiated | 0 | 0 |
| Undifferentiated | 0 | 0 |
| Not Evaluate | 0 | 0 |
| Unknown | 1 (20.0) | 0 |
| Other | 4 (80.0) | 1 (20.0) |
|  | | |
| Clinical Stage at Initial Diagnosis, n (%) |  |  |
| Stage I | 0 | 0 |
| Stage IA | 0 | 0 |
| Stage IB | 0 | 0 |
| Stage IIA | 0 | 0 |
| Stage IIB | 0 | 0 |
| Stage IIC | 1 (20.0) | 0 |
| Stage IIIA | 0 | 0 |
| Stage IIIB | 1 (20.0) | 1 (20.0) |
| Stage IIIC | 0 | 0 |
| Stage IVA | 0 | 0 |
| Stage IVB | 1 (20.0) | 0 |
| Stage IVC | 0 | 0 |
| Not Evaluate | 0 | 0 |
| Unknown | 1 (20.0) | 3 (60.0) |
| Other | 1 (20.0) | 1 (20.0) |
|  | | |
| T Staging at Initial Diagnosis, n (%) |  |  |
| Tx | 0 | 1 (20.0) |
| T0 | 0 | 0 |
| Tis | 0 | 0 |
| T1a | 0 | 0 |
| T1b | 0 | 0 |
| T1c | 0 | 0 |
| T2a | 0 | 0 |
| T2b | 0 | 0 |
| T3 | 1 (20.0) | 2 (40.0) |
| T4 | 1 (20.0) | 0 |
| T4a | 2 (40.0) | 0 |
| T4b | 1 (20.0) | 0 |
| Not Evaluate | 0 | 0 |
| Unknown | 0 | 2 (40.0) |
| Other | 0 | 0 |
|  | | |
| N Staging at Initial Diagnosis, n (%) |  |  |
| Nx | 1 (20.0) | 0 |
| N0 | 1 (20.0) | 1 (20.0) |
| N1 | 0 | 1 (20.0) |
| N2 | 2 (40.0) | 0 |
| N3 | 0 | 0 |
| Not Evaluate | 0 | 0 |
| Unknown | 0 | 2 (40.0) |
| Other | 1 (20.0) | 1 (20.0) |
|  | | |
| M Staging at Initial Diagnosis, n (%) |  |  |
| Mx | 1 (20.0) | 1 (20.0) |
| M0 | 2 (40.0) | 1 (20.0) |
| M1a | 0 | 0 |
| M1b | 1 (20.0) | 0 |
| M1c | 0 | 0 |
| Not Evaluate | 0 | 0 |
| Unknown | 0 | 2 (40.0) |
| Other | 1 (20.0) | 1 (20.0) |
|  | | |
| Clinical Stage at Study Entry, n (%) |  |  |
| Stage I | 0 | 0 |
| Stage IA | 0 | 0 |
| Stage IB | 0 | 0 |
| Stage IIA | 0 | 0 |
| Stage IIB | 0 | 0 |
| Stage IIC | 0 | 0 |
| Stage IIIA | 0 | 0 |
| Stage IIIB | 0 | 0 |
| Stage IIIC | 0 | 0 |
| Stage IVA | 2 (40.0) | 2 (40.0) |
| Stage IVB | 2 (40.0) | 2 (40.0) |
| Stage IVC | 1 (20.0) | 1 (20.0) |
| Not Evaluate | 0 | 0 |
| Unknown | 0 | 0 |
| Other | 0 | 0 |
|  | | |
| T Staging at Study Entry, n (%) |  |  |
| Tx | 2 (40.0) | 2 (40.0) |
| T0 | 2 (40.0) | 1 (20.0) |
| Tis | 0 | 0 |
| T1a | 0 | 0 |
| T1b | 0 | 0 |
| T1c | 0 | 0 |
| T2a | 0 | 0 |
| T2b | 0 | 0 |
| T3 | 0 | 0 |
| T4 | 1 (20.0) | 0 |
| T4a | 0 | 0 |
| T4b | 0 | 1 (20.0) |
| Not Evaluate | 0 | 0 |
| Unknown | 0 | 1 (20.0) |
| Other | 0 | 0 |
|  | | |
| N Staging at Study Entry, n (%) |  |  |
| Nx | 2 (40.0) | 1 (20.0) |
| N0 | 1 (20.0) | 3 (60.0) |
| N1 | 0 | 0 |
| N2 | 1 (20.0) | 1 (20.0) |
| N3 | 0 | 0 |
| Not Evaluate | 0 | 0 |
| Unknown | 1 (20.0) | 0 |
| Other | 0 | 0 |
|  | | |
| M Staging at Study Entry, n (%) |  |  |
| Mx | 0 | 0 |
| M0 | 0 | 0 |
| M1a | 2 (40.0) | 2 (40.0) |
| M1b | 2 (40.0) | 2 (40.0) |
| M1c | 1 (20.0) | 1 (20.0) |
| Not Evaluate | 0 | 0 |
| Unknown | 0 | 0 |
| Other | 0 | 0 |
|  | | |
| Metastases, n (%) |  |  |
| Yes | 5 (100) | 5 (100) |
| No | 0 | 0 |
|  | | |
| Sites of Metastases at study entry, n (%) |  |  |
| Lymph Node | 2 (40.0) | 3 (60.0) |
| Bone | 1 (20.0) | 0 |
| Adrenal | 0 | 0 |
| Brain | 0 | 0 |
| Liver | 2 (40.0) | 3 (60.0) |
| Lung | 3 (60.0) | 3 (60.0) |
| Peritoneum | 1 (20.0) | 1 (20.0) |
| Mediastinum | 0 | 0 |
| Head and neck | 0 | 0 |
| Pericardium | 0 | 0 |
| Pleura | 1 (20.0) | 0 |
| Spleen | 0 | 0 |
| Pancreas | 0 | 0 |
| Kidney | 0 | 0 |
| Uterus and accessories | 0 | 0 |
| Intestines | 0 | 0 |
| Skin | 0 | 0 |
| Other | 2 (40.0) | 2 (40.0) |
|  | | |
| Number of metastatic organs at study entry, n (%) |  |  |
| One | 2 (40.0) | 2 (40.0) |
| Two | 1 (20.0) | 1 (20.0) |
| Three | 0 | 1 (20.0) |
| Four | 1 (20.0) | 0 |
| Five | 1 (20.0) | 1 (20.0) |
| Six | 0 | 0 |
| More | 0 | 0 |
|  | | |
| Smoking History, n (%) |  |  |
| Never | 4 (80.0) | 4 (80.0) |
| Former | 1 (20.0) | 1 (20.0) |
| Current | 0 | 0 |
|  | | |
| Number of cigarettes per day (cigarettes/day) |  |  |
| n | 1 | 1 |
| Mean (STD) | 60.0 (NA) | 8.0 (NA) |
| Median (Q1, Q3) | 60.0 (60.0, 60.0) | 8.0 (8.0, 8.0) |
| Min, Max | 60, 60 | 8, 8 |
|  | | |
| Total years of smoking (years) |  |  |
| n | 1 | 1 |
| Mean (STD) | 10.0 (NA) | 40.0 (NA) |
| Median (Q1, Q3) | 10.0 (10.0, 10.0) | 40.0 (40.0, 40.0) |
| Min, Max | 10, 10 | 40, 40 |
|  | | |
| Years since smoking cessation (Years) |  |  |
| n | 1 | 1 |
| Mean (STD) | 0.00 (NA) | 1.22 (NA) |
| Median (Q1, Q3) | 0.00 (0.00, 0.00) | 1.22 (1.22, 1.22) |
| Min, Max | 0.00, 0.00 | 1.22, 1.22 |
|  | | |
| Baseline ECOG Performance, n (%) |  |  |
| 0 | 0 | 0 |
| 1 | 5 (100) | 5 (100) |
|  | | |
| Baseline PD-L1 |  |  |
| Yes | 3 (60.0) | 0 |
| <10%\* | 3 (100) | 0 |
| ≥10%\* | 0 | 0 |
| No | 2 (40.0) | 5 (100) |
|  | | |
| Baseline TMB |  |  |
| Yes | 3 (60.0) | 0 |
| <10mut/Mb# | 2 (66.7) | 0 |
| ≥10mut/Mb# | 1 (33.3) | 0 |
| No | 2 (40.0) | 5 (100) |
|  | | |
| KRAS G12C Mutation, n (%) |  |  |
| Negative | 0 | 0 |
| Positive | 5 (100) | 5 (100) |
| Not Done | 0 | 0 |
| Other | 0 | 0 |
|  | | |
| KRAS G12C Mutation Ratio (%) |  |  |
| n | 3 | 4 |
| Mean (STD) | 22.323 (9.6153) | 24.343 (11.3951) |
| Median (Q1, Q3) | 24.000 (11.980, 30.990) | 26.100 (14.935, 33.750) |
| Min, Max | 11.98, 30.99 | 10.77, 34.40 |
|  | | |
| STK11 Mutation, n (%) |  |  |
| Negative | 3 (60.0) | 1 (20.0) |
| Positive | 0 | 0 |
| Not Done | 2 (40.0) | 4 (80.0) |
| Other | 0 | 0 |
|  | | |
| Sum of the Diameters across Target Lesions at Baseline (mm) |  |  |
| n | 5 | 5 |
| Mean (STD) | 42.014 (27.7510) | 80.928 (51.3395) |
| Median (Q1, Q3) | 35.600 (26.370, 55.000) | 71.000 (38.740, 106.800) |
| Min, Max | 10.60, 82.50 | 32.20, 155.90 |
|  | | |
| Non-Target Lesions Existed, n (%) |  |  |
| Yes | 5 (100) | 4 (80.0) |
| No | 0 | 1 (20.0) |

Percentages are based on the number of subjects of each respective group in the Full Analysis Set.

\* Percentages are based on the number of subjects who had baseline PD-L1 Test.

# Percentages are based on the number of subjects who had baseline TMB Test.

Time from initial Tumor Diagnosis to ICF (months) = (Date of Informed Consent – Date of tumor diagnosis + 1) / 30.4375.

Years since smoking cessation (years) = (Date of Informed Consent – Date of last smoking +1) / 365.25.

Source Data: Listing 16.2.4.2.3.1, 16.2.4.2.3.2

|  |  |  |
| --- | --- | --- |
| Program: t-base.sas | DCO: 27APR2024 | Executed: 07JUL2024 20:34 |

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| --- | --- |
| **InxMed (Shanghai) Co., Ltd.  Protocol No. IN10018-602** |  |

**Table 14.1.4.5 Prior Anti-cancer Therapy - Phase II part 2 - CRC (Safety Analysis Set)**

|  | Treatment Group (N = 5) n (%) | Control Group (N = 5) n (%) |
| --- | --- | --- |
| Subjects with at least one Prior Anti-cancer Therapy | 5 (100) | 5 (100) |
|  | | |
| Systemic | 5 (100) | 5 (100) |
| Treatment line\* |  |  |
| Neoadjuvant | 2 (40.0) | 1 (20.0) |
| Adjuvant | 1 (20.0) | 1 (20.0) |
| First-line treatment | 4 (80.0) | 5 (100) |
| First-line maintain | 0 | 0 |
| Second-line treatment | 3 (60.0) | 4 (80.0) |
| Second-line maintain | 0 | 0 |
| Third-line treatment | 0 | 2 (40.0) |
| Third-line maintain | 0 | 0 |
| >Third-line treatment | 0 | 0 |
| Other | 0 | 0 |
|  | | |
| Maximum Treatment line\* |  |  |
| Neoadjuvant | 0 | 0 |
| Adjuvant | 0 | 0 |
| First-line treatment | 2 (40.0) | 1 (20.0) |
| First-line maintain | 0 | 0 |
| Second-line treatment | 3 (60.0) | 2 (40.0) |
| Second-line maintain | 0 | 0 |
| Third-line treatment | 0 | 2 (40.0) |
| Third-line maintain | 0 | 0 |
| >Third-line treatment | 0 | 0 |
|  | | |
| Treatment Type\* |  |  |
| Chemotherapy | 5 (100) | 5 (100) |
| Immunotherapy | 1 (20.0) | 2 (40.0) |
| Targeted therapy | 4 (80.0) | 4 (80.0) |
| Endocrine therapy | 0 | 0 |
| Chinese herbal therapy | 0 | 0 |
| Other | 0 | 1 (20.0) |
|  | | |
| Radiotherapy | 0 | 1 (20.0) |
|  | | |
| Surgery | 4 (80.0) | 4 (80.0) |
|  | | |
| Other | 2 (40.0) | 1 (20.0) |

Percentages are based on the number of subjects of each respective group in the Safety Analysis Set.

\*Percentages are based on the number of Systemic subjects of each respective group in the Safety Analysis Set.

Source Data: Listing 16.2.4.7.1, 16.2.4.7.2, 16.2.4.7.3, 16.2.4.7.4

|  |  |  |
| --- | --- | --- |
| Program: t-cm-anti.sas | DCO: 27APR2024 | Executed: 07JUL2024 20:34 |

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| --- | --- |
| **InxMed (Shanghai) Co., Ltd.  Protocol No. IN10018-602** |  |

**Table 14.1.4.6 Summary of Prior Systemic Anti-cancer Therapy by ATC Classification 2nd Level and Preferred Name - Phase II part 2 - CRC (Safety Analysis Set)**

| ATC Classification 2nd Level  Preferred Name | Treatment Group (N = 5) n (%) | Control Group (N = 5) n (%) |
| --- | --- | --- |
| Subjects with at least one Prior Systemic Anti-cancer Therapy | 5 (100) | 5 (100) |
|  | | |
| ANTINEOPLASTIC AGENTS | 5 (100) | 5 (100) |
| CAPECITABINE | 5 (100) | 3 (60.0) |
| BEVACIZUMAB | 4 (80.0) | 4 (80.0) |
| OXALIPLATIN | 4 (80.0) | 5 (100) |
| IRINOTECAN | 3 (60.0) | 3 (60.0) |
| FLUOROURACIL | 1 (20.0) | 4 (80.0) |
| IRINOTECAN HYDROCHLORIDE | 1 (20.0) | 0 |
| REGORAFENIB | 1 (20.0) | 1 (20.0) |
| TISLELIZUMAB | 1 (20.0) | 1 (20.0) |
| RALTITREXED | 0 | 1 (20.0) |
| SINTILIMAB | 0 | 1 (20.0) |
| TRIFLURIDINE | 0 | 1 (20.0) |
|  | | |
| ALL OTHER THERAPEUTIC PRODUCTS | 1 (20.0) | 4 (80.0) |
| CALCIUM FOLINATE | 1 (20.0) | 4 (80.0) |
| CALCIUM LEVOFOLINATE | 0 | 1 (20.0) |
|  | | |
| Uncoded | 1 (20.0) | 0 |
| ~OXALIPLATIN | 1 (20.0) | 0 |

Prior systemic anti-cancer therapy are coded with WHODrug Global-B3 202203.

Percentages are based on the number of subjects of each respective group in the Safety Analysis Set.

Source Data: Listing 16.2.4.7.1

|  |  |  |
| --- | --- | --- |
| Program: t-cm-soc-pt.sas | DCO: 27APR2024 | Executed: 08JUL2024 17:25 |

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| --- | --- |
| **InxMed (Shanghai) Co., Ltd.  Protocol No. IN10018-602** |  |

**Table 14.1.5.3 Summary of Medical History by SOC and PT - Phase II part 2 - CRC (Safety Analysis Set)**

| System Organ Class  Preferred Term | Treatment Group (N = 5) n (%) | Control Group (N = 5) n (%) |
| --- | --- | --- |
| Subjects with at least one Medical History | 4 (80.0) | 5 (100) |
|  | | |
| Investigations | 4 (80.0) | 2 (40.0) |
| Blood alkaline phosphatase increased | 2 (40.0) | 1 (20.0) |
| Fibrin D dimer increased | 2 (40.0) | 1 (20.0) |
| Gamma-glutamyltransferase increased | 2 (40.0) | 2 (40.0) |
| Platelet count decreased | 2 (40.0) | 0 |
| Aspartate aminotransferase increased | 1 (20.0) | 1 (20.0) |
| Blood bilirubin increased | 1 (20.0) | 1 (20.0) |
| C-reactive protein increased | 1 (20.0) | 1 (20.0) |
| Low density lipoprotein increased | 1 (20.0) | 0 |
| Alanine aminotransferase increased | 0 | 1 (20.0) |
| Hepatitis B DNA increased | 0 | 1 (20.0) |
| Lymphocyte count decreased | 0 | 1 (20.0) |
| Neutrophil count increased | 0 | 1 (20.0) |
| Serum amyloid A protein increased | 0 | 1 (20.0) |
|  | | |
| Metabolism and nutrition disorders | 3 (60.0) | 4 (80.0) |
| Hypoalbuminaemia | 2 (40.0) | 1 (20.0) |
| Hypercholesterolaemia | 1 (20.0) | 1 (20.0) |
| Hypertriglyceridaemia | 1 (20.0) | 1 (20.0) |
| Hyponatraemia | 1 (20.0) | 1 (20.0) |
| Decreased appetite | 0 | 1 (20.0) |
| Diabetes mellitus | 0 | 1 (20.0) |
| Hyperglycaemia | 0 | 1 (20.0) |
| Hyperlipidaemia | 0 | 1 (20.0) |
| Hypokalaemia | 0 | 1 (20.0) |
|  | | |
| Blood and lymphatic system disorders | 2 (40.0) | 2 (40.0) |
| Anaemia | 2 (40.0) | 2 (40.0) |
| Leukocytosis | 0 | 1 (20.0) |
|  | | |
| Gastrointestinal disorders | 2 (40.0) | 2 (40.0) |
| Abdominal pain | 1 (20.0) | 0 |
| Constipation | 1 (20.0) | 1 (20.0) |
| Haematochezia | 1 (20.0) | 0 |
| Proctalgia | 1 (20.0) | 0 |
| Abdominal pain lower | 0 | 1 (20.0) |
| Dental caries | 0 | 1 (20.0) |
| Nausea | 0 | 1 (20.0) |
|  | | |
| Cardiac disorders | 1 (20.0) | 1 (20.0) |
| Sinus bradycardia | 1 (20.0) | 0 |
| Atrioventricular block first degree | 0 | 1 (20.0) |
|  | | |
| Eye disorders | 1 (20.0) | 4 (80.0) |
| Cataract | 1 (20.0) | 4 (80.0) |
| Pinguecula | 0 | 1 (20.0) |
| Pterygium | 0 | 1 (20.0) |
| Refraction disorder | 0 | 1 (20.0) |
|  | | |
| General disorders and administration site conditions | 1 (20.0) | 1 (20.0) |
| Oedema peripheral | 1 (20.0) | 0 |
| Fatigue | 0 | 1 (20.0) |
|  | | |
| Musculoskeletal and connective tissue disorders | 1 (20.0) | 3 (60.0) |
| Back pain | 1 (20.0) | 1 (20.0) |
| Arthralgia | 0 | 1 (20.0) |
| Groin pain | 0 | 1 (20.0) |
| Pain in extremity | 0 | 1 (20.0) |
|  | | |
| Renal and urinary disorders | 1 (20.0) | 1 (20.0) |
| Proteinuria | 1 (20.0) | 1 (20.0) |
| Renal atrophy | 0 | 1 (20.0) |
|  | | |
| Vascular disorders | 1 (20.0) | 2 (40.0) |
| Hypertension | 1 (20.0) | 2 (40.0) |
|  | | |
| Hepatobiliary disorders | 0 | 2 (40.0) |
| Hepatic steatosis | 0 | 1 (20.0) |
| Ocular icterus | 0 | 1 (20.0) |
|  | | |
| Infections and infestations | 0 | 1 (20.0) |
| Urinary tract infection | 0 | 1 (20.0) |
|  | | |
| Injury, poisoning and procedural complications | 0 | 1 (20.0) |
| Ankle fracture | 0 | 1 (20.0) |
|  | | |
| Nervous system disorders | 0 | 1 (20.0) |
| Hypoaesthesia | 0 | 1 (20.0) |
|  | | |
| Psychiatric disorders | 0 | 1 (20.0) |
| Insomnia | 0 | 1 (20.0) |
|  | | |
| Uncoded | 1 (20.0) | 0 |
| ~WEAK | 1 (20.0) | 0 |

Medical history are coded with MedDRA 25.0.

Percentages are based on the number of subjects of each respective group in the Safety Analysis Set.

Source Data: Listing 16.2.4.8

|  |  |  |
| --- | --- | --- |
| Program: t-mh-soc-pt.sas | DCO: 27APR2024 | Executed: 07JUL2024 20:34 |

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| **InxMed (Shanghai) Co., Ltd.  Protocol No. IN10018-602** |  |

**Table 14.1.6.1.3 Summary of Prior Medications by ATC Classification 2nd Level and Preferred Name - Phase II part 2 - CRC (Safety Analysis Set)**

| ATC Classification 2nd Level  Preferred Name | Treatment Group (N = 5) n (%) | Control Group (N = 5) n (%) |
| --- | --- | --- |
| Subjects with at Least One Prior Medications | 2 (40.0) | 1 (20.0) |
|  | | |
| BILE AND LIVER THERAPY | 1 (20.0) | 0 |
| POLYENE PHOSPHATIDYLCHOLINE | 1 (20.0) | 0 |
|  | | |
| DRUGS FOR TREATMENT OF BONE DISEASES | 1 (20.0) | 0 |
| DENOSUMAB | 1 (20.0) | 0 |
|  | | |
| IMMUNOSTIMULANTS | 1 (20.0) | 0 |
| LEUCOGEN | 1 (20.0) | 0 |
| SANGUISORBA OFFICINALIS ROOT | 1 (20.0) | 0 |
|  | | |
| ANTIBACTERIALS FOR SYSTEMIC USE | 0 | 1 (20.0) |
| LEVOFLOXACIN HYDROCHLORIDE | 0 | 1 (20.0) |
|  | | |
| CALCIUM CHANNEL BLOCKERS | 0 | 1 (20.0) |
| AMLODIPINE BESILATE | 0 | 1 (20.0) |

Prior medications are defined as the medication taken exclusively before the first administration of D-1553/IN10018 (i.e., stop before the first administration of D-1553/IN10018).

Prior medications are coded with WHODrug Global-B3 202203.

Percentages are based on the number of subjects of each respective group in the Safety Analysis Set.

Source Data: Listing 16.2.4.9

|  |  |  |
| --- | --- | --- |
| Program: t-cm-soc-pt.sas | DCO: 27APR2024 | Executed: 08JUL2024 17:25 |

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| **InxMed (Shanghai) Co., Ltd.  Protocol No. IN10018-602** |  |

**Table 14.1.6.2.3 Summary of Concomitant Medications by ATC Classification 2nd Level and Preferred Name - Phase II part 2 - CRC (Safety Analysis Set)**

| ATC Classification 2nd Level  Preferred Name | Treatment Group (N = 5) n (%) | Control Group (N = 5) n (%) |
| --- | --- | --- |
| Subjects with at least one Concomitant Medications | 5 (100) | 3 (60.0) |
|  | | |
| ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATORY/ANTIINFECTIVE AGENTS | 4 (80.0) | 0 |
| MONTMORILLONITE | 3 (60.0) | 0 |
| LOPERAMIDE HYDROCHLORIDE | 2 (40.0) | 0 |
| BERBERINE HYDROCHLORIDE | 1 (20.0) | 0 |
| BIFIDOBACTERIUM LONGUM;ENTEROCOCCUS FAECALIS;LACTOBACILLUS ACIDOPHILUS | 1 (20.0) | 0 |
|  | | |
| ANTITHROMBOTIC AGENTS | 2 (40.0) | 0 |
| ENOXAPARIN SODIUM | 1 (20.0) | 0 |
| SODIUM FERULATE | 1 (20.0) | 0 |
|  | | |
| BILE AND LIVER THERAPY | 2 (40.0) | 2 (40.0) |
| POLYENE PHOSPHATIDYLCHOLINE | 2 (40.0) | 1 (20.0) |
| DIAMMONIUM GLYCYRRHIZINATE | 1 (20.0) | 0 |
| BICYCLOL | 0 | 1 (20.0) |
| DL-METHIONINE;GLYCINE;GLYCYRRHIZIC ACID, AMMONIUM SALT | 0 | 1 (20.0) |
| URSODEOXYCHOLIC ACID | 0 | 1 (20.0) |
|  | | |
| BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS | 2 (40.0) | 0 |
| POTASSIUM CHLORIDE | 1 (20.0) | 0 |
| SODIUM CHLORIDE | 1 (20.0) | 0 |
|  | | |
| DRUGS FOR ACID RELATED DISORDERS | 2 (40.0) | 1 (20.0) |
| ESOMEPRAZOLE MAGNESIUM | 1 (20.0) | 0 |
| OMEPRAZOLE SODIUM | 1 (20.0) | 0 |
| OMEPRAZOLE | 0 | 1 (20.0) |
|  | | |
| AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM | 1 (20.0) | 1 (20.0) |
| HYDROCHLOROTHIAZIDE;IRBESARTAN | 1 (20.0) | 1 (20.0) |
|  | | |
| ANTIBACTERIALS FOR SYSTEMIC USE | 1 (20.0) | 2 (40.0) |
| PIPERACILLIN SODIUM;TAZOBACTAM SODIUM | 1 (20.0) | 0 |
| AMOXICILLIN | 0 | 1 (20.0) |
| CEFDINIR | 0 | 1 (20.0) |
| CEFOPERAZONE SODIUM;SULBACTAM SODIUM | 0 | 1 (20.0) |
| CEFTRIAXONE SODIUM | 0 | 1 (20.0) |
| ERTAPENEM | 0 | 1 (20.0) |
| FAROPENEM SODIUM | 0 | 1 (20.0) |
| OMADACYCLINE | 0 | 1 (20.0) |
|  | | |
| ANTIEMETICS AND ANTINAUSEANTS | 1 (20.0) | 1 (20.0) |
| METOCLOPRAMIDE HYDROCHLORIDE | 1 (20.0) | 0 |
| TROPISETRON HYDROCHLORIDE | 0 | 1 (20.0) |
|  | | |
| ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS | 1 (20.0) | 2 (40.0) |
| CELECOXIB | 1 (20.0) | 1 (20.0) |
| ADEMETIONINE | 0 | 1 (20.0) |
| CORYDALIS BUNGEANA HERB;ISATIS TINCTORIA ROOT;SCUTELLARIA BAICALENSIS ROOT;TARAXACUM MONGOLICUM HERB | 0 | 1 (20.0) |
|  | | |
| ANTIPRURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. | 1 (20.0) | 0 |
| LORATADINE | 1 (20.0) | 0 |
|  | | |
| APPETITE STIMULANTS | 1 (20.0) | 0 |
| MEGESTROL ACETATE | 1 (20.0) | 0 |
|  | | |
| DIGESTIVES, INCL. ENZYMES | 1 (20.0) | 0 |
| ALPHA-AMYLASE SWINE PANCREAS;AMYLASE;CELLULASE;PANCRELIPASE;PAPAIN;PEPSIN;TRYPSIN;URSODEOXYCHOLIC ACID | 1 (20.0) | 0 |
|  | | |
| DRUGS FOR CONSTIPATION | 1 (20.0) | 0 |
| GLYCEROL | 1 (20.0) | 0 |
| LACTULOSE | 1 (20.0) | 0 |
|  | | |
| EMOLLIENTS AND PROTECTIVES | 1 (20.0) | 0 |
| TOCOPHEROL;UREA | 1 (20.0) | 0 |
|  | | |
| GENERAL NUTRIENTS | 1 (20.0) | 0 |
| OTHER NUTRIENTS | 1 (20.0) | 0 |
|  | | |
| IMMUNOSTIMULANTS | 1 (20.0) | 1 (20.0) |
| ACONITUM CARMICHAELII ROOT;ANGELICA SINENSIS ROOT;ASTRAGALUS MONGHOLICUS ROOT;CULLEN CORYLIFOLIUM FRUIT;EPIMEDIUM SPP. LEAF;GLYCYRRHIZA SPP. ROOT WITH RHIZOME;LYCIUM BARBARUM FRUIT;OPHIOPOGONJAPONICUS ROOT TUBER;PHRAGMITES COMMUNIS RHIZOME;RUBIA CORDIFOLIA ROOT WITH RHIZOME;SPATHOLOBUS SUBERECTUS STEM | 1 (20.0) | 0 |
| GRANULOCYTE COLONY STIMULATING FACTOR | 1 (20.0) | 0 |
| LEUCOGEN | 1 (20.0) | 1 (20.0) |
| ANGELICA SINENSIS ROOT;ASINI CORII COLLA;ASTRAGALUS MONGHOLICUS ROOT;EPIMEDIUM BREVICORNU HERB;LESPEDEZA BUERGERI;SOPHORA FLAVESCENS ROOT;ZIZIPHUS JUJUBA FRUIT | 0 | 1 (20.0) |
|  | | |
| MINERAL SUPPLEMENTS | 1 (20.0) | 1 (20.0) |
| CALCIUM CARBONATE;COLECALCIFEROL | 1 (20.0) | 0 |
| POTASSIUM CHLORIDE | 0 | 1 (20.0) |
|  | | |
| VITAMINS | 1 (20.0) | 0 |
| PYRIDOXINE HYDROCHLORIDE | 1 (20.0) | 0 |
|  | | |
| ANALGESICS | 0 | 2 (40.0) |
| AMINOPHENAZONE;BARBITAL;PHENAZONE | 0 | 1 (20.0) |
| BIDENS BITERNATA;CAFFEINE;CHLORPHENAMINE MALEATE;CHRYSANTHEMUM INDICUM FLOWER;ILEX ASPRELLA ROOT;MELICOPE PTELEIFOLIA;MENTHA CANADENSIS OIL;PARACETAMOL | 0 | 1 (20.0) |
| TRAMADOL HYDROCHLORIDE | 0 | 1 (20.0) |
|  | | |
| ANTIANEMIC PREPARATIONS | 0 | 1 (20.0) |
| IRON POLYSACCHARIDE COMPLEX | 0 | 1 (20.0) |
|  | | |
| ANTIHISTAMINES FOR SYSTEMIC USE | 0 | 1 (20.0) |
| KETOTIFEN FUMARATE | 0 | 1 (20.0) |
|  | | |
| ANTIVIRALS FOR SYSTEMIC USE | 0 | 1 (20.0) |
| NUCLEOSIDES AND NUCLEOTIDES EXCL. REVERSE TRANSCRIPTASE INHIBITORS | 0 | 1 (20.0) |
| PROTEASE INHIBITORS | 0 | 1 (20.0) |
|  | | |
| COUGH AND COLD PREPARATIONS | 0 | 1 (20.0) |
| CAMPHOR;GLYCYRRHIZA GLABRA;ILLICIUM VERUM OIL;PAPAVER SOMNIFERUM;SODIUM BENZOATE | 0 | 1 (20.0) |
| CINEOLE;DIPENTEN;PINENE | 0 | 1 (20.0) |
|  | | |
| DIURETICS | 0 | 1 (20.0) |
| FUROSEMIDE | 0 | 1 (20.0) |
| SPIRONOLACTONE | 0 | 1 (20.0) |
|  | | |
| DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES | 0 | 1 (20.0) |
| AMINOPHYLLINE;CHLORPHENAMINE MALEATE;METHOXYPHENAMINE HYDROCHLORIDE;NOSCAPINE | 0 | 1 (20.0) |

Concomitant medications are defined as the medications taken during the treatment period (i.e. medication not stop before the first administration of D-1553/IN10018). If the timing of the medication cannot be established in relation to the first administration of D-1553/IN10018, it will be considered as concomitant medication to be more conservative.

Concomitant medications are coded with WHODrug Global-B3 202203.

Percentages are based on the number of subjects of each respective group in the Safety Analysis Set.

Source Data: Listing 16.2.4.9

|  |  |  |
| --- | --- | --- |
| Program: t-cm-soc-pt.sas | DCO: 27APR2024 | Executed: 08JUL2024 17:25 |

|  |  |
| --- | --- |
| **InxMed (Shanghai) Co., Ltd.  Protocol No. IN10018-602** |  |

**Table 14.1.7.3 Summary of New Anti-cancer Therapies - Phase II part 2 - CRC (Safety Analysis Set)**

|  | Treatment Group (N = 5) n (%) | Control Group (N = 5) n (%) |
| --- | --- | --- |
| Subjects with at least one New Anti-cancer Therapy | 0 | 0 |
|  | | |
| Systemic | 0 | 0 |
| Treatment Type\* |  |  |
| Chemotherapy | 0 | 0 |
| Immunotherapy | 0 | 0 |
| Targeted therapy | 0 | 0 |
| Endocrine therapy | 0 | 0 |
| Chinese herbal therapy | 0 | 0 |
| Other | 0 | 0 |
|  | | |
| Radiotherapy | 0 | 0 |
|  | | |
| Surgery | 0 | 0 |
|  | | |
| Other | 0 | 0 |

Percentages are based on the number of subjects of each respective group in the Safety Analysis Set.

\*Percentages are based on the number of Systemic subjects of each respective group in the Safety Analysis Set.

Source Data: Listing 16.2.4.11.1, 16.2.4.11.2, 16.2.4.11.3, 16.2.4.11.4

|  |  |  |
| --- | --- | --- |
| Program: t-cm-new.sas | DCO: 27APR2024 | Executed: 07JUL2024 20:34 |

|  |  |
| --- | --- |
| **InxMed (Shanghai) Co., Ltd.  Protocol No. IN10018-602** |  |

**Table 14.1.8.3 Summary of Drug Exposure - Phase II part 2 - CRC (Safety Analysis Set)**

|  | Treatment Group | |  | Control Group |
| --- | --- | --- | --- | --- |
|  | D-1553 (N = 5) | IN10018 (N = 5) |  | D-1553 (N = 5) |
| Total Duration of treatment (days) |  |  |  |  |
| n | 5 | 5 |  | 5 |
| Mean (STD) | 55.4 (38.96) | 55.4 (38.96) |  | 47.8 (32.89) |
| Median (Q1, Q3) | 40.0 (32.0, 93.0) | 40.0 (32.0, 93.0) |  | 41.0 (37.0, 51.0) |
| Min, Max | 12, 100 | 12, 100 |  | 10, 100 |
|  | | | | |
| Actual Cumulative Dose (mg) |  |  |  |  |
| n | 5 | 5 |  | 5 |
| Mean (STD) | 63960.0 (45363.73) | 4810.0 (3652.81) |  | 56520.0 (38076.13) |
| Median (Q1, Q3) | 42600.0 (38400.0, 109800.0) | 3200.0 (2200.0, 8350.0) |  | 48600.0 (44400.0, 61200.0) |
| Min, Max | 14400, 114600 | 1200, 9100 |  | 12000, 116400 |
|  | | | | |
| Actual Dose Intensity (mg/day) |  |  |  |  |
| n | 5 | 5 |  | 5 |
| Mean (STD) | 1159.0516 (72.9482) | 87.2699 (19.3106) |  | 1189.8732 (15.7908) |
| Median (Q1, Q3) | 1200.0000 (1098.0000, 1200.0000) | 97.8495 (83.5000, 100.0000) |  | 1200.0000 (1185.3659, 1200.0000) |
| Min, Max | 1065.0000, 1232.2581 | 55.0000, 100.0000 |  | 1164.0000, 1200.0000 |
|  | | | | |
| Relative Dose Intensity (%) |  |  |  |  |
| n | 5 | 5 |  | 5 |
| Mean (STD) | 96.59 (6.079) | 87.27 (19.311) |  | 99.16 (1.316) |
| Median (Q1, Q3) | 100.00 (91.50, 100.00) | 97.85 (83.50, 100.00) |  | 100.00 (98.78, 100.00) |
| Min, Max | 88.8, 102.7 | 55.0, 100.0 |  | 97.0, 100.0 |
|  | | | | |
| Dose Adjustments, n (%) |  |  |  |  |
| Yes | 3 (60.0) | 3 (60.0) |  | 2 (40.0) |
| No | 2 (40.0) | 2 (40.0) |  | 3 (60.0) |
|  | | | | |
| Subjects with Dose Adjustments, n (%) |  |  |  |  |
| Adverse Event | 2 (40.0) | 3 (60.0) |  | 1 (20.0) |
| Disease Progression | 0 | 0 |  | 1 (20.0) |
| Other | 1 (20.0) | 0 |  | 1 (20.0) |

Total duration of treatment (days) = Date of last D-1553/IN10018 administration – Date of first D-1553/IN10018 administration + 1.

Actual cumulative dose (mg) = Sum of all actual administered dose.

Actual dose intensity (mg / day) = Actual cumulative dose (mg) / total duration of treatment (days).

Relative dose intensity (%) = Actual dose intensity (mg / day) / planned dose intensity (mg / day) \*100.

Percentages are based on the number of subjects of each respective group in the Safety Analysis Set.

Source Data: Listing 16.2.5.1.1, 16.2.5.1.2

|  |  |  |
| --- | --- | --- |
| Program: t-ex-sum.sas | DCO: 27APR2024 | Executed: 07JUL2024 20:35 |

|  |  |
| --- | --- |
| **InxMed (Shanghai) Co., Ltd.  Protocol No. IN10018-602** |  |

**Table 14.2.1.1.5.1 Summary of Confirmed Best Overall Response based on RECIST 1.1 Criteria - Phase II part 2 - CRC (Intention-to-treat Population)**

|  | Treatment Group (N = 5) n (%) | Control Group (N = 5) n (%) |
| --- | --- | --- |
| Best Overall Response (BOR) |  |  |
| Complete Response (CR) | 0 | 0 |
| Partial Response (PR) | 1 (20.0) | 0 |
| Stable Disease (SD) | 1 (20.0) | 1 (20.0) |
| Progressive Disease (PD) | 0 | 1 (20.0) |
| Not Evaluable (NE) | 0 | 1 (20.0) |
| Not Applicable (NA) | 3 (60.0) | 2 (40.0) |
|  | | |
| Objective Response Rate (ORR) | 1 (20.0) | 0 |
| 90% CI [1] | 1.0, 65.7 | 0, 45.1 |
| 95% CI [1] | 0.5, 71.6 | 0, 52.2 |
|  | | |
| Treatment group vs. Control Group |  |  |
| Rates difference (90% CI) [2] | 18.21 (-21.81, 58.24) |  |
| Rates difference (95% CI) [2] | 16.33 (-31.61, 64.27) |  |
| One-side P-value [3] | 0.1459 |  |
|  | | |
| Disease Control Rate (DCR) | 2 (40.0) | 1 (20.0) |
| 95% CI [1] | 5.3, 85.3 | 0.5, 71.6 |
|  | | |
| Treatment group vs. Control Group |  |  |
| Rates difference (90% CI) [2] | 15.91 (-29.79, 61.60) |  |
| Rates difference (95% CI) [2] | 14.49 (-38.05, 67.03) |  |
| One-side P-value [3] | 0.2451 |  |

[1] The confidence intervals are calculated using Clopper Pearson method.

[2] The rates difference and its 90% and 95% CI estimated by Miettinen-Nurminen method.

[3] P value calculated by Pearson Chi-square test.

ORR = CR + PR.

DCR = CR + PR + SD (SD should be lasting more than 6 weeks).

Confirmed ORR/DCR/BOR represents responses confirmed by a follow-up scan ≥ four weeks after initial CR/PR.

Percentages are based on the number of subjects of each respective group in the Intention-to-treat Population.

Source Data: Listing 16.2.6.2.2

|  |  |  |
| --- | --- | --- |
| Program: t-bor.sas | DCO: 27APR2024 | Executed: 09JUL2024 11:16 |

|  |  |
| --- | --- |
| **InxMed (Shanghai) Co., Ltd.  Protocol No. IN10018-602** |  |

**Table 14.2.1.1.5.2 Summary of Unconfirmed Best Overall Response based on RECIST 1.1 Criteria - Phase II part 2 - CRC (Intention-to-treat Population)**

|  | Treatment Group (N = 5) n (%) | Control Group (N = 5) n (%) |
| --- | --- | --- |
| Best Overall Response (BOR) |  |  |
| Complete Response (CR) | 0 | 0 |
| Partial Response (PR) | 1 (20.0) | 0 |
| Stable Disease (SD) | 1 (20.0) | 1 (20.0) |
| Progressive Disease (PD) | 0 | 1 (20.0) |
| Not Evaluable (NE) | 0 | 1 (20.0) |
| Not Applicable (NA) | 3 (60.0) | 2 (40.0) |
|  | | |
| Objective Response Rate (ORR) | 1 (20.0) | 0 |
| 90% CI [1] | 1.0, 65.7 | 0, 45.1 |
| 95% CI [1] | 0.5, 71.6 | 0, 52.2 |
|  | | |
| Treatment group vs. Control Group |  |  |
| Rates difference (90% CI) [2] | 18.21 (-21.81, 58.24) |  |
| Rates difference (95% CI) [2] | 16.33 (-31.61, 64.27) |  |
| One-side P-value [3] | 0.1459 |  |
|  | | |
| Disease Control Rate (DCR) | 2 (40.0) | 1 (20.0) |
| 95% CI [1] | 5.3, 85.3 | 0.5, 71.6 |
|  | | |
| Treatment group vs. Control Group |  |  |
| Rates difference (90% CI) [2] | 15.91 (-29.79, 61.60) |  |
| Rates difference (95% CI) [2] | 14.49 (-38.05, 67.03) |  |
| One-side P-value [3] | 0.2451 |  |

[1] The confidence intervals are calculated using Clopper Pearson method.

[2] The rates difference and its 90% and 95% CI estimated by Miettinen-Nurminen method.

[3] P value calculated by Pearson Chi-square test.

ORR = CR + PR.

DCR = CR + PR + SD (SD should be lasting more than 6 weeks).

Unconfirmed ORR/DCR/BOR represents responses not be confirmed by a follow-up scan ≥ four weeks after initial CR/PR.

Percentages are based on the number of subjects of each respective group in the Intention-to-treat Population.

Source Data: Listing 16.2.6.2.2

|  |  |  |
| --- | --- | --- |
| Program: t-bor.sas | DCO: 27APR2024 | Executed: 09JUL2024 11:16 |

|  |  |
| --- | --- |
| **InxMed (Shanghai) Co., Ltd.  Protocol No. IN10018-602** |  |

**Table 14.2.1.2.5.1 Summary of Confirmed Best Overall Response based on RECIST 1.1 Criteria - Phase II part 2 - CRC (Response Evaluation Set)**

|  | Treatment Group (N = 2) n (%) | Control Group (N = 3) n (%) |
| --- | --- | --- |
| Best Overall Response (BOR) |  |  |
| Complete Response (CR) | 0 | 0 |
| Partial Response (PR) | 1 (50.0) | 0 |
| Stable Disease (SD) | 1 (50.0) | 1 (33.3) |
| Progressive Disease (PD) | 0 | 1 (33.3) |
| Not Evaluable (NE) | 0 | 1 (33.3) |
|  | | |
| Objective Response Rate (ORR) | 1 (50.0) | 0 |
| 90% CI [1] | 2.5, 97.5 | 0, 63.2 |
| 95% CI [1] | 1.3, 98.7 | 0, 70.8 |
|  | | |
| Treatment group vs. Control Group |  |  |
| Rates difference (90% CI) [2] | 34.50 (-20.64, 89.64) |  |
| Rates difference (95% CI) [2] | 29.29 (-33.43, 92.01) |  |
| One-side P-value [3] | 0.0855 |  |
|  | | |
| Disease Control Rate (DCR) | 2 (100) | 1 (33.3) |
| 95% CI [1] | 15.8, 100 | 0.8, 90.6 |
|  | | |
| Treatment group vs. Control Group |  |  |
| Rates difference (90% CI) [2] | 38.73 (-15.81, 93.27) |  |
| Rates difference (95% CI) [2] | 32.82 (-29.14, 94.79) |  |
| One-side P-value [3] | 0.0680 |  |

[1] The confidence intervals are calculated using Clopper Pearson method.

[2] The rates difference and its 90% and 95% CI estimated by Miettinen-Nurminen method.

[3] P value calculated by Pearson Chi-square test.

ORR = CR + PR.

DCR = CR + PR + SD (SD should be lasting more than 6 weeks).

Confirmed ORR/DCR/BOR represents responses confirmed by a follow-up scan ≥ four weeks after initial CR/PR.

Percentages are based on the number of subjects of each respective group in the Response Evaluation Set.

The confidence intervals are calculated using Clopper Pearson method.

Source Data: Listing 16.2.6.2.1

|  |  |  |
| --- | --- | --- |
| Program: t-bor.sas | DCO: 27APR2024 | Executed: 09JUL2024 11:16 |

|  |  |
| --- | --- |
| **InxMed (Shanghai) Co., Ltd.  Protocol No. IN10018-602** |  |

**Table 14.2.1.2.5.2 Summary of Unconfirmed Best Overall Response based on RECIST 1.1 Criteria - Phase II part 2 - CRC (Response Evaluation Set)**

|  | Treatment Group (N = 2) n (%) | Control Group (N = 3) n (%) |
| --- | --- | --- |
| Best Overall Response (BOR) |  |  |
| Complete Response (CR) | 0 | 0 |
| Partial Response (PR) | 1 (50.0) | 0 |
| Stable Disease (SD) | 1 (50.0) | 1 (33.3) |
| Progressive Disease (PD) | 0 | 1 (33.3) |
| Not Evaluable (NE) | 0 | 1 (33.3) |
|  | | |
| Objective Response Rate (ORR) | 1 (50.0) | 0 |
| 90% CI [1] | 2.5, 97.5 | 0, 63.2 |
| 95% CI [1] | 1.3, 98.7 | 0, 70.8 |
|  | | |
| Treatment group vs. Control Group |  |  |
| Rates difference (90% CI) [2] | 34.50 (-20.64, 89.64) |  |
| Rates difference (95% CI) [2] | 29.29 (-33.43, 92.01) |  |
| One-side P-value [3] | 0.0855 |  |
|  | | |
| Disease Control Rate (DCR) | 2 (100) | 1 (33.3) |
| 95% CI [1] | 15.8, 100 | 0.8, 90.6 |
|  | | |
| Treatment group vs. Control Group |  |  |
| Rates difference (90% CI) [2] | 38.73 (-15.81, 93.27) |  |
| Rates difference (95% CI) [2] | 32.82 (-29.14, 94.79) |  |
| One-side P-value [3] | 0.0680 |  |

[1] The confidence intervals are calculated using Clopper Pearson method.

[2] The rates difference and its 90% and 95% CI estimated by Miettinen-Nurminen method.

[3] P value calculated by Pearson Chi-square test.

ORR = CR + PR.

DCR = CR + PR + SD (SD should be lasting more than 6 weeks).

Unconfirmed ORR/DCR/BOR represents responses not be confirmed by a follow-up scan ≥ four weeks after initial CR/PR.

Percentages are based on the number of subjects of each respective group in the Response Evaluation Set.

The confidence intervals are calculated using Clopper Pearson method.

Source Data: Listing 16.2.6.2.1

|  |  |  |
| --- | --- | --- |
| Program: t-bor.sas | DCO: 27APR2024 | Executed: 09JUL2024 11:16 |

|  |  |
| --- | --- |
| **InxMed (Shanghai) Co., Ltd.  Protocol No. IN10018-602** |  |

**Table 14.2.1.3.3.1 Summary of Confirmed Objective Response Rate Subgroup Analysis - Phase II part 2 - CRC (Intention-to-treat Population)**

| Subgroup |  | | Treatment Group | Control Group |
| --- | --- | --- | --- | --- |
| Age | <65 years | N | 4 | 3 |
|  |  | Confirmed ORR, n (%) | 0 | 0 |
|  |  | 95% CI | 0, 60.2 | 0, 70.8 |
|  | | | | |
|  | >=65 years | N | 1 | 2 |
|  |  | Confirmed ORR, n (%) | 1 (100) | 0 |
|  | | | | |
| Sex | Male | N | 1 | 1 |
|  |  | Confirmed ORR, n (%) | 0 | 0 |
|  | | | | |
|  | Female | N | 4 | 4 |
|  |  | Confirmed ORR, n (%) | 1 (25.0) | 0 |
|  |  | 95% CI | 0.6, 80.6 | 0, 60.2 |
|  | | | | |
| Previous lines of anti-cancer therapy | <=2 | N | 5 | 3 |
|  |  | Confirmed ORR, n (%) | 1 (20.0) | 0 |
|  |  | 95% CI | 0.5, 71.6 | 0, 70.8 |
|  | | | | |
|  | >=3 | N | 0 | 2 |
|  |  | Confirmed ORR, n (%) | 0 | 0 |
|  | | | | |
| Baseline ECOG status | 1 | N | 5 | 5 |
|  |  | Confirmed ORR, n (%) | 1 (20.0) | 0 |
|  |  | 95% CI | 0.5, 71.6 | 0, 52.2 |
|  | | | | |
| Differentiation | Well or moderate differentiated | N | 0 | 4 |
|  |  | Confirmed ORR, n (%) | 0 | 0 |
|  |  | 95% CI |  | 0, 60.2 |
|  | | | | |
| Types of cancer | Colon | N | 3 | 2 |
|  |  | Confirmed ORR, n (%) | 1 (33.3) | 0 |
|  |  | 95% CI | 0.8, 90.6 |  |
|  | | | | |
|  | Rectal | N | 2 | 2 |
|  |  | Confirmed ORR, n (%) | 0 | 0 |
|  | | | | |
| Number of metastatic organs | <=3 | N | 3 | 4 |
|  |  | Confirmed ORR, n (%) | 1 (33.3) | 0 |
|  |  | 95% CI | 0.8, 90.6 | 0, 60.2 |
|  | | | | |
|  | >3 | N | 2 | 1 |
|  |  | Confirmed ORR, n (%) | 0 | 0 |
|  | | | | |
| Brain metastasis | No | N | 5 | 5 |
|  |  | Confirmed ORR, n (%) | 1 (20.0) | 0 |
|  |  | 95% CI | 0.5, 71.6 | 0, 52.2 |
|  | | | | |
| Liver metastasis | Yes | N | 2 | 3 |
|  |  | Confirmed ORR, n (%) | 0 | 0 |
|  |  | 95% CI |  | 0, 70.8 |
|  | | | | |
|  | No | N | 3 | 2 |
|  |  | Confirmed ORR, n (%) | 1 (33.3) | 0 |
|  |  | 95% CI | 0.8, 90.6 |  |
|  | | | | |
| Lung metastasis | Yes | N | 3 | 3 |
|  |  | Confirmed ORR, n (%) | 0 | 0 |
|  |  | 95% CI | 0, 70.8 | 0, 70.8 |
|  | | | | |
|  | No | N | 2 | 2 |
|  |  | Confirmed ORR, n (%) | 1 (50.0) | 0 |
|  | | | | |
| Peritoneum metastasis | Yes | N | 1 | 1 |
|  |  | Confirmed ORR, n (%) | 1 (100) | 0 |
|  | | | | |
|  | No | N | 4 | 4 |
|  |  | Confirmed ORR, n (%) | 0 | 0 |
|  |  | 95% CI | 0, 60.2 | 0, 60.2 |
|  | | | | |
| Previously-treated with bevacizumab | Yes | N | 4 | 4 |
|  |  | Confirmed ORR, n (%) | 1 (25.0) | 0 |
|  |  | 95% CI | 0.6, 80.6 | 0, 60.2 |
|  | | | | |
|  | No | N | 1 | 1 |
|  |  | Confirmed ORR, n (%) | 0 | 0 |
|  | | | | |
| Previously-treated with Oxaliplatin | Yes | N | 4 | 5 |
|  |  | Confirmed ORR, n (%) | 0 | 0 |
|  |  | 95% CI | 0, 60.2 | 0, 52.2 |
|  | | | | |
|  | No | N | 1 | 0 |
|  |  | Confirmed ORR, n (%) | 1 (100) | 0 |
|  | | | | |
| Previously-treated with Irinotecan | Yes | N | 3 | 3 |
|  |  | Confirmed ORR, n (%) | 1 (33.3) | 0 |
|  |  | 95% CI | 0.8, 90.6 | 0, 70.8 |
|  | | | | |
|  | No | N | 2 | 2 |
|  |  | Confirmed ORR, n (%) | 0 | 0 |
|  | | | | |
| TNM staging | IVA | N | 2 | 2 |
|  |  | Confirmed ORR, n (%) | 0 | 0 |
|  | | | | |
|  | IVB | N | 2 | 2 |
|  |  | Confirmed ORR, n (%) | 0 | 0 |
|  | | | | |
|  | IVC | N | 1 | 1 |
|  |  | Confirmed ORR, n (%) | 1 (100) | 0 |
|  | | | | |
| TP53 | Wild-type | N | 5 | 5 |
|  |  | Confirmed ORR, n (%) | 1 (20.0) | 0 |
|  |  | 95% CI | 0.5, 71.6 | 0, 52.2 |
|  | | | | |
| STK11 | Wild-type | N | 5 | 5 |
|  |  | Confirmed ORR, n (%) | 1 (20.0) | 0 |
|  |  | 95% CI | 0.5, 71.6 | 0, 52.2 |
|  | | | | |
| KEAP1 | Wild-type | N | 5 | 5 |
|  |  | Confirmed ORR, n (%) | 1 (20.0) | 0 |
|  |  | 95% CI | 0.5, 71.6 | 0, 52.2 |
|  | | | | |
| EGFR | Wild-type | N | 5 | 5 |
|  |  | Confirmed ORR, n (%) | 1 (20.0) | 0 |
|  |  | 95% CI | 0.5, 71.6 | 0, 52.2 |
|  | | | | |
| BRAF | Wild-type | N | 5 | 5 |
|  |  | Confirmed ORR, n (%) | 1 (20.0) | 0 |
|  |  | 95% CI | 0.5, 71.6 | 0, 52.2 |
|  | | | | |
| ALK | Wild-type | N | 5 | 5 |
|  |  | Confirmed ORR, n (%) | 1 (20.0) | 0 |
|  |  | 95% CI | 0.5, 71.6 | 0, 52.2 |
|  | | | | |
| MET | Wild-type | N | 5 | 5 |
|  |  | Confirmed ORR, n (%) | 1 (20.0) | 0 |
|  |  | 95% CI | 0.5, 71.6 | 0, 52.2 |
|  | | | | |
| RET | Wild-type | N | 5 | 5 |
|  |  | Confirmed ORR, n (%) | 1 (20.0) | 0 |
|  |  | 95% CI | 0.5, 71.6 | 0, 52.2 |
|  | | | | |
| ROS1 | Wild-type | N | 5 | 5 |
|  |  | Confirmed ORR, n (%) | 1 (20.0) | 0 |
|  |  | 95% CI | 0.5, 71.6 | 0, 52.2 |
|  | | | | |
| ERBB2 | Wild-type | N | 5 | 5 |
|  |  | Confirmed ORR, n (%) | 1 (20.0) | 0 |
|  |  | 95% CI | 0.5, 71.6 | 0, 52.2 |
|  | | | | |
| NTRK1 | Wild-type | N | 5 | 5 |
|  |  | Confirmed ORR, n (%) | 1 (20.0) | 0 |
|  |  | 95% CI | 0.5, 71.6 | 0, 52.2 |
|  | | | | |
| NTRK2 | Wild-type | N | 5 | 5 |
|  |  | Confirmed ORR, n (%) | 1 (20.0) | 0 |
|  |  | 95% CI | 0.5, 71.6 | 0, 52.2 |
|  | | | | |
| NTRK3 | Wild-type | N | 5 | 5 |
|  |  | Confirmed ORR, n (%) | 1 (20.0) | 0 |
|  |  | 95% CI | 0.5, 71.6 | 0, 52.2 |
|  | | | | |
| KRAS(other than G12C) | Wild-type | N | 5 | 5 |
|  |  | Confirmed ORR, n (%) | 1 (20.0) | 0 |
|  |  | 95% CI | 0.5, 71.6 | 0, 52.2 |
|  | | | | |
| NRAS | Wild-type | N | 5 | 5 |
|  |  | Confirmed ORR, n (%) | 1 (20.0) | 0 |
|  |  | 95% CI | 0.5, 71.6 | 0, 52.2 |
|  | | | | |
| HRAS | Wild-type | N | 5 | 5 |
|  |  | Confirmed ORR, n (%) | 1 (20.0) | 0 |
|  |  | 95% CI | 0.5, 71.6 | 0, 52.2 |
|  | | | | |
| PIK3CA | Wild-type | N | 5 | 5 |
|  |  | Confirmed ORR, n (%) | 1 (20.0) | 0 |
|  |  | 95% CI | 0.5, 71.6 | 0, 52.2 |
|  | | | | |
| PIK3R1 | Wild-type | N | 5 | 5 |
|  |  | Confirmed ORR, n (%) | 1 (20.0) | 0 |
|  |  | 95% CI | 0.5, 71.6 | 0, 52.2 |
|  | | | | |
| MAP2K1 | Wild-type | N | 5 | 5 |
|  |  | Confirmed ORR, n (%) | 1 (20.0) | 0 |
|  |  | 95% CI | 0.5, 71.6 | 0, 52.2 |
|  | | | | |
| RAF1 | Wild-type | N | 5 | 5 |
|  |  | Confirmed ORR, n (%) | 1 (20.0) | 0 |
|  |  | 95% CI | 0.5, 71.6 | 0, 52.2 |
|  | | | | |
| FGFR3 | Wild-type | N | 5 | 5 |
|  |  | Confirmed ORR, n (%) | 1 (20.0) | 0 |
|  |  | 95% CI | 0.5, 71.6 | 0, 52.2 |
|  | | | | |
| NF1 | Wild-type | N | 5 | 5 |
|  |  | Confirmed ORR, n (%) | 1 (20.0) | 0 |
|  |  | 95% CI | 0.5, 71.6 | 0, 52.2 |
|  | | | | |
| PTEN | Wild-type | N | 5 | 5 |
|  |  | Confirmed ORR, n (%) | 1 (20.0) | 0 |
|  |  | 95% CI | 0.5, 71.6 | 0, 52.2 |
|  | | | | |
| APC | Wild-type | N | 5 | 5 |
|  |  | Confirmed ORR, n (%) | 1 (20.0) | 0 |
|  |  | 95% CI | 0.5, 71.6 | 0, 52.2 |
|  | | | | |
| POLE | Wild-type | N | 5 | 5 |
|  |  | Confirmed ORR, n (%) | 1 (20.0) | 0 |
|  |  | 95% CI | 0.5, 71.6 | 0, 52.2 |

ORR = CR + PR.

Confirmed ORR represents responses confirmed by a follow-up scan ≥ four weeks after initial CR/PR.

Percentages are based on the number of subjects of each respective subgroup in the Intention-to-treat Population.

The confidence intervals are calculated using Clopper Pearson method.

If sample size below 3, the confidence interval will not be generated for the confirmed ORR.

Source Data: Listing 16.2.6.2.1

|  |  |  |
| --- | --- | --- |
| Program: t-orr-subgrp-part2.sas | DCO: 27APR2024 | Executed: 09JUL2024 11:30 |

|  |  |
| --- | --- |
| **InxMed (Shanghai) Co., Ltd.  Protocol No. IN10018-602** |  |

**Table 14.2.1.3.3.2 Summary of Unconfirmed Objective Response Rate Subgroup Analysis - Phase II part 2 - CRC (Intention-to-treat Population)**

| Subgroup |  | | Treatment Group | Control Group |
| --- | --- | --- | --- | --- |
| Age | <65 years | N | 4 | 3 |
|  |  | Unconfirmed ORR, n (%) | 0 | 0 |
|  |  | 95% CI | 0, 60.2 | 0, 70.8 |
|  | | | | |
|  | >=65 years | N | 1 | 2 |
|  |  | Unconfirmed ORR, n (%) | 1 (100) | 0 |
|  | | | | |
| Sex | Male | N | 1 | 1 |
|  |  | Unconfirmed ORR, n (%) | 0 | 0 |
|  | | | | |
|  | Female | N | 4 | 4 |
|  |  | Unconfirmed ORR, n (%) | 1 (25.0) | 0 |
|  |  | 95% CI | 0.6, 80.6 | 0, 60.2 |
|  | | | | |
| Previous lines of anti-cancer therapy | <=2 | N | 5 | 3 |
|  |  | Unconfirmed ORR, n (%) | 1 (20.0) | 0 |
|  |  | 95% CI | 0.5, 71.6 | 0, 70.8 |
|  | | | | |
|  | >=3 | N | 0 | 2 |
|  |  | Unconfirmed ORR, n (%) | 0 | 0 |
|  | | | | |
| Baseline ECOG status | 1 | N | 5 | 5 |
|  |  | Unconfirmed ORR, n (%) | 1 (20.0) | 0 |
|  |  | 95% CI | 0.5, 71.6 | 0, 52.2 |
|  | | | | |
| Differentiation | Well or moderate differentiated | N | 0 | 4 |
|  |  | Unconfirmed ORR, n (%) | 0 | 0 |
|  |  | 95% CI |  | 0, 60.2 |
|  | | | | |
| Types of cancer | Colon | N | 3 | 2 |
|  |  | Unconfirmed ORR, n (%) | 1 (33.3) | 0 |
|  |  | 95% CI | 0.8, 90.6 |  |
|  | | | | |
|  | Rectal | N | 2 | 2 |
|  |  | Unconfirmed ORR, n (%) | 0 | 0 |
|  | | | | |
| Number of metastatic organs | <=3 | N | 3 | 4 |
|  |  | Unconfirmed ORR, n (%) | 1 (33.3) | 0 |
|  |  | 95% CI | 0.8, 90.6 | 0, 60.2 |
|  | | | | |
|  | >3 | N | 2 | 1 |
|  |  | Unconfirmed ORR, n (%) | 0 | 0 |
|  | | | | |
| Brain metastasis | No | N | 5 | 5 |
|  |  | Unconfirmed ORR, n (%) | 1 (20.0) | 0 |
|  |  | 95% CI | 0.5, 71.6 | 0, 52.2 |
|  | | | | |
| Liver metastasis | Yes | N | 2 | 3 |
|  |  | Unconfirmed ORR, n (%) | 0 | 0 |
|  |  | 95% CI |  | 0, 70.8 |
|  | | | | |
|  | No | N | 3 | 2 |
|  |  | Unconfirmed ORR, n (%) | 1 (33.3) | 0 |
|  |  | 95% CI | 0.8, 90.6 |  |
|  | | | | |
| Lung metastasis | Yes | N | 3 | 3 |
|  |  | Unconfirmed ORR, n (%) | 0 | 0 |
|  |  | 95% CI | 0, 70.8 | 0, 70.8 |
|  | | | | |
|  | No | N | 2 | 2 |
|  |  | Unconfirmed ORR, n (%) | 1 (50.0) | 0 |
|  | | | | |
| Peritoneum metastasis | Yes | N | 1 | 1 |
|  |  | Unconfirmed ORR, n (%) | 1 (100) | 0 |
|  | | | | |
|  | No | N | 4 | 4 |
|  |  | Unconfirmed ORR, n (%) | 0 | 0 |
|  |  | 95% CI | 0, 60.2 | 0, 60.2 |
|  | | | | |
| Previously-treated with bevacizumab | Yes | N | 4 | 4 |
|  |  | Unconfirmed ORR, n (%) | 1 (25.0) | 0 |
|  |  | 95% CI | 0.6, 80.6 | 0, 60.2 |
|  | | | | |
|  | No | N | 1 | 1 |
|  |  | Unconfirmed ORR, n (%) | 0 | 0 |
|  | | | | |
| Previously-treated with Oxaliplatin | Yes | N | 4 | 5 |
|  |  | Unconfirmed ORR, n (%) | 0 | 0 |
|  |  | 95% CI | 0, 60.2 | 0, 52.2 |
|  | | | | |
|  | No | N | 1 | 0 |
|  |  | Unconfirmed ORR, n (%) | 1 (100) | 0 |
|  | | | | |
| Previously-treated with Irinotecan | Yes | N | 3 | 3 |
|  |  | Unconfirmed ORR, n (%) | 1 (33.3) | 0 |
|  |  | 95% CI | 0.8, 90.6 | 0, 70.8 |
|  | | | | |
|  | No | N | 2 | 2 |
|  |  | Unconfirmed ORR, n (%) | 0 | 0 |
|  | | | | |
| TNM staging | IVA | N | 2 | 2 |
|  |  | Unconfirmed ORR, n (%) | 0 | 0 |
|  | | | | |
|  | IVB | N | 2 | 2 |
|  |  | Unconfirmed ORR, n (%) | 0 | 0 |
|  | | | | |
|  | IVC | N | 1 | 1 |
|  |  | Unconfirmed ORR, n (%) | 1 (100) | 0 |
|  | | | | |
| TP53 | Wild-type | N | 5 | 5 |
|  |  | Unconfirmed ORR, n (%) | 1 (20.0) | 0 |
|  |  | 95% CI | 0.5, 71.6 | 0, 52.2 |
|  | | | | |
| STK11 | Wild-type | N | 5 | 5 |
|  |  | Unconfirmed ORR, n (%) | 1 (20.0) | 0 |
|  |  | 95% CI | 0.5, 71.6 | 0, 52.2 |
|  | | | | |
| KEAP1 | Wild-type | N | 5 | 5 |
|  |  | Unconfirmed ORR, n (%) | 1 (20.0) | 0 |
|  |  | 95% CI | 0.5, 71.6 | 0, 52.2 |
|  | | | | |
| EGFR | Wild-type | N | 5 | 5 |
|  |  | Unconfirmed ORR, n (%) | 1 (20.0) | 0 |
|  |  | 95% CI | 0.5, 71.6 | 0, 52.2 |
|  | | | | |
| BRAF | Wild-type | N | 5 | 5 |
|  |  | Unconfirmed ORR, n (%) | 1 (20.0) | 0 |
|  |  | 95% CI | 0.5, 71.6 | 0, 52.2 |
|  | | | | |
| ALK | Wild-type | N | 5 | 5 |
|  |  | Unconfirmed ORR, n (%) | 1 (20.0) | 0 |
|  |  | 95% CI | 0.5, 71.6 | 0, 52.2 |
|  | | | | |
| MET | Wild-type | N | 5 | 5 |
|  |  | Unconfirmed ORR, n (%) | 1 (20.0) | 0 |
|  |  | 95% CI | 0.5, 71.6 | 0, 52.2 |
|  | | | | |
| RET | Wild-type | N | 5 | 5 |
|  |  | Unconfirmed ORR, n (%) | 1 (20.0) | 0 |
|  |  | 95% CI | 0.5, 71.6 | 0, 52.2 |
|  | | | | |
| ROS1 | Wild-type | N | 5 | 5 |
|  |  | Unconfirmed ORR, n (%) | 1 (20.0) | 0 |
|  |  | 95% CI | 0.5, 71.6 | 0, 52.2 |
|  | | | | |
| ERBB2 | Wild-type | N | 5 | 5 |
|  |  | Unconfirmed ORR, n (%) | 1 (20.0) | 0 |
|  |  | 95% CI | 0.5, 71.6 | 0, 52.2 |
|  | | | | |
| NTRK1 | Wild-type | N | 5 | 5 |
|  |  | Unconfirmed ORR, n (%) | 1 (20.0) | 0 |
|  |  | 95% CI | 0.5, 71.6 | 0, 52.2 |
|  | | | | |
| NTRK2 | Wild-type | N | 5 | 5 |
|  |  | Unconfirmed ORR, n (%) | 1 (20.0) | 0 |
|  |  | 95% CI | 0.5, 71.6 | 0, 52.2 |
|  | | | | |
| NTRK3 | Wild-type | N | 5 | 5 |
|  |  | Unconfirmed ORR, n (%) | 1 (20.0) | 0 |
|  |  | 95% CI | 0.5, 71.6 | 0, 52.2 |
|  | | | | |
| KRAS(other than G12C) | Wild-type | N | 5 | 5 |
|  |  | Unconfirmed ORR, n (%) | 1 (20.0) | 0 |
|  |  | 95% CI | 0.5, 71.6 | 0, 52.2 |
|  | | | | |
| NRAS | Wild-type | N | 5 | 5 |
|  |  | Unconfirmed ORR, n (%) | 1 (20.0) | 0 |
|  |  | 95% CI | 0.5, 71.6 | 0, 52.2 |
|  | | | | |
| HRAS | Wild-type | N | 5 | 5 |
|  |  | Unconfirmed ORR, n (%) | 1 (20.0) | 0 |
|  |  | 95% CI | 0.5, 71.6 | 0, 52.2 |
|  | | | | |
| PIK3CA | Wild-type | N | 5 | 5 |
|  |  | Unconfirmed ORR, n (%) | 1 (20.0) | 0 |
|  |  | 95% CI | 0.5, 71.6 | 0, 52.2 |
|  | | | | |
| PIK3R1 | Wild-type | N | 5 | 5 |
|  |  | Unconfirmed ORR, n (%) | 1 (20.0) | 0 |
|  |  | 95% CI | 0.5, 71.6 | 0, 52.2 |
|  | | | | |
| MAP2K1 | Wild-type | N | 5 | 5 |
|  |  | Unconfirmed ORR, n (%) | 1 (20.0) | 0 |
|  |  | 95% CI | 0.5, 71.6 | 0, 52.2 |
|  | | | | |
| RAF1 | Wild-type | N | 5 | 5 |
|  |  | Unconfirmed ORR, n (%) | 1 (20.0) | 0 |
|  |  | 95% CI | 0.5, 71.6 | 0, 52.2 |
|  | | | | |
| FGFR3 | Wild-type | N | 5 | 5 |
|  |  | Unconfirmed ORR, n (%) | 1 (20.0) | 0 |
|  |  | 95% CI | 0.5, 71.6 | 0, 52.2 |
|  | | | | |
| NF1 | Wild-type | N | 5 | 5 |
|  |  | Unconfirmed ORR, n (%) | 1 (20.0) | 0 |
|  |  | 95% CI | 0.5, 71.6 | 0, 52.2 |
|  | | | | |
| PTEN | Wild-type | N | 5 | 5 |
|  |  | Unconfirmed ORR, n (%) | 1 (20.0) | 0 |
|  |  | 95% CI | 0.5, 71.6 | 0, 52.2 |
|  | | | | |
| APC | Wild-type | N | 5 | 5 |
|  |  | Unconfirmed ORR, n (%) | 1 (20.0) | 0 |
|  |  | 95% CI | 0.5, 71.6 | 0, 52.2 |
|  | | | | |
| POLE | Wild-type | N | 5 | 5 |
|  |  | Unconfirmed ORR, n (%) | 1 (20.0) | 0 |
|  |  | 95% CI | 0.5, 71.6 | 0, 52.2 |

ORR = CR + PR.

Unconfirmed ORR represents responses not be confirmed by a follow-up scan ≥ four weeks after initial CR/PR.

Percentages are based on the number of subjects of each respective subgroup in the Intention-to-treat Population.

The confidence intervals are calculated using Clopper Pearson method.

If sample size below 3, the confidence interval will not be generated for the unconfirmed ORR.

Source Data: Listing 16.2.6.2.1

|  |  |  |
| --- | --- | --- |
| Program: t-orr-subgrp-part2.sas | DCO: 27APR2024 | Executed: 09JUL2024 11:30 |

|  |  |
| --- | --- |
| **InxMed (Shanghai) Co., Ltd.  Protocol No. IN10018-602** |  |

**Table 14.2.1.4.3.1 Summary of Confirmed Objective Response Rate Subgroup Analysis - Phase II part 2 - CRC (Response Evaluation Set)**

| Subgroup |  | | Treatment Group | Control Group |
| --- | --- | --- | --- | --- |
| Age | <65 years | N | 1 | 2 |
|  |  | Confirmed ORR, n (%) | 0 | 0 |
|  | | | | |
|  | >=65 years | N | 1 | 1 |
|  |  | Confirmed ORR, n (%) | 1 (100) | 0 |
|  | | | | |
| Sex | Female | N | 2 | 3 |
|  |  | Confirmed ORR, n (%) | 1 (50.0) | 0 |
|  |  | 95% CI |  | 0, 70.8 |
|  | | | | |
| Previous lines of anti-cancer therapy | <=2 | N | 2 | 1 |
|  |  | Confirmed ORR, n (%) | 1 (50.0) | 0 |
|  | | | | |
|  | >=3 | N | 0 | 2 |
|  |  | Confirmed ORR, n (%) | 0 | 0 |
|  | | | | |
| Baseline ECOG status | 1 | N | 2 | 3 |
|  |  | Confirmed ORR, n (%) | 1 (50.0) | 0 |
|  |  | 95% CI |  | 0, 70.8 |
|  | | | | |
| Differentiation | Well or moderate differentiated | N | 0 | 3 |
|  |  | Confirmed ORR, n (%) | 0 | 0 |
|  |  | 95% CI |  | 0, 70.8 |
|  | | | | |
| Types of cancer | Colon | N | 1 | 1 |
|  |  | Confirmed ORR, n (%) | 1 (100) | 0 |
|  | | | | |
|  | Rectal | N | 1 | 1 |
|  |  | Confirmed ORR, n (%) | 0 | 0 |
|  | | | | |
| Number of metastatic organs | <=3 | N | 2 | 2 |
|  |  | Confirmed ORR, n (%) | 1 (50.0) | 0 |
|  | | | | |
|  | >3 | N | 0 | 1 |
|  |  | Confirmed ORR, n (%) | 0 | 0 |
|  | | | | |
| Brain metastasis | No | N | 2 | 3 |
|  |  | Confirmed ORR, n (%) | 1 (50.0) | 0 |
|  |  | 95% CI |  | 0, 70.8 |
|  | | | | |
| Liver metastasis | Yes | N | 0 | 2 |
|  |  | Confirmed ORR, n (%) | 0 | 0 |
|  | | | | |
|  | No | N | 2 | 1 |
|  |  | Confirmed ORR, n (%) | 1 (50.0) | 0 |
|  | | | | |
| Lung metastasis | Yes | N | 1 | 3 |
|  |  | Confirmed ORR, n (%) | 0 | 0 |
|  |  | 95% CI |  | 0, 70.8 |
|  | | | | |
|  | No | N | 1 | 0 |
|  |  | Confirmed ORR, n (%) | 1 (100) | 0 |
|  | | | | |
| Peritoneum metastasis | Yes | N | 1 | 1 |
|  |  | Confirmed ORR, n (%) | 1 (100) | 0 |
|  | | | | |
|  | No | N | 1 | 2 |
|  |  | Confirmed ORR, n (%) | 0 | 0 |
|  | | | | |
| Previously-treated with bevacizumab | Yes | N | 2 | 2 |
|  |  | Confirmed ORR, n (%) | 1 (50.0) | 0 |
|  | | | | |
|  | No | N | 0 | 1 |
|  |  | Confirmed ORR, n (%) | 0 | 0 |
|  | | | | |
| Previously-treated with Oxaliplatin | Yes | N | 1 | 3 |
|  |  | Confirmed ORR, n (%) | 0 | 0 |
|  |  | 95% CI |  | 0, 70.8 |
|  | | | | |
|  | No | N | 1 | 0 |
|  |  | Confirmed ORR, n (%) | 1 (100) | 0 |
|  | | | | |
| Previously-treated with Irinotecan | Yes | N | 1 | 1 |
|  |  | Confirmed ORR, n (%) | 1 (100) | 0 |
|  | | | | |
|  | No | N | 1 | 2 |
|  |  | Confirmed ORR, n (%) | 0 | 0 |
|  | | | | |
| TNM staging | IVA | N | 1 | 1 |
|  |  | Confirmed ORR, n (%) | 0 | 0 |
|  | | | | |
|  | IVB | N | 0 | 1 |
|  |  | Confirmed ORR, n (%) | 0 | 0 |
|  | | | | |
|  | IVC | N | 1 | 1 |
|  |  | Confirmed ORR, n (%) | 1 (100) | 0 |
|  | | | | |
| TP53 | Wild-type | N | 2 | 3 |
|  |  | Confirmed ORR, n (%) | 1 (50.0) | 0 |
|  |  | 95% CI |  | 0, 70.8 |
|  | | | | |
| STK11 | Wild-type | N | 2 | 3 |
|  |  | Confirmed ORR, n (%) | 1 (50.0) | 0 |
|  |  | 95% CI |  | 0, 70.8 |
|  | | | | |
| KEAP1 | Wild-type | N | 2 | 3 |
|  |  | Confirmed ORR, n (%) | 1 (50.0) | 0 |
|  |  | 95% CI |  | 0, 70.8 |
|  | | | | |
| EGFR | Wild-type | N | 2 | 3 |
|  |  | Confirmed ORR, n (%) | 1 (50.0) | 0 |
|  |  | 95% CI |  | 0, 70.8 |
|  | | | | |
| BRAF | Wild-type | N | 2 | 3 |
|  |  | Confirmed ORR, n (%) | 1 (50.0) | 0 |
|  |  | 95% CI |  | 0, 70.8 |
|  | | | | |
| ALK | Wild-type | N | 2 | 3 |
|  |  | Confirmed ORR, n (%) | 1 (50.0) | 0 |
|  |  | 95% CI |  | 0, 70.8 |
|  | | | | |
| MET | Wild-type | N | 2 | 3 |
|  |  | Confirmed ORR, n (%) | 1 (50.0) | 0 |
|  |  | 95% CI |  | 0, 70.8 |
|  | | | | |
| RET | Wild-type | N | 2 | 3 |
|  |  | Confirmed ORR, n (%) | 1 (50.0) | 0 |
|  |  | 95% CI |  | 0, 70.8 |
|  | | | | |
| ROS1 | Wild-type | N | 2 | 3 |
|  |  | Confirmed ORR, n (%) | 1 (50.0) | 0 |
|  |  | 95% CI |  | 0, 70.8 |
|  | | | | |
| ERBB2 | Wild-type | N | 2 | 3 |
|  |  | Confirmed ORR, n (%) | 1 (50.0) | 0 |
|  |  | 95% CI |  | 0, 70.8 |
|  | | | | |
| NTRK1 | Wild-type | N | 2 | 3 |
|  |  | Confirmed ORR, n (%) | 1 (50.0) | 0 |
|  |  | 95% CI |  | 0, 70.8 |
|  | | | | |
| NTRK2 | Wild-type | N | 2 | 3 |
|  |  | Confirmed ORR, n (%) | 1 (50.0) | 0 |
|  |  | 95% CI |  | 0, 70.8 |
|  | | | | |
| NTRK3 | Wild-type | N | 2 | 3 |
|  |  | Confirmed ORR, n (%) | 1 (50.0) | 0 |
|  |  | 95% CI |  | 0, 70.8 |
|  | | | | |
| KRAS(other than G12C) | Wild-type | N | 2 | 3 |
|  |  | Confirmed ORR, n (%) | 1 (50.0) | 0 |
|  |  | 95% CI |  | 0, 70.8 |
|  | | | | |
| NRAS | Wild-type | N | 2 | 3 |
|  |  | Confirmed ORR, n (%) | 1 (50.0) | 0 |
|  |  | 95% CI |  | 0, 70.8 |
|  | | | | |
| HRAS | Wild-type | N | 2 | 3 |
|  |  | Confirmed ORR, n (%) | 1 (50.0) | 0 |
|  |  | 95% CI |  | 0, 70.8 |
|  | | | | |
| PIK3CA | Wild-type | N | 2 | 3 |
|  |  | Confirmed ORR, n (%) | 1 (50.0) | 0 |
|  |  | 95% CI |  | 0, 70.8 |
|  | | | | |
| PIK3R1 | Wild-type | N | 2 | 3 |
|  |  | Confirmed ORR, n (%) | 1 (50.0) | 0 |
|  |  | 95% CI |  | 0, 70.8 |
|  | | | | |
| MAP2K1 | Wild-type | N | 2 | 3 |
|  |  | Confirmed ORR, n (%) | 1 (50.0) | 0 |
|  |  | 95% CI |  | 0, 70.8 |
|  | | | | |
| RAF1 | Wild-type | N | 2 | 3 |
|  |  | Confirmed ORR, n (%) | 1 (50.0) | 0 |
|  |  | 95% CI |  | 0, 70.8 |
|  | | | | |
| FGFR3 | Wild-type | N | 2 | 3 |
|  |  | Confirmed ORR, n (%) | 1 (50.0) | 0 |
|  |  | 95% CI |  | 0, 70.8 |
|  | | | | |
| NF1 | Wild-type | N | 2 | 3 |
|  |  | Confirmed ORR, n (%) | 1 (50.0) | 0 |
|  |  | 95% CI |  | 0, 70.8 |
|  | | | | |
| PTEN | Wild-type | N | 2 | 3 |
|  |  | Confirmed ORR, n (%) | 1 (50.0) | 0 |
|  |  | 95% CI |  | 0, 70.8 |
|  | | | | |
| APC | Wild-type | N | 2 | 3 |
|  |  | Confirmed ORR, n (%) | 1 (50.0) | 0 |
|  |  | 95% CI |  | 0, 70.8 |
|  | | | | |
| POLE | Wild-type | N | 2 | 3 |
|  |  | Confirmed ORR, n (%) | 1 (50.0) | 0 |
|  |  | 95% CI |  | 0, 70.8 |

ORR = CR + PR.

Confirmed ORR represents responses confirmed by a follow-up scan ≥ four weeks after initial CR/PR.

Percentages are based on the number of subjects of each respective subgroup in the Response Evaluation Set.

The confidence intervals are calculated using Clopper Pearson method.

If sample size below 3, the confidence interval will not be generated for the confirmed ORR.

Source Data: Listing 16.2.6.2.1

|  |  |  |
| --- | --- | --- |
| Program: t-orr-subgrp-part2.sas | DCO: 27APR2024 | Executed: 09JUL2024 11:30 |

|  |  |
| --- | --- |
| **InxMed (Shanghai) Co., Ltd.  Protocol No. IN10018-602** |  |

**Table 14.2.1.4.3.2 Summary of Unconfirmed Objective Response Rate Subgroup Analysis - Phase II part 2 - CRC (Response Evaluation Set)**

| Subgroup |  | | Treatment Group | Control Group |
| --- | --- | --- | --- | --- |
| Age | <65 years | N | 1 | 2 |
|  |  | Unconfirmed ORR, n (%) | 0 | 0 |
|  | | | | |
|  | >=65 years | N | 1 | 1 |
|  |  | Unconfirmed ORR, n (%) | 1 (100) | 0 |
|  | | | | |
| Sex | Female | N | 2 | 3 |
|  |  | Unconfirmed ORR, n (%) | 1 (50.0) | 0 |
|  |  | 95% CI |  | 0, 70.8 |
|  | | | | |
| Previous lines of anti-cancer therapy | <=2 | N | 2 | 1 |
|  |  | Unconfirmed ORR, n (%) | 1 (50.0) | 0 |
|  | | | | |
|  | >=3 | N | 0 | 2 |
|  |  | Unconfirmed ORR, n (%) | 0 | 0 |
|  | | | | |
| Baseline ECOG status | 1 | N | 2 | 3 |
|  |  | Unconfirmed ORR, n (%) | 1 (50.0) | 0 |
|  |  | 95% CI |  | 0, 70.8 |
|  | | | | |
| Differentiation | Well or moderate differentiated | N | 0 | 3 |
|  |  | Unconfirmed ORR, n (%) | 0 | 0 |
|  |  | 95% CI |  | 0, 70.8 |
|  | | | | |
| Types of cancer | Colon | N | 1 | 1 |
|  |  | Unconfirmed ORR, n (%) | 1 (100) | 0 |
|  | | | | |
|  | Rectal | N | 1 | 1 |
|  |  | Unconfirmed ORR, n (%) | 0 | 0 |
|  | | | | |
| Number of metastatic organs | <=3 | N | 2 | 2 |
|  |  | Unconfirmed ORR, n (%) | 1 (50.0) | 0 |
|  | | | | |
|  | >3 | N | 0 | 1 |
|  |  | Unconfirmed ORR, n (%) | 0 | 0 |
|  | | | | |
| Brain metastasis | No | N | 2 | 3 |
|  |  | Unconfirmed ORR, n (%) | 1 (50.0) | 0 |
|  |  | 95% CI |  | 0, 70.8 |
|  | | | | |
| Liver metastasis | Yes | N | 0 | 2 |
|  |  | Unconfirmed ORR, n (%) | 0 | 0 |
|  | | | | |
|  | No | N | 2 | 1 |
|  |  | Unconfirmed ORR, n (%) | 1 (50.0) | 0 |
|  | | | | |
| Lung metastasis | Yes | N | 1 | 3 |
|  |  | Unconfirmed ORR, n (%) | 0 | 0 |
|  |  | 95% CI |  | 0, 70.8 |
|  | | | | |
|  | No | N | 1 | 0 |
|  |  | Unconfirmed ORR, n (%) | 1 (100) | 0 |
|  | | | | |
| Peritoneum metastasis | Yes | N | 1 | 1 |
|  |  | Unconfirmed ORR, n (%) | 1 (100) | 0 |
|  | | | | |
|  | No | N | 1 | 2 |
|  |  | Unconfirmed ORR, n (%) | 0 | 0 |
|  | | | | |
| Previously-treated with bevacizumab | Yes | N | 2 | 2 |
|  |  | Unconfirmed ORR, n (%) | 1 (50.0) | 0 |
|  | | | | |
|  | No | N | 0 | 1 |
|  |  | Unconfirmed ORR, n (%) | 0 | 0 |
|  | | | | |
| Previously-treated with Oxaliplatin | Yes | N | 1 | 3 |
|  |  | Unconfirmed ORR, n (%) | 0 | 0 |
|  |  | 95% CI |  | 0, 70.8 |
|  | | | | |
|  | No | N | 1 | 0 |
|  |  | Unconfirmed ORR, n (%) | 1 (100) | 0 |
|  | | | | |
| Previously-treated with Irinotecan | Yes | N | 1 | 1 |
|  |  | Unconfirmed ORR, n (%) | 1 (100) | 0 |
|  | | | | |
|  | No | N | 1 | 2 |
|  |  | Unconfirmed ORR, n (%) | 0 | 0 |
|  | | | | |
| TNM staging | IVA | N | 1 | 1 |
|  |  | Unconfirmed ORR, n (%) | 0 | 0 |
|  | | | | |
|  | IVB | N | 0 | 1 |
|  |  | Unconfirmed ORR, n (%) | 0 | 0 |
|  | | | | |
|  | IVC | N | 1 | 1 |
|  |  | Unconfirmed ORR, n (%) | 1 (100) | 0 |
|  | | | | |
| TP53 | Wild-type | N | 2 | 3 |
|  |  | Unconfirmed ORR, n (%) | 1 (50.0) | 0 |
|  |  | 95% CI |  | 0, 70.8 |
|  | | | | |
| STK11 | Wild-type | N | 2 | 3 |
|  |  | Unconfirmed ORR, n (%) | 1 (50.0) | 0 |
|  |  | 95% CI |  | 0, 70.8 |
|  | | | | |
| KEAP1 | Wild-type | N | 2 | 3 |
|  |  | Unconfirmed ORR, n (%) | 1 (50.0) | 0 |
|  |  | 95% CI |  | 0, 70.8 |
|  | | | | |
| EGFR | Wild-type | N | 2 | 3 |
|  |  | Unconfirmed ORR, n (%) | 1 (50.0) | 0 |
|  |  | 95% CI |  | 0, 70.8 |
|  | | | | |
| BRAF | Wild-type | N | 2 | 3 |
|  |  | Unconfirmed ORR, n (%) | 1 (50.0) | 0 |
|  |  | 95% CI |  | 0, 70.8 |
|  | | | | |
| ALK | Wild-type | N | 2 | 3 |
|  |  | Unconfirmed ORR, n (%) | 1 (50.0) | 0 |
|  |  | 95% CI |  | 0, 70.8 |
|  | | | | |
| MET | Wild-type | N | 2 | 3 |
|  |  | Unconfirmed ORR, n (%) | 1 (50.0) | 0 |
|  |  | 95% CI |  | 0, 70.8 |
|  | | | | |
| RET | Wild-type | N | 2 | 3 |
|  |  | Unconfirmed ORR, n (%) | 1 (50.0) | 0 |
|  |  | 95% CI |  | 0, 70.8 |
|  | | | | |
| ROS1 | Wild-type | N | 2 | 3 |
|  |  | Unconfirmed ORR, n (%) | 1 (50.0) | 0 |
|  |  | 95% CI |  | 0, 70.8 |
|  | | | | |
| ERBB2 | Wild-type | N | 2 | 3 |
|  |  | Unconfirmed ORR, n (%) | 1 (50.0) | 0 |
|  |  | 95% CI |  | 0, 70.8 |
|  | | | | |
| NTRK1 | Wild-type | N | 2 | 3 |
|  |  | Unconfirmed ORR, n (%) | 1 (50.0) | 0 |
|  |  | 95% CI |  | 0, 70.8 |
|  | | | | |
| NTRK2 | Wild-type | N | 2 | 3 |
|  |  | Unconfirmed ORR, n (%) | 1 (50.0) | 0 |
|  |  | 95% CI |  | 0, 70.8 |
|  | | | | |
| NTRK3 | Wild-type | N | 2 | 3 |
|  |  | Unconfirmed ORR, n (%) | 1 (50.0) | 0 |
|  |  | 95% CI |  | 0, 70.8 |
|  | | | | |
| KRAS(other than G12C) | Wild-type | N | 2 | 3 |
|  |  | Unconfirmed ORR, n (%) | 1 (50.0) | 0 |
|  |  | 95% CI |  | 0, 70.8 |
|  | | | | |
| NRAS | Wild-type | N | 2 | 3 |
|  |  | Unconfirmed ORR, n (%) | 1 (50.0) | 0 |
|  |  | 95% CI |  | 0, 70.8 |
|  | | | | |
| HRAS | Wild-type | N | 2 | 3 |
|  |  | Unconfirmed ORR, n (%) | 1 (50.0) | 0 |
|  |  | 95% CI |  | 0, 70.8 |
|  | | | | |
| PIK3CA | Wild-type | N | 2 | 3 |
|  |  | Unconfirmed ORR, n (%) | 1 (50.0) | 0 |
|  |  | 95% CI |  | 0, 70.8 |
|  | | | | |
| PIK3R1 | Wild-type | N | 2 | 3 |
|  |  | Unconfirmed ORR, n (%) | 1 (50.0) | 0 |
|  |  | 95% CI |  | 0, 70.8 |
|  | | | | |
| MAP2K1 | Wild-type | N | 2 | 3 |
|  |  | Unconfirmed ORR, n (%) | 1 (50.0) | 0 |
|  |  | 95% CI |  | 0, 70.8 |
|  | | | | |
| RAF1 | Wild-type | N | 2 | 3 |
|  |  | Unconfirmed ORR, n (%) | 1 (50.0) | 0 |
|  |  | 95% CI |  | 0, 70.8 |
|  | | | | |
| FGFR3 | Wild-type | N | 2 | 3 |
|  |  | Unconfirmed ORR, n (%) | 1 (50.0) | 0 |
|  |  | 95% CI |  | 0, 70.8 |
|  | | | | |
| NF1 | Wild-type | N | 2 | 3 |
|  |  | Unconfirmed ORR, n (%) | 1 (50.0) | 0 |
|  |  | 95% CI |  | 0, 70.8 |
|  | | | | |
| PTEN | Wild-type | N | 2 | 3 |
|  |  | Unconfirmed ORR, n (%) | 1 (50.0) | 0 |
|  |  | 95% CI |  | 0, 70.8 |
|  | | | | |
| APC | Wild-type | N | 2 | 3 |
|  |  | Unconfirmed ORR, n (%) | 1 (50.0) | 0 |
|  |  | 95% CI |  | 0, 70.8 |
|  | | | | |
| POLE | Wild-type | N | 2 | 3 |
|  |  | Unconfirmed ORR, n (%) | 1 (50.0) | 0 |
|  |  | 95% CI |  | 0, 70.8 |

ORR = CR + PR.

Unconfirmed ORR represents responses not be confirmed by a follow-up scan ≥ four weeks after initial CR/PR.

Percentages are based on the number of subjects of each respective subgroup in the Response Evaluation Set.

The confidence intervals are calculated using Clopper Pearson method.

If sample size below 3, the confidence interval will not be generated for the unconfirmed ORR.

Source Data: Listing 16.2.6.2.1

|  |  |  |
| --- | --- | --- |
| Program: t-orr-subgrp-part2.sas | DCO: 27APR2024 | Executed: 09JUL2024 11:30 |

|  |  |
| --- | --- |
| **InxMed (Shanghai) Co., Ltd.  Protocol No. IN10018-602** |  |

**Table 14.2.2.1.5 Progression Free Survival based on RECIST 1.1 Criteria - Phase II part 2 - CRC (Intention-to-treat Population)**

|  | Treatment Group (N = 5) | Control Group (N = 5) |
| --- | --- | --- |
| Progressive Disease or Death, n (%) | 0 | 1 (20.0) |
| Censored, n (%) | 5 (100) | 4 (80.0) |
|  | | |
| Progression Free Survival (months) |  |  |
| Minimum | 0.03+ | 0.03+ |
| 25th Percentile (95% CI) | NE (NE, NE) | 1.38 (1.38, NE) |
| Median (95% CI) | NE (NE, NE) | NE (1.38, NE) |
| 75th Percentile (95% CI) | NE (NE, NE) | NE (1.38, NE) |
| Maximum | 2.69+ | 2.73+ |
|  | | |
| Probability (%) of Being Progression-free at Least: |  |  |
| 3 months (95% CI) | NE (NE, NE) | NE (NE, NE) |
|  | | |
| Log-rank One-side P-value [1] (Treatment Group vs. Control Group) | 0.1587 |  |
|  | | |
| COX proportional hazard model [2] |  |  |
| HR (95% CI) (Treatment Group vs. Control Group) | 0 (0, NE) |  |
| One-side P-Value | 0.4995 |  |

[1] The treatment difference was assessed by the log-rank test.

[2] The hazard ratio and its 95% confidence interval calculated by Cox model with Group as the independent variable.

Percentages are based on the number of subjects of each respective group in the Intention-to-treat Population.

PFS is defined as the time from first dose administration to first documentation of PD or death of any cause, whichever occurs first.

For minimum and maximum, + indicates a censored observation.

For quartiles, NE indicates the value was not estimable.

Source Data: Listing 16.2.6.4.2

|  |  |  |
| --- | --- | --- |
| Program: t-pfs.sas | DCO: 27APR2024 | Executed: 07JUL2024 20:36 |

|  |  |
| --- | --- |
| **InxMed (Shanghai) Co., Ltd.  Protocol No. IN10018-602** |  |

**Table 14.2.2.2.2 Summary of PFS Subgroup Analysis - Phase II part 2 - CRC (Intention-to-treat Population)**

| Subgroup |  | | Treatment Group | Control Group |
| --- | --- | --- | --- | --- |
| Age | <65 years | N | 4 | 3 |
|  |  | Progressive Diease or Death, n (%) | 0 | 1 (33.3) |
|  |  | Censored, n (%) | 4 (100) | 2 (66.7) |
|  | | | | |
|  | >=65 years | N | 1 | 2 |
|  |  | Progressive Diease or Death, n (%) | 0 | 0 |
|  |  | Censored, n (%) | 1 (100) | 2 (100) |
|  | | | | |
| Sex | Male | N | 1 | 1 |
|  |  | Progressive Diease or Death, n (%) | 0 | 0 |
|  |  | Censored, n (%) | 1 (100) | 1 (100) |
|  | | | | |
|  | Female | N | 4 | 4 |
|  |  | Progressive Diease or Death, n (%) | 0 | 1 (25.0) |
|  |  | Censored, n (%) | 4 (100) | 3 (75.0) |
|  | | | | |
| Previous lines of anti-cancer therapy | <=2 | N | 5 | 3 |
|  |  | Progressive Diease or Death, n (%) | 0 | 0 |
|  |  | Censored, n (%) | 5 (100) | 3 (100) |
|  | | | | |
|  | >=3 | N |  | 2 |
|  |  | Progressive Diease or Death, n (%) |  | 1 (50.0) |
|  |  | Censored, n (%) |  | 1 (50.0) |
|  | | | | |
| Baseline ECOG status | 1 | N | 5 | 5 |
|  |  | Progressive Diease or Death, n (%) | 0 | 1 (20.0) |
|  |  | Censored, n (%) | 5 (100) | 4 (80.0) |
|  | | | | |
| Differentiation | Well or moderate differentiated | N |  | 4 |
|  |  | Progressive Diease or Death, n (%) |  | 1 (25.0) |
|  |  | Censored, n (%) |  | 3 (75.0) |
|  | | | | |
| Types of cancer | Colon | N | 3 | 2 |
|  |  | Progressive Diease or Death, n (%) | 0 | 0 |
|  |  | Censored, n (%) | 3 (100) | 2 (100) |
|  | | | | |
|  | Rectal | N | 2 | 2 |
|  |  | Progressive Diease or Death, n (%) | 0 | 0 |
|  |  | Censored, n (%) | 2 (100) | 2 (100) |
|  | | | | |
| Number of metastatic organs | <=3 | N | 3 | 4 |
|  |  | Progressive Diease or Death, n (%) | 0 | 0 |
|  |  | Censored, n (%) | 3 (100) | 4 (100) |
|  | | | | |
|  | >3 | N | 2 | 1 |
|  |  | Progressive Diease or Death, n (%) | 0 | 1 (100) |
|  |  | Censored, n (%) | 2 (100) | 0 |
|  | | | | |
| Brain metastasis | No | N | 5 | 5 |
|  |  | Progressive Diease or Death, n (%) | 0 | 1 (20.0) |
|  |  | Censored, n (%) | 5 (100) | 4 (80.0) |
|  | | | | |
| Liver metastasis | Yes | N | 2 | 3 |
|  |  | Progressive Diease or Death, n (%) | 0 | 1 (33.3) |
|  |  | Censored, n (%) | 2 (100) | 2 (66.7) |
|  | | | | |
|  | No | N | 3 | 2 |
|  |  | Progressive Diease or Death, n (%) | 0 | 0 |
|  |  | Censored, n (%) | 3 (100) | 2 (100) |
|  | | | | |
| Lung metastasis | Yes | N | 3 | 3 |
|  |  | Progressive Diease or Death, n (%) | 0 | 1 (33.3) |
|  |  | Censored, n (%) | 3 (100) | 2 (66.7) |
|  | | | | |
|  | No | N | 2 | 2 |
|  |  | Progressive Diease or Death, n (%) | 0 | 0 |
|  |  | Censored, n (%) | 2 (100) | 2 (100) |
|  | | | | |
| Peritoneum metastasis | Yes | N | 1 | 1 |
|  |  | Progressive Diease or Death, n (%) | 0 | 1 (100) |
|  |  | Censored, n (%) | 1 (100) | 0 |
|  | | | | |
|  | No | N | 4 | 4 |
|  |  | Progressive Diease or Death, n (%) | 0 | 0 |
|  |  | Censored, n (%) | 4 (100) | 4 (100) |
|  | | | | |
| Previously-treated with bevacizumab | Yes | N | 4 | 4 |
|  |  | Progressive Diease or Death, n (%) | 0 | 1 (25.0) |
|  |  | Censored, n (%) | 4 (100) | 3 (75.0) |
|  | | | | |
|  | No | N | 1 | 1 |
|  |  | Progressive Diease or Death, n (%) | 0 | 0 |
|  |  | Censored, n (%) | 1 (100) | 1 (100) |
|  | | | | |
| Previously-treated with Oxaliplatin | Yes | N | 4 | 5 |
|  |  | Progressive Diease or Death, n (%) | 0 | 1 (20.0) |
|  |  | Censored, n (%) | 4 (100) | 4 (80.0) |
|  | | | | |
|  | No | N | 1 |  |
|  |  | Progressive Diease or Death, n (%) | 0 |  |
|  |  | Censored, n (%) | 1 (100) |  |
|  | | | | |
| Previously-treated with Irinotecan | Yes | N | 3 | 3 |
|  |  | Progressive Diease or Death, n (%) | 0 | 1 (33.3) |
|  |  | Censored, n (%) | 3 (100) | 2 (66.7) |
|  | | | | |
|  | No | N | 2 | 2 |
|  |  | Progressive Diease or Death, n (%) | 0 | 0 |
|  |  | Censored, n (%) | 2 (100) | 2 (100) |
|  | | | | |
| TNM staging | IVA | N | 2 | 2 |
|  |  | Progressive Diease or Death, n (%) | 0 | 0 |
|  |  | Censored, n (%) | 2 (100) | 2 (100) |
|  | | | | |
|  | IVB | N | 2 | 2 |
|  |  | Progressive Diease or Death, n (%) | 0 | 0 |
|  |  | Censored, n (%) | 2 (100) | 2 (100) |
|  | | | | |
|  | IVC | N | 1 | 1 |
|  |  | Progressive Diease or Death, n (%) | 0 | 1 (100) |
|  |  | Censored, n (%) | 1 (100) | 0 |
|  | | | | |
| TP53 | Wild-type | N | 5 | 5 |
|  |  | Progressive Diease or Death, n (%) | 0 | 1 (20.0) |
|  |  | Censored, n (%) | 5 (100) | 4 (80.0) |
|  | | | | |
| STK11 | Wild-type | N | 5 | 5 |
|  |  | Progressive Diease or Death, n (%) | 0 | 1 (20.0) |
|  |  | Censored, n (%) | 5 (100) | 4 (80.0) |
|  | | | | |
| KEAP1 | Wild-type | N | 5 | 5 |
|  |  | Progressive Diease or Death, n (%) | 0 | 1 (20.0) |
|  |  | Censored, n (%) | 5 (100) | 4 (80.0) |
|  | | | | |
| EGFR | Wild-type | N | 5 | 5 |
|  |  | Progressive Diease or Death, n (%) | 0 | 1 (20.0) |
|  |  | Censored, n (%) | 5 (100) | 4 (80.0) |
|  | | | | |
| BRAF | Wild-type | N | 5 | 5 |
|  |  | Progressive Diease or Death, n (%) | 0 | 1 (20.0) |
|  |  | Censored, n (%) | 5 (100) | 4 (80.0) |
|  | | | | |
| ALK | Wild-type | N | 5 | 5 |
|  |  | Progressive Diease or Death, n (%) | 0 | 1 (20.0) |
|  |  | Censored, n (%) | 5 (100) | 4 (80.0) |
|  | | | | |
| MET | Wild-type | N | 5 | 5 |
|  |  | Progressive Diease or Death, n (%) | 0 | 1 (20.0) |
|  |  | Censored, n (%) | 5 (100) | 4 (80.0) |
|  | | | | |
| RET | Wild-type | N | 5 | 5 |
|  |  | Progressive Diease or Death, n (%) | 0 | 1 (20.0) |
|  |  | Censored, n (%) | 5 (100) | 4 (80.0) |
|  | | | | |
| ROS1 | Wild-type | N | 5 | 5 |
|  |  | Progressive Diease or Death, n (%) | 0 | 1 (20.0) |
|  |  | Censored, n (%) | 5 (100) | 4 (80.0) |
|  | | | | |
| ERBB2 | Wild-type | N | 5 | 5 |
|  |  | Progressive Diease or Death, n (%) | 0 | 1 (20.0) |
|  |  | Censored, n (%) | 5 (100) | 4 (80.0) |
|  | | | | |
| NTRK1 | Wild-type | N | 5 | 5 |
|  |  | Progressive Diease or Death, n (%) | 0 | 1 (20.0) |
|  |  | Censored, n (%) | 5 (100) | 4 (80.0) |
|  | | | | |
| NTRK2 | Wild-type | N | 5 | 5 |
|  |  | Progressive Diease or Death, n (%) | 0 | 1 (20.0) |
|  |  | Censored, n (%) | 5 (100) | 4 (80.0) |
|  | | | | |
| NTRK3 | Wild-type | N | 5 | 5 |
|  |  | Progressive Diease or Death, n (%) | 0 | 1 (20.0) |
|  |  | Censored, n (%) | 5 (100) | 4 (80.0) |
|  | | | | |
| KRAS(other than G12C) | Wild-type | N | 5 | 5 |
|  |  | Progressive Diease or Death, n (%) | 0 | 1 (20.0) |
|  |  | Censored, n (%) | 5 (100) | 4 (80.0) |
|  | | | | |
| NRAS | Wild-type | N | 5 | 5 |
|  |  | Progressive Diease or Death, n (%) | 0 | 1 (20.0) |
|  |  | Censored, n (%) | 5 (100) | 4 (80.0) |
|  | | | | |
| HRAS | Wild-type | N | 5 | 5 |
|  |  | Progressive Diease or Death, n (%) | 0 | 1 (20.0) |
|  |  | Censored, n (%) | 5 (100) | 4 (80.0) |
|  | | | | |
| PIK3CA | Wild-type | N | 5 | 5 |
|  |  | Progressive Diease or Death, n (%) | 0 | 1 (20.0) |
|  |  | Censored, n (%) | 5 (100) | 4 (80.0) |
|  | | | | |
| PIK3R1 | Wild-type | N | 5 | 5 |
|  |  | Progressive Diease or Death, n (%) | 0 | 1 (20.0) |
|  |  | Censored, n (%) | 5 (100) | 4 (80.0) |
|  | | | | |
| MAP2K1 | Wild-type | N | 5 | 5 |
|  |  | Progressive Diease or Death, n (%) | 0 | 1 (20.0) |
|  |  | Censored, n (%) | 5 (100) | 4 (80.0) |
|  | | | | |
| RAF1 | Wild-type | N | 5 | 5 |
|  |  | Progressive Diease or Death, n (%) | 0 | 1 (20.0) |
|  |  | Censored, n (%) | 5 (100) | 4 (80.0) |
|  | | | | |
| FGFR3 | Wild-type | N | 5 | 5 |
|  |  | Progressive Diease or Death, n (%) | 0 | 1 (20.0) |
|  |  | Censored, n (%) | 5 (100) | 4 (80.0) |
|  | | | | |
| NF1 | Wild-type | N | 5 | 5 |
|  |  | Progressive Diease or Death, n (%) | 0 | 1 (20.0) |
|  |  | Censored, n (%) | 5 (100) | 4 (80.0) |
|  | | | | |
| PTEN | Wild-type | N | 5 | 5 |
|  |  | Progressive Diease or Death, n (%) | 0 | 1 (20.0) |
|  |  | Censored, n (%) | 5 (100) | 4 (80.0) |
|  | | | | |
| APC | Wild-type | N | 5 | 5 |
|  |  | Progressive Diease or Death, n (%) | 0 | 1 (20.0) |
|  |  | Censored, n (%) | 5 (100) | 4 (80.0) |
|  | | | | |
| POLE | Wild-type | N | 5 | 5 |
|  |  | Progressive Diease or Death, n (%) | 0 | 1 (20.0) |
|  |  | Censored, n (%) | 5 (100) | 4 (80.0) |

mPFS: Median Progression Free Survival.

Percentages are based on the number of subjects of each respective subgroup in the Intention-to-treat Population.

If the number of event of a subgroup falls below 5, then the Kaplan-Meier analysis will not be conducted.

Source Data: Listing 16.2.6.4.2

|  |  |  |
| --- | --- | --- |
| Program: t-pfs-subgrp-part2.sas | DCO: 27APR2024 | Executed: 07JUL2024 20:36 |

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| **InxMed (Shanghai) Co., Ltd.  Protocol No. IN10018-602** |  |

**Table 14.2.3.1.5.1 Duration of Response based on RECIST 1.1 Criteria (Confirmed) - Phase II part 2 - CRC (Intention-to-treatment Population)**

|  | Treatment Group (N = 5) | Control Group (N = 5) |
| --- | --- | --- |
| Subjects with CR/PR, n (%) [1] | 1 (20.0) | 0 |
| Progressive Disease or Death, n (%) [2] | 0 | 0 |
| Censored, n (%) [2] | 1 (100) | 0 |
|  | | |
| Duration of Response (months) |  |  |
| Minimum | 1.22+ | NE |
| 25th Percentile (95% CI) | NE (NE, NE) | NE (NE, NE) |
| Median (95% CI) | NE (NE, NE) | NE (NE, NE) |
| 75th Percentile (95% CI) | NE (NE, NE) | NE (NE, NE) |
| Maximum | 1.22+ | NE |
|  | | |
| Probability (%) of Being Event-free at Least: |  |  |
| 3 months (95% CI) | NE (NE, NE) | NE (NE, NE) |
|  | | |
| Log-rank One-side P-value [3] (Treatment Group vs. Control Group) | NE |  |
|  | | |
| COX proportional hazard model [4] |  |  |
| HR (95% CI) (Treatment Group vs. Control Group) | NE (NE, NE) |  |
| One-side P-Value | NE |  |

[1] Percentages are based on the number of subjects of each respective group in the Intention-to-treatment Population.

[2] Percentages are based on the number of subjects with CR/PR of each respective group in the Intention-to-treatment Population.

[3] The treatment difference was assessed by the log-rank test.

[4] The hazard ratio and its 95% confidence interval calculated by Cox model with Group as the independent variable.

DOR is defined as the time from the first documented evidence of response (CR or PR) until disease progression (based on RECIST v1.1) or death due to any cause, whichever occurs first.

Confirmed DOR represents responses confirmed by a follow-up scan ≥ four weeks after initial CR/PR.

For minimum and maximum, + indicates a censored observation.

For quartiles, NE indicates the value was not estimable.

Source Data: Listing 16.2.6.3.2

|  |  |  |
| --- | --- | --- |
| Program: t-dor.sas | DCO: 27APR2024 | Executed: 09JUL2024 11:30 |

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| --- | --- |
| **InxMed (Shanghai) Co., Ltd.  Protocol No. IN10018-602** |  |

**Table 14.2.3.1.5.2 Duration of Response based on RECIST 1.1 Criteria (Unconfirmed) - Phase II part 2 - CRC (Intention-to-treatment Population)**

|  | Treatment Group (N = 5) | Control Group (N = 5) |
| --- | --- | --- |
| Subjects with CR/PR, n (%) [1] | 1 (20.0) | 0 |
| Progressive Disease or Death, n (%) [2] | 0 | 0 |
| Censored, n (%) [2] | 1 (100) | 0 |
|  | | |
| Duration of Response (months) |  |  |
| Minimum | 1.22+ | NE |
| 25th Percentile (95% CI) | NE (NE, NE) | NE (NE, NE) |
| Median (95% CI) | NE (NE, NE) | NE (NE, NE) |
| 75th Percentile (95% CI) | NE (NE, NE) | NE (NE, NE) |
| Maximum | 1.22+ | NE |
|  | | |
| Probability (%) of Being Event-free at Least: |  |  |
| 3 months (95% CI) | NE (NE, NE) | NE (NE, NE) |
|  | | |
| Log-rank One-side P-value [3] (Treatment Group vs. Control Group) | NE |  |
|  | | |
| COX proportional hazard model [4] |  |  |
| HR (95% CI) (Treatment Group vs. Control Group) | NE (NE, NE) |  |
| One-side P-Value | NE |  |

[1] Percentages are based on the number of subjects of each respective group in the Intention-to-treatment Population.

[2] Percentages are based on the number of subjects with CR/PR of each respective group in the Intention-to-treatment Population.

[3] The treatment difference was assessed by the log-rank test.

[4] The hazard ratio and its 95% confidence interval calculated by Cox model with Group as the independent variable.

DOR is defined as the time from the first documented evidence of response (CR or PR) until disease progression (based on RECIST v1.1) or death due to any cause, whichever occurs first.

Unconfirmed DOR represents responses not be confirmed by a follow-up scan ≥ four weeks after initial CR/PR.

For minimum and maximum, + indicates a censored observation.

For quartiles, NE indicates the value was not estimable.

Source Data: Listing 16.2.6.3.2

|  |  |  |
| --- | --- | --- |
| Program: t-dor.sas | DCO: 27APR2024 | Executed: 09JUL2024 11:30 |

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| --- | --- |
| **InxMed (Shanghai) Co., Ltd.  Protocol No. IN10018-602** |  |

**Table 14.2.4.1.5 Overall Survival - Phase II part 2 - CRC (Intention-to-treat Population)**

|  | Treatment Group (N = 5) | Control Group (N = 5) |
| --- | --- | --- |
| Death, n (%) | 0 | 1 (20.0) |
| Censored, n (%) | 5 (100) | 4 (80.0) |
|  | | |
| Overall Survival (months) |  |  |
| Minimum | 0.39+ | 0.33+ |
| 25th Percentile (95% CI) | NE (NE, NE) | 3.22 (3.22, NE) |
| Median (95% CI) | NE (NE, NE) | NE (3.22, NE) |
| 75th Percentile (95% CI) | NE (NE, NE) | NE (3.22, NE) |
| Maximum | 3.29+ | 3.29+ |
|  | | |
| Probability (%) of Survival at Least: |  |  |
| 3 months (95% CI) | 100 (NE, NE) | 100 (NE, NE) |
| 6 months (95% CI) | NE (NE, NE) | NE (NE, NE) |
|  | | |
| Log-rank One-side P-value [1] (Treatment Group vs. Control Group) | 0.2398 |  |
|  | | |
| COX proportional hazard model [2] |  |  |
| HR (95% CI) (Treatment Group vs. Control Group) | 0 (0, NE) |  |
| One-side P-Value | 0.4995 |  |

[1] The treatment difference was assessed by the log-rank test.

[2] The hazard ratio and its 95% confidence interval calculated by Cox model with Group as the independent variable.

Percentages are based on the number of subjects of each respective group in the Intention-to-treat Population.

OS is defined as the time from the first dose administration to the death due to any cause.

For minimum and maximum, + indicates a censored observation.

For quartiles, NE indicates the value was not estimable.

Source Data: Listing 16.2.6.5.2

|  |  |  |
| --- | --- | --- |
| Program: t-os.sas | DCO: 27APR2024 | Executed: 07JUL2024 20:36 |

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| --- | --- |
| **InxMed (Shanghai) Co., Ltd.  Protocol No. IN10018-602** |  |

**Table 14.2.4.2.2 Summary of OS Subgroup Analysis - Phase II part 2 - CRC (Intention-to-treat Population)**

| Subgroup |  | | Treatment Group | Control Group |
| --- | --- | --- | --- | --- |
| Age | <65 years | N | 4 | 3 |
|  |  | Death, n (%) | 0 | 1 (33.3) |
|  |  | Censored, n (%) | 4 (100) | 2 (66.7) |
|  | | | | |
|  | >=65 years | N | 1 | 2 |
|  |  | Death, n (%) | 0 | 0 |
|  |  | Censored, n (%) | 1 (100) | 2 (100) |
|  | | | | |
| Sex | Male | N | 1 | 1 |
|  |  | Death, n (%) | 0 | 0 |
|  |  | Censored, n (%) | 1 (100) | 1 (100) |
|  | | | | |
|  | Female | N | 4 | 4 |
|  |  | Death, n (%) | 0 | 1 (25.0) |
|  |  | Censored, n (%) | 4 (100) | 3 (75.0) |
|  | | | | |
| Previous lines of anti-cancer therapy | <=2 | N | 5 | 3 |
|  |  | Death, n (%) | 0 | 0 |
|  |  | Censored, n (%) | 5 (100) | 3 (100) |
|  | | | | |
|  | >=3 | N |  | 2 |
|  |  | Death, n (%) |  | 1 (50.0) |
|  |  | Censored, n (%) |  | 1 (50.0) |
|  | | | | |
| Baseline ECOG status | 1 | N | 5 | 5 |
|  |  | Death, n (%) | 0 | 1 (20.0) |
|  |  | Censored, n (%) | 5 (100) | 4 (80.0) |
|  | | | | |
| Differentiation | Well or moderate differentiated | N |  | 4 |
|  |  | Death, n (%) |  | 1 (25.0) |
|  |  | Censored, n (%) |  | 3 (75.0) |
|  | | | | |
| Types of cancer | Colon | N | 3 | 2 |
|  |  | Death, n (%) | 0 | 0 |
|  |  | Censored, n (%) | 3 (100) | 2 (100) |
|  | | | | |
|  | Rectal | N | 2 | 2 |
|  |  | Death, n (%) | 0 | 0 |
|  |  | Censored, n (%) | 2 (100) | 2 (100) |
|  | | | | |
| Number of metastatic organs | <=3 | N | 3 | 4 |
|  |  | Death, n (%) | 0 | 0 |
|  |  | Censored, n (%) | 3 (100) | 4 (100) |
|  | | | | |
|  | >3 | N | 2 | 1 |
|  |  | Death, n (%) | 0 | 1 (100) |
|  |  | Censored, n (%) | 2 (100) | 0 |
|  | | | | |
| Brain metastasis | No | N | 5 | 5 |
|  |  | Death, n (%) | 0 | 1 (20.0) |
|  |  | Censored, n (%) | 5 (100) | 4 (80.0) |
|  | | | | |
| Liver metastasis | Yes | N | 2 | 3 |
|  |  | Death, n (%) | 0 | 1 (33.3) |
|  |  | Censored, n (%) | 2 (100) | 2 (66.7) |
|  | | | | |
|  | No | N | 3 | 2 |
|  |  | Death, n (%) | 0 | 0 |
|  |  | Censored, n (%) | 3 (100) | 2 (100) |
|  | | | | |
| Lung metastasis | Yes | N | 3 | 3 |
|  |  | Death, n (%) | 0 | 1 (33.3) |
|  |  | Censored, n (%) | 3 (100) | 2 (66.7) |
|  | | | | |
|  | No | N | 2 | 2 |
|  |  | Death, n (%) | 0 | 0 |
|  |  | Censored, n (%) | 2 (100) | 2 (100) |
|  | | | | |
| Peritoneum metastasis | Yes | N | 1 | 1 |
|  |  | Death, n (%) | 0 | 1 (100) |
|  |  | Censored, n (%) | 1 (100) | 0 |
|  | | | | |
|  | No | N | 4 | 4 |
|  |  | Death, n (%) | 0 | 0 |
|  |  | Censored, n (%) | 4 (100) | 4 (100) |
|  | | | | |
| Previously-treated with bevacizumab | Yes | N | 4 | 4 |
|  |  | Death, n (%) | 0 | 1 (25.0) |
|  |  | Censored, n (%) | 4 (100) | 3 (75.0) |
|  | | | | |
|  | No | N | 1 | 1 |
|  |  | Death, n (%) | 0 | 0 |
|  |  | Censored, n (%) | 1 (100) | 1 (100) |
|  | | | | |
| Previously-treated with Oxaliplatin | Yes | N | 4 | 5 |
|  |  | Death, n (%) | 0 | 1 (20.0) |
|  |  | Censored, n (%) | 4 (100) | 4 (80.0) |
|  | | | | |
|  | No | N | 1 |  |
|  |  | Death, n (%) | 0 |  |
|  |  | Censored, n (%) | 1 (100) |  |
|  | | | | |
| Previously-treated with Irinotecan | Yes | N | 3 | 3 |
|  |  | Death, n (%) | 0 | 1 (33.3) |
|  |  | Censored, n (%) | 3 (100) | 2 (66.7) |
|  | | | | |
|  | No | N | 2 | 2 |
|  |  | Death, n (%) | 0 | 0 |
|  |  | Censored, n (%) | 2 (100) | 2 (100) |
|  | | | | |
| TNM staging | IVA | N | 2 | 2 |
|  |  | Death, n (%) | 0 | 0 |
|  |  | Censored, n (%) | 2 (100) | 2 (100) |
|  | | | | |
|  | IVB | N | 2 | 2 |
|  |  | Death, n (%) | 0 | 0 |
|  |  | Censored, n (%) | 2 (100) | 2 (100) |
|  | | | | |
|  | IVC | N | 1 | 1 |
|  |  | Death, n (%) | 0 | 1 (100) |
|  |  | Censored, n (%) | 1 (100) | 0 |
|  | | | | |
| TP53 | Wild-type | N | 5 | 5 |
|  |  | Death, n (%) | 0 | 1 (20.0) |
|  |  | Censored, n (%) | 5 (100) | 4 (80.0) |
|  | | | | |
| STK11 | Wild-type | N | 5 | 5 |
|  |  | Death, n (%) | 0 | 1 (20.0) |
|  |  | Censored, n (%) | 5 (100) | 4 (80.0) |
|  | | | | |
| KEAP1 | Wild-type | N | 5 | 5 |
|  |  | Death, n (%) | 0 | 1 (20.0) |
|  |  | Censored, n (%) | 5 (100) | 4 (80.0) |
|  | | | | |
| EGFR | Wild-type | N | 5 | 5 |
|  |  | Death, n (%) | 0 | 1 (20.0) |
|  |  | Censored, n (%) | 5 (100) | 4 (80.0) |
|  | | | | |
| BRAF | Wild-type | N | 5 | 5 |
|  |  | Death, n (%) | 0 | 1 (20.0) |
|  |  | Censored, n (%) | 5 (100) | 4 (80.0) |
|  | | | | |
| ALK | Wild-type | N | 5 | 5 |
|  |  | Death, n (%) | 0 | 1 (20.0) |
|  |  | Censored, n (%) | 5 (100) | 4 (80.0) |
|  | | | | |
| MET | Wild-type | N | 5 | 5 |
|  |  | Death, n (%) | 0 | 1 (20.0) |
|  |  | Censored, n (%) | 5 (100) | 4 (80.0) |
|  | | | | |
| RET | Wild-type | N | 5 | 5 |
|  |  | Death, n (%) | 0 | 1 (20.0) |
|  |  | Censored, n (%) | 5 (100) | 4 (80.0) |
|  | | | | |
| ROS1 | Wild-type | N | 5 | 5 |
|  |  | Death, n (%) | 0 | 1 (20.0) |
|  |  | Censored, n (%) | 5 (100) | 4 (80.0) |
|  | | | | |
| ERBB2 | Wild-type | N | 5 | 5 |
|  |  | Death, n (%) | 0 | 1 (20.0) |
|  |  | Censored, n (%) | 5 (100) | 4 (80.0) |
|  | | | | |
| NTRK1 | Wild-type | N | 5 | 5 |
|  |  | Death, n (%) | 0 | 1 (20.0) |
|  |  | Censored, n (%) | 5 (100) | 4 (80.0) |
|  | | | | |
| NTRK2 | Wild-type | N | 5 | 5 |
|  |  | Death, n (%) | 0 | 1 (20.0) |
|  |  | Censored, n (%) | 5 (100) | 4 (80.0) |
|  | | | | |
| NTRK3 | Wild-type | N | 5 | 5 |
|  |  | Death, n (%) | 0 | 1 (20.0) |
|  |  | Censored, n (%) | 5 (100) | 4 (80.0) |
|  | | | | |
| KRAS(other than G12C) | Wild-type | N | 5 | 5 |
|  |  | Death, n (%) | 0 | 1 (20.0) |
|  |  | Censored, n (%) | 5 (100) | 4 (80.0) |
|  | | | | |
| NRAS | Wild-type | N | 5 | 5 |
|  |  | Death, n (%) | 0 | 1 (20.0) |
|  |  | Censored, n (%) | 5 (100) | 4 (80.0) |
|  | | | | |
| HRAS | Wild-type | N | 5 | 5 |
|  |  | Death, n (%) | 0 | 1 (20.0) |
|  |  | Censored, n (%) | 5 (100) | 4 (80.0) |
|  | | | | |
| PIK3CA | Wild-type | N | 5 | 5 |
|  |  | Death, n (%) | 0 | 1 (20.0) |
|  |  | Censored, n (%) | 5 (100) | 4 (80.0) |
|  | | | | |
| PIK3R1 | Wild-type | N | 5 | 5 |
|  |  | Death, n (%) | 0 | 1 (20.0) |
|  |  | Censored, n (%) | 5 (100) | 4 (80.0) |
|  | | | | |
| MAP2K1 | Wild-type | N | 5 | 5 |
|  |  | Death, n (%) | 0 | 1 (20.0) |
|  |  | Censored, n (%) | 5 (100) | 4 (80.0) |
|  | | | | |
| RAF1 | Wild-type | N | 5 | 5 |
|  |  | Death, n (%) | 0 | 1 (20.0) |
|  |  | Censored, n (%) | 5 (100) | 4 (80.0) |
|  | | | | |
| FGFR3 | Wild-type | N | 5 | 5 |
|  |  | Death, n (%) | 0 | 1 (20.0) |
|  |  | Censored, n (%) | 5 (100) | 4 (80.0) |
|  | | | | |
| NF1 | Wild-type | N | 5 | 5 |
|  |  | Death, n (%) | 0 | 1 (20.0) |
|  |  | Censored, n (%) | 5 (100) | 4 (80.0) |
|  | | | | |
| PTEN | Wild-type | N | 5 | 5 |
|  |  | Death, n (%) | 0 | 1 (20.0) |
|  |  | Censored, n (%) | 5 (100) | 4 (80.0) |
|  | | | | |
| APC | Wild-type | N | 5 | 5 |
|  |  | Death, n (%) | 0 | 1 (20.0) |
|  |  | Censored, n (%) | 5 (100) | 4 (80.0) |
|  | | | | |
| POLE | Wild-type | N | 5 | 5 |
|  |  | Death, n (%) | 0 | 1 (20.0) |
|  |  | Censored, n (%) | 5 (100) | 4 (80.0) |

mOS: Median Overall Survival

Percentages are based on the number of subjects of each respective subgroup in the Intention-to-treat Population.

If the number of event of a subgroup falls below 5, then the Kaplan-Meier analysis will not be conducted.

Source Data: Listing 16.2.6.5.2

|  |  |  |
| --- | --- | --- |
| Program: t-pfs-subgrp-part2.sas | DCO: 27APR2024 | Executed: 07JUL2024 20:36 |

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| --- | --- |
| **InxMed (Shanghai) Co., Ltd.  Protocol No. IN10018-602** |  |

**Table 14.3.1.1.5 Overview of All AEs - Phase II part 2 - CRC (Safety Analysis Set)**

|  | Treatment Group (N = 5) n (%) | Control Group (N = 5) n (%) | Total (N = 10) n (%) |
| --- | --- | --- | --- |
| All AEs | 5 (100) | 5 (100) | 10 (100) |
|  | | | |
| All TEAEs | 5 (100) | 5 (100) | 10 (100) |
| Related to D-1553 | 5 (100) | 5 (100) | 10 (100) |
| Related to IN10018 | 5 (100) | 1 (20.0) | 6 (60.0) |
|  | | | |
| CTCAE Grade 3/4 TEAEs | 2 (40.0) | 1 (20.0) | 3 (30.0) |
| Related to D-1553 | 2 (40.0) | 1 (20.0) | 3 (30.0) |
| Related to IN10018 | 2 (40.0) | 0 | 2 (20.0) |
|  | | | |
| TEAEs Leading to D-1553 Dose Reduction | 0 | 0 | 0 |
| Related to D-1553 | 0 | 0 | 0 |
|  | | | |
| TEAEs Leading to IN10018 Dose Reduction | 1 (20.0) | 0 | 1 (10.0) |
| Related to IN10018 | 1 (20.0) | 0 | 1 (10.0) |
|  | | | |
| TEAEs Leading to D-1553 Drug Interruption | 2 (40.0) | 2 (40.0) | 4 (40.0) |
| Related to D-1553 | 2 (40.0) | 2 (40.0) | 4 (40.0) |
|  | | | |
| TEAEs Leading to IN10018 Drug Interruption | 2 (40.0) | 0 | 2 (20.0) |
| Related to IN10018 | 2 (40.0) | 0 | 2 (20.0) |
|  | | | |
| TEAEs Leading to D-1553 Drug Withdrawn | 0 | 0 | 0 |
| Related to D-1553 | 0 | 0 | 0 |
|  | | | |
| TEAEs Leading to IN10018 Drug Withdrawn | 0 | 0 | 0 |
| Related to IN10018 | 0 | 0 | 0 |
|  | | | |
| TEAEs of Special Interest (AESI) | 0 | 0 | 0 |
| Abnormal liver function | 0 | 0 | 0 |
| Related to D-1553 | 0 | 0 | 0 |
| Related to IN10018 | 0 | 0 | 0 |
| Proteinuria | 0 | 0 | 0 |
| Related to D-1553 | 0 | 0 | 0 |
| Related to IN10018 | 0 | 0 | 0 |
|  | | | |
| CTCAE Grade 3/4 AESI | 0 | 0 | 0 |
| CTCAE Grade 3/4 Abnormal liver function | 0 | 0 | 0 |
| CTCAE Grade 3 Proteinuria | 0 | 0 | 0 |
|  | | | |
| Treatment-emergent SAEs | 2 (40.0) | 1 (20.0) | 3 (30.0) |
| Related to D-1553 | 2 (40.0) | 0 | 2 (20.0) |
| Related to IN10018 | 2 (40.0) | 0 | 2 (20.0) |
| SAEs Leading to Death | 0 | 0 | 0 |
| SAEs Leading to Life Threatening | 0 | 0 | 0 |
| SAEs Leading to Congenital Anomaly or Birth Defect | 0 | 0 | 0 |
| SAEs Leading to Disability or Permanent Damage | 0 | 0 | 0 |
| SAEs Leading to Hospitalization (Initial or Prolonged) | 2 (40.0) | 1 (20.0) | 3 (30.0) |
| SAEs leading to Other Important Medical Events | 0 | 0 | 0 |
|  | | | |
| TEAEs Leading to Death | 0 | 0 | 0 |
| Related to D-1553 | 0 | 0 | 0 |
| Related to IN10018 | 0 | 0 | 0 |

TEAE is defined as any AE that newly occurs or worsen after the first investigational drug administration and within end of safety follow up period (i.e., within 30 calendar days after the last administration of investigational drug or the start of new anti-cancer therapy (whichever occurs earlier)). If the timing of the AE cannot be established in relation to the first administration of investigational drug, it will be considered as TEAE to be more conservative.

D-1553 related TEAE is defined as the relationship with D-1553 as 'Definitely Related' or 'Probably Related' or 'Possibly Related' or 'Related/Reasonable Possibility'. To be conservative, if the relationship is missing, TEAE is still considered as D-1553 related TEAE.

IN10018 related TEAE is defined as the relationship with IN10018 as 'Definitely Related' or 'Probably Related' or 'Possibly Related' or 'Related/Reasonable Possibility'. To be conservative, if the relationship is missing, TEAE is still considered as IN10018 related TEAE.

Subjects with multiple occurrences of adverse events in the same category are counted only once in that category at the maximum severity.

Percentages are based on the number of subjects of each respective group in the Safety Analysis Set.

Source Data: Listing 16.2.7.1

|  |  |  |
| --- | --- | --- |
| Program: t-ae-sum.sas | DCO: 27APR2024 | Executed: 07JUL2024 20:36 |

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| --- | --- |
| **InxMed (Shanghai) Co., Ltd.  Protocol No. IN10018-602** |  |

**Table 14.3.1.1.6 Overview of All AEs by Grouped PT - Phase II part 2 - CRC (Safety Analysis Set)**

|  | Treatment Group (N = 5) n (%) | Control Group (N = 5) n (%) | Total (N = 10) n (%) |
| --- | --- | --- | --- |
| All AEs | 5 (100) | 5 (100) | 10 (100) |
|  | | | |
| All TEAEs | 5 (100) | 5 (100) | 10 (100) |
| Related to D-1553 | 5 (100) | 5 (100) | 10 (100) |
| Related to IN10018 | 5 (100) | 1 (20.0) | 6 (60.0) |
|  | | | |
| CTCAE Grade 3/4 TEAEs | 2 (40.0) | 1 (20.0) | 3 (30.0) |
| Related to D-1553 | 2 (40.0) | 1 (20.0) | 3 (30.0) |
| Related to IN10018 | 2 (40.0) | 0 | 2 (20.0) |
|  | | | |
| TEAEs Leading to D-1553 Dose Reduction | 0 | 0 | 0 |
| Related to D-1553 | 0 | 0 | 0 |
|  | | | |
| TEAEs Leading to IN10018 Dose Reduction | 1 (20.0) | 0 | 1 (10.0) |
| Related to IN10018 | 1 (20.0) | 0 | 1 (10.0) |
|  | | | |
| TEAEs Leading to D-1553 Drug Interruption | 2 (40.0) | 2 (40.0) | 4 (40.0) |
| Related to D-1553 | 2 (40.0) | 2 (40.0) | 4 (40.0) |
|  | | | |
| TEAEs Leading to IN10018 Drug Interruption | 2 (40.0) | 0 | 2 (20.0) |
| Related to IN10018 | 2 (40.0) | 0 | 2 (20.0) |
|  | | | |
| TEAEs Leading to D-1553 Drug Withdrawn | 0 | 0 | 0 |
| Related to D-1553 | 0 | 0 | 0 |
|  | | | |
| TEAEs Leading to IN10018 Drug Withdrawn | 0 | 0 | 0 |
| Related to IN10018 | 0 | 0 | 0 |
|  | | | |
| TEAEs of Special Interest (AESI) | 0 | 0 | 0 |
| Abnormal liver function | 0 | 0 | 0 |
| Related to D-1553 | 0 | 0 | 0 |
| Related to IN10018 | 0 | 0 | 0 |
| Proteinuria | 0 | 0 | 0 |
| Related to D-1553 | 0 | 0 | 0 |
| Related to IN10018 | 0 | 0 | 0 |
|  | | | |
| CTCAE Grade 3/4 AESI | 0 | 0 | 0 |
| CTCAE Grade 3/4 Abnormal liver function | 0 | 0 | 0 |
| CTCAE Grade 3 Proteinuria | 0 | 0 | 0 |
|  | | | |
| Treatment-emergent SAEs | 2 (40.0) | 1 (20.0) | 3 (30.0) |
| Related to D-1553 | 2 (40.0) | 0 | 2 (20.0) |
| Related to IN10018 | 2 (40.0) | 0 | 2 (20.0) |
| SAEs Leading to Death | 0 | 0 | 0 |
| SAEs Leading to Life Threatening | 0 | 0 | 0 |
| SAEs Leading to Congenital Anomaly or Birth Defect | 0 | 0 | 0 |
| SAEs Leading to Disability or Permanent Damage | 0 | 0 | 0 |
| SAEs Leading to Hospitalization (Initial or Prolonged) | 2 (40.0) | 1 (20.0) | 3 (30.0) |
| SAEs leading to Other Important Medical Events | 0 | 0 | 0 |
|  | | | |
| TEAEs Leading to Death | 0 | 0 | 0 |
| Related to D-1553 | 0 | 0 | 0 |
| Related to IN10018 | 0 | 0 | 0 |

TEAE is defined as any AE that newly occurs or worsen after the first investigational drug administration and within end of safety follow up period (i.e., within 30 calendar days after the last administration of investigational drug or the start of new anti-cancer therapy (whichever occurs earlier)). If the timing of the AE cannot be established in relation to the first administration of investigational drug, it will be considered as TEAE to be more conservative.

D-1553 related TEAE is defined as the relationship with D-1553 as 'Definitely Related' or 'Probably Related' or 'Possibly Related' or 'Related/Reasonable Possibility'. To be conservative, if the relationship is missing, TEAE is still considered as D-1553 related TEAE.

IN10018 related TEAE is defined as the relationship with IN10018 as 'Definitely Related' or 'Probably Related' or 'Possibly Related' or 'Related/Reasonable Possibility'. To be conservative, if the relationship is missing, TEAE is still considered as IN10018 related TEAE.

Subjects with multiple occurrences of adverse events in the same category are counted only once in that category at the maximum severity.

Percentages are based on the number of subjects of each respective group in the Safety Analysis Set.

Source Data: Listing 16.2.7.1

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| --- | --- | --- |
| Program: t-ae-sum.sas | DCO: 27APR2024 | Executed: 07JUL2024 20:36 |

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| **InxMed (Shanghai) Co., Ltd.  Protocol No. IN10018-602** |  |

**Table 14.3.1.3.1.5 Summary of TEAEs by SOC and PT - Phase II part 2 - CRC (Safety Analysis Set)**

| System Organ Class  Preferred Term | Treatment Group (N = 5) n (%) | Control Group (N = 5) n (%) | Total (N = 10) n (%) |
| --- | --- | --- | --- |
| All TEAEs | 5 (100) | 5 (100) | 10 (100) |
|  | | | |
| Gastrointestinal disorders | 5 (100) | 3 (60.0) | 8 (80.0) |
| Diarrhoea | 5 (100) | 0 | 5 (50.0) |
| Nausea | 3 (60.0) | 2 (40.0) | 5 (50.0) |
| Abdominal distension | 2 (40.0) | 0 | 2 (20.0) |
| Vomiting | 1 (20.0) | 1 (20.0) | 2 (20.0) |
| Abdominal discomfort | 0 | 1 (20.0) | 1 (10.0) |
| Intestinal obstruction | 1 (20.0) | 0 | 1 (10.0) |
| Toothache | 0 | 1 (20.0) | 1 (10.0) |
|  | | | |
| Investigations | 4 (80.0) | 4 (80.0) | 8 (80.0) |
| Alanine aminotransferase increased | 2 (40.0) | 2 (40.0) | 4 (40.0) |
| Aspartate aminotransferase increased | 1 (20.0) | 2 (40.0) | 3 (30.0) |
| C-reactive protein increased | 2 (40.0) | 1 (20.0) | 3 (30.0) |
| Electrocardiogram QT prolonged | 1 (20.0) | 1 (20.0) | 2 (20.0) |
| Gamma-glutamyltransferase increased | 1 (20.0) | 1 (20.0) | 2 (20.0) |
| Lymphocyte count decreased | 0 | 2 (40.0) | 2 (20.0) |
| Neutrophil count decreased | 1 (20.0) | 1 (20.0) | 2 (20.0) |
| Platelet count decreased | 1 (20.0) | 1 (20.0) | 2 (20.0) |
| Weight decreased | 2 (40.0) | 0 | 2 (20.0) |
| White blood cell count decreased | 1 (20.0) | 1 (20.0) | 2 (20.0) |
| Blood alkaline phosphatase increased | 1 (20.0) | 0 | 1 (10.0) |
| Blood bilirubin increased | 0 | 1 (20.0) | 1 (10.0) |
| Blood creatine phosphokinase increased | 0 | 1 (20.0) | 1 (10.0) |
| Blood lactate dehydrogenase increased | 0 | 1 (20.0) | 1 (10.0) |
| Blood urine | 1 (20.0) | 0 | 1 (10.0) |
| Electrocardiogram PR prolongation | 1 (20.0) | 0 | 1 (10.0) |
| Electrocardiogram QRS complex prolonged | 0 | 1 (20.0) | 1 (10.0) |
| Leukocyte alkaline phosphatase increased | 0 | 1 (20.0) | 1 (10.0) |
| Neutrophil count increased | 0 | 1 (20.0) | 1 (10.0) |
| Procalcitonin increased | 1 (20.0) | 0 | 1 (10.0) |
| Red blood cell sedimentation rate increased | 1 (20.0) | 0 | 1 (10.0) |
| Serum amyloid A protein increased | 0 | 1 (20.0) | 1 (10.0) |
| Serum ferritin increased | 0 | 1 (20.0) | 1 (10.0) |
| Total bile acids increased | 0 | 1 (20.0) | 1 (10.0) |
|  | | | |
| Metabolism and nutrition disorders | 4 (80.0) | 3 (60.0) | 7 (70.0) |
| Hypertriglyceridaemia | 2 (40.0) | 2 (40.0) | 4 (40.0) |
| Hypercholesterolaemia | 2 (40.0) | 1 (20.0) | 3 (30.0) |
| Hyperglycaemia | 1 (20.0) | 2 (40.0) | 3 (30.0) |
| Hypokalaemia | 1 (20.0) | 2 (40.0) | 3 (30.0) |
| Hypoalbuminaemia | 2 (40.0) | 0 | 2 (20.0) |
| Decreased appetite | 1 (20.0) | 0 | 1 (10.0) |
| Hypermagnesaemia | 0 | 1 (20.0) | 1 (10.0) |
| Hyperphosphataemia | 1 (20.0) | 0 | 1 (10.0) |
| Hyponatraemia | 1 (20.0) | 0 | 1 (10.0) |
| Hypozincaemia | 0 | 1 (20.0) | 1 (10.0) |
|  | | | |
| Musculoskeletal and connective tissue disorders | 4 (80.0) | 1 (20.0) | 5 (50.0) |
| Myalgia | 2 (40.0) | 0 | 2 (20.0) |
| Arthritis | 1 (20.0) | 0 | 1 (10.0) |
| Joint swelling | 0 | 1 (20.0) | 1 (10.0) |
| Pain in extremity | 1 (20.0) | 0 | 1 (10.0) |
|  | | | |
| Cardiac disorders | 2 (40.0) | 2 (40.0) | 4 (40.0) |
| Sinus bradycardia | 2 (40.0) | 0 | 2 (20.0) |
| Atrioventricular block first degree | 1 (20.0) | 0 | 1 (10.0) |
| Pericardial effusion | 0 | 1 (20.0) | 1 (10.0) |
| Supraventricular extrasystoles | 0 | 1 (20.0) | 1 (10.0) |
| Tachycardia | 0 | 1 (20.0) | 1 (10.0) |
|  | | | |
| General disorders and administration site conditions | 2 (40.0) | 2 (40.0) | 4 (40.0) |
| Influenza like illness | 1 (20.0) | 1 (20.0) | 2 (20.0) |
| Asthenia | 1 (20.0) | 0 | 1 (10.0) |
| Fatigue | 0 | 1 (20.0) | 1 (10.0) |
| Pyrexia | 0 | 1 (20.0) | 1 (10.0) |
|  | | | |
| Renal and urinary disorders | 4 (80.0) | 0 | 4 (40.0) |
| Proteinuria | 3 (60.0) | 0 | 3 (30.0) |
| Haematuria | 2 (40.0) | 0 | 2 (20.0) |
| Acute kidney injury | 1 (20.0) | 0 | 1 (10.0) |
|  | | | |
| Respiratory, thoracic and mediastinal disorders | 1 (20.0) | 3 (60.0) | 4 (40.0) |
| Productive cough | 1 (20.0) | 1 (20.0) | 2 (20.0) |
| Cough | 0 | 1 (20.0) | 1 (10.0) |
| Hiccups | 0 | 1 (20.0) | 1 (10.0) |
| Pleural effusion | 0 | 1 (20.0) | 1 (10.0) |
| Rhinorrhoea | 0 | 1 (20.0) | 1 (10.0) |
|  | | | |
| Blood and lymphatic system disorders | 2 (40.0) | 1 (20.0) | 3 (30.0) |
| Anaemia | 2 (40.0) | 1 (20.0) | 3 (30.0) |
| Leukocytosis | 0 | 1 (20.0) | 1 (10.0) |
|  | | | |
| Infections and infestations | 0 | 2 (40.0) | 2 (20.0) |
| COVID-19 | 0 | 1 (20.0) | 1 (10.0) |
| Laryngopharyngitis | 0 | 1 (20.0) | 1 (10.0) |
| Pneumonia | 0 | 1 (20.0) | 1 (10.0) |
|  | | | |
| Eye disorders | 1 (20.0) | 0 | 1 (10.0) |
| Periorbital pain | 1 (20.0) | 0 | 1 (10.0) |
|  | | | |
| Nervous system disorders | 1 (20.0) | 0 | 1 (10.0) |
| Hypoaesthesia | 1 (20.0) | 0 | 1 (10.0) |
|  | | | |
| Psychiatric disorders | 1 (20.0) | 0 | 1 (10.0) |
| Insomnia | 1 (20.0) | 0 | 1 (10.0) |
|  | | | |
| Skin and subcutaneous tissue disorders | 1 (20.0) | 0 | 1 (10.0) |
| Pruritus | 1 (20.0) | 0 | 1 (10.0) |
| Rash | 1 (20.0) | 0 | 1 (10.0) |

TEAE is defined as any AE that newly occurs or worsen after the first investigational drug administration and within end of safety follow up period (i.e., within 30 calendar days after the last administration of investigational drug or the start of new anti-cancer therapy (whichever occurs earlier)). If the timing of the AE cannot be established in relation to the first administration of investigational drug, it will be considered as TEAE to be more conservative.

Adverse events are coded with MedDRA 25.0.

Subjects with multiple occurrences of adverse events in the same preferred term are counted only once within that preferred term.

Subjects with multiple occurrences of adverse events in the same system organ class are counted only once within that system organ class.

Percentages are based on the number of subjects of each respective group in Safety Analysis Set.

Source Data: Listing 16.2.7.1

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| --- | --- | --- |
| Program: t-ae-soc-pt.sas | DCO: 27APR2024 | Executed: 08JUL2024 17:16 |

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| **InxMed (Shanghai) Co., Ltd.  Protocol No. IN10018-602** |  |

**Table 14.3.1.3.1.6 Summary of TEAEs by Grouped SOC and Grouped PT - Phase II part 2 - CRC (Safety Analysis Set)**

| System Organ Class  Preferred Term | Treatment Group (N = 5) n (%) | Control Group (N = 5) n (%) | Total (N = 10) n (%) |
| --- | --- | --- | --- |
| All TEAEs | 5 (100) | 5 (100) | 10 (100) |
|  | | | |
| Gastrointestinal disorders | 5 (100) | 3 (60.0) | 8 (80.0) |
| Diarrhoea | 5 (100) | 0 | 5 (50.0) |
| Nausea | 3 (60.0) | 2 (40.0) | 5 (50.0) |
| Abdominal distension | 2 (40.0) | 0 | 2 (20.0) |
| Vomiting | 1 (20.0) | 1 (20.0) | 2 (20.0) |
| Abdominal discomfort | 0 | 1 (20.0) | 1 (10.0) |
| Intestinal obstruction | 1 (20.0) | 0 | 1 (10.0) |
| Toothache | 0 | 1 (20.0) | 1 (10.0) |
|  | | | |
| Investigations | 4 (80.0) | 4 (80.0) | 8 (80.0) |
| Alanine aminotransferase increased | 2 (40.0) | 2 (40.0) | 4 (40.0) |
| Aspartate aminotransferase increased | 1 (20.0) | 2 (40.0) | 3 (30.0) |
| C-reactive protein increased | 2 (40.0) | 1 (20.0) | 3 (30.0) |
| Electrocardiogram QT prolonged | 1 (20.0) | 1 (20.0) | 2 (20.0) |
| Gamma-glutamyltransferase increased | 1 (20.0) | 1 (20.0) | 2 (20.0) |
| Lymphocyte count decreased | 0 | 2 (40.0) | 2 (20.0) |
| Neutrophil count decreased | 1 (20.0) | 1 (20.0) | 2 (20.0) |
| Platelet count decreased | 1 (20.0) | 1 (20.0) | 2 (20.0) |
| Weight decreased | 2 (40.0) | 0 | 2 (20.0) |
| White blood cell count decreased | 1 (20.0) | 1 (20.0) | 2 (20.0) |
| Blood alkaline phosphatase increased | 1 (20.0) | 0 | 1 (10.0) |
| Blood bilirubin increased | 0 | 1 (20.0) | 1 (10.0) |
| Blood creatine phosphokinase increased | 0 | 1 (20.0) | 1 (10.0) |
| Blood lactate dehydrogenase increased | 0 | 1 (20.0) | 1 (10.0) |
| Electrocardiogram PR prolongation | 1 (20.0) | 0 | 1 (10.0) |
| Electrocardiogram QRS complex prolonged | 0 | 1 (20.0) | 1 (10.0) |
| Leukocyte alkaline phosphatase increased | 0 | 1 (20.0) | 1 (10.0) |
| Neutrophil count increased | 0 | 1 (20.0) | 1 (10.0) |
| Procalcitonin increased | 1 (20.0) | 0 | 1 (10.0) |
| Red blood cell sedimentation rate increased | 1 (20.0) | 0 | 1 (10.0) |
| Serum amyloid A protein increased | 0 | 1 (20.0) | 1 (10.0) |
| Serum ferritin increased | 0 | 1 (20.0) | 1 (10.0) |
| Total bile acids increased | 0 | 1 (20.0) | 1 (10.0) |
|  | | | |
| Metabolism and nutrition disorders# | 4 (80.0) | 3 (60.0) | 7 (70.0) |
| Hypertriglyceridaemia | 2 (40.0) | 2 (40.0) | 4 (40.0) |
| Hypercholesterolaemia\* | 2 (40.0) | 1 (20.0) | 3 (30.0) |
| Hyperglycaemia | 1 (20.0) | 2 (40.0) | 3 (30.0) |
| Hypokalaemia | 1 (20.0) | 2 (40.0) | 3 (30.0) |
| Hypoalbuminaemia | 2 (40.0) | 0 | 2 (20.0) |
| Decreased appetite | 1 (20.0) | 0 | 1 (10.0) |
| Hypermagnesaemia | 0 | 1 (20.0) | 1 (10.0) |
| Hyperphosphataemia | 1 (20.0) | 0 | 1 (10.0) |
| Hyponatraemia | 1 (20.0) | 0 | 1 (10.0) |
| Hypozincaemia | 0 | 1 (20.0) | 1 (10.0) |
|  | | | |
| Musculoskeletal and connective tissue disorders | 4 (80.0) | 1 (20.0) | 5 (50.0) |
| Myalgia | 2 (40.0) | 0 | 2 (20.0) |
| Arthritis | 1 (20.0) | 0 | 1 (10.0) |
| Joint swelling | 0 | 1 (20.0) | 1 (10.0) |
| Pain in extremity | 1 (20.0) | 0 | 1 (10.0) |
|  | | | |
| Cardiac disorders | 2 (40.0) | 2 (40.0) | 4 (40.0) |
| Sinus bradycardia | 2 (40.0) | 0 | 2 (20.0) |
| Atrioventricular block first degree | 1 (20.0) | 0 | 1 (10.0) |
| Pericardial effusion | 0 | 1 (20.0) | 1 (10.0) |
| Supraventricular extrasystoles | 0 | 1 (20.0) | 1 (10.0) |
| Tachycardia | 0 | 1 (20.0) | 1 (10.0) |
|  | | | |
| General disorders and administration site conditions# | 2 (40.0) | 2 (40.0) | 4 (40.0) |
| Fatigue\* | 1 (20.0) | 1 (20.0) | 2 (20.0) |
| Influenza like illness | 1 (20.0) | 1 (20.0) | 2 (20.0) |
| Pyrexia | 0 | 1 (20.0) | 1 (10.0) |
|  | | | |
| Renal and urinary disorders# | 4 (80.0) | 0 | 4 (40.0) |
| Proteinuria\* | 3 (60.0) | 0 | 3 (30.0) |
| Haematuria\* | 2 (40.0) | 0 | 2 (20.0) |
| Acute kidney injury | 1 (20.0) | 0 | 1 (10.0) |
|  | | | |
| Respiratory, thoracic and mediastinal disorders | 1 (20.0) | 3 (60.0) | 4 (40.0) |
| Productive cough | 1 (20.0) | 1 (20.0) | 2 (20.0) |
| Cough | 0 | 1 (20.0) | 1 (10.0) |
| Hiccups | 0 | 1 (20.0) | 1 (10.0) |
| Pleural effusion | 0 | 1 (20.0) | 1 (10.0) |
| Rhinorrhoea | 0 | 1 (20.0) | 1 (10.0) |
|  | | | |
| Blood and lymphatic system disorders# | 2 (40.0) | 1 (20.0) | 3 (30.0) |
| Anaemia | 2 (40.0) | 1 (20.0) | 3 (30.0) |
| Leukocytosis\* | 0 | 1 (20.0) | 1 (10.0) |
|  | | | |
| Infections and infestations | 0 | 2 (40.0) | 2 (20.0) |
| COVID-19 | 0 | 1 (20.0) | 1 (10.0) |
| Laryngopharyngitis | 0 | 1 (20.0) | 1 (10.0) |
| Pneumonia | 0 | 1 (20.0) | 1 (10.0) |
|  | | | |
| Eye disorders | 1 (20.0) | 0 | 1 (10.0) |
| Periorbital pain | 1 (20.0) | 0 | 1 (10.0) |
|  | | | |
| Nervous system disorders | 1 (20.0) | 0 | 1 (10.0) |
| Hypoaesthesia | 1 (20.0) | 0 | 1 (10.0) |
|  | | | |
| Psychiatric disorders | 1 (20.0) | 0 | 1 (10.0) |
| Insomnia | 1 (20.0) | 0 | 1 (10.0) |
|  | | | |
| Skin and subcutaneous tissue disorders | 1 (20.0) | 0 | 1 (10.0) |
| Pruritus | 1 (20.0) | 0 | 1 (10.0) |
| Rash | 1 (20.0) | 0 | 1 (10.0) |

TEAE is defined as any AE that newly occurs or worsen after the first investigational drug administration and within end of safety follow up period (i.e., within 30 calendar days after the last administration of investigational drug or the start of new anti-cancer therapy (whichever occurs earlier)). If the timing of the AE cannot be established in relation to the first administration of investigational drug, it will be considered as TEAE to be more conservative.

Adverse events are coded with MedDRA 25.0.

Subjects with multiple occurrences of adverse events in the same grouped preferred term are counted only once within that grouped preferred term.

Subjects with multiple occurrences of adverse events in the same grouped system organ class are counted only once within that grouped system organ class.

Percentages are based on the number of subjects of each respective group in Safety Analysis Set.

#: Grouped SOC. \*: Grouped PT.  
Source Data: Listing 16.2.7.1

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| --- | --- | --- |
| Program: t-ae-soc-pt.sas | DCO: 27APR2024 | Executed: 08JUL2024 17:16 |

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| --- | --- |
| **InxMed (Shanghai) Co., Ltd.  Protocol No. IN10018-602** |  |

**Table 14.3.1.3.2.5 Summary of D-1553 Related TEAEs by SOC and PT - Phase II part 2 - CRC (Safety Analysis Set)**

| System Organ Class  Preferred Term | Treatment Group (N = 5) n (%) | Control Group (N = 5) n (%) | Total (N = 10) n (%) |
| --- | --- | --- | --- |
| D-1553 Related TEAEs | 5 (100) | 5 (100) | 10 (100) |
|  | | | |
| Gastrointestinal disorders | 5 (100) | 3 (60.0) | 8 (80.0) |
| Diarrhoea | 5 (100) | 0 | 5 (50.0) |
| Nausea | 3 (60.0) | 2 (40.0) | 5 (50.0) |
| Abdominal distension | 2 (40.0) | 0 | 2 (20.0) |
| Vomiting | 1 (20.0) | 1 (20.0) | 2 (20.0) |
| Abdominal discomfort | 0 | 1 (20.0) | 1 (10.0) |
| Intestinal obstruction | 1 (20.0) | 0 | 1 (10.0) |
| Toothache | 0 | 1 (20.0) | 1 (10.0) |
|  | | | |
| Investigations | 4 (80.0) | 4 (80.0) | 8 (80.0) |
| Alanine aminotransferase increased | 2 (40.0) | 2 (40.0) | 4 (40.0) |
| Aspartate aminotransferase increased | 1 (20.0) | 2 (40.0) | 3 (30.0) |
| C-reactive protein increased | 1 (20.0) | 1 (20.0) | 2 (20.0) |
| Electrocardiogram QT prolonged | 1 (20.0) | 1 (20.0) | 2 (20.0) |
| Gamma-glutamyltransferase increased | 1 (20.0) | 1 (20.0) | 2 (20.0) |
| Lymphocyte count decreased | 0 | 2 (40.0) | 2 (20.0) |
| Neutrophil count decreased | 1 (20.0) | 1 (20.0) | 2 (20.0) |
| Platelet count decreased | 1 (20.0) | 1 (20.0) | 2 (20.0) |
| Weight decreased | 2 (40.0) | 0 | 2 (20.0) |
| White blood cell count decreased | 1 (20.0) | 1 (20.0) | 2 (20.0) |
| Blood alkaline phosphatase increased | 1 (20.0) | 0 | 1 (10.0) |
| Blood bilirubin increased | 0 | 1 (20.0) | 1 (10.0) |
| Blood creatine phosphokinase increased | 0 | 1 (20.0) | 1 (10.0) |
| Blood lactate dehydrogenase increased | 0 | 1 (20.0) | 1 (10.0) |
| Blood urine | 1 (20.0) | 0 | 1 (10.0) |
| Electrocardiogram PR prolongation | 1 (20.0) | 0 | 1 (10.0) |
| Electrocardiogram QRS complex prolonged | 0 | 1 (20.0) | 1 (10.0) |
| Neutrophil count increased | 0 | 1 (20.0) | 1 (10.0) |
| Serum amyloid A protein increased | 0 | 1 (20.0) | 1 (10.0) |
| Total bile acids increased | 0 | 1 (20.0) | 1 (10.0) |
|  | | | |
| Metabolism and nutrition disorders | 4 (80.0) | 3 (60.0) | 7 (70.0) |
| Hypercholesterolaemia | 2 (40.0) | 1 (20.0) | 3 (30.0) |
| Hyperglycaemia | 1 (20.0) | 1 (20.0) | 2 (20.0) |
| Hypertriglyceridaemia | 1 (20.0) | 1 (20.0) | 2 (20.0) |
| Hypokalaemia | 1 (20.0) | 1 (20.0) | 2 (20.0) |
| Decreased appetite | 1 (20.0) | 0 | 1 (10.0) |
| Hypermagnesaemia | 0 | 1 (20.0) | 1 (10.0) |
| Hyperphosphataemia | 1 (20.0) | 0 | 1 (10.0) |
| Hypozincaemia | 0 | 1 (20.0) | 1 (10.0) |
|  | | | |
| Cardiac disorders | 2 (40.0) | 2 (40.0) | 4 (40.0) |
| Atrioventricular block first degree | 1 (20.0) | 0 | 1 (10.0) |
| Pericardial effusion | 0 | 1 (20.0) | 1 (10.0) |
| Sinus bradycardia | 1 (20.0) | 0 | 1 (10.0) |
| Supraventricular extrasystoles | 0 | 1 (20.0) | 1 (10.0) |
| Tachycardia | 0 | 1 (20.0) | 1 (10.0) |
|  | | | |
| Renal and urinary disorders | 4 (80.0) | 0 | 4 (40.0) |
| Proteinuria | 3 (60.0) | 0 | 3 (30.0) |
| Haematuria | 2 (40.0) | 0 | 2 (20.0) |
| Acute kidney injury | 1 (20.0) | 0 | 1 (10.0) |
|  | | | |
| General disorders and administration site conditions | 1 (20.0) | 2 (40.0) | 3 (30.0) |
| Asthenia | 1 (20.0) | 0 | 1 (10.0) |
| Fatigue | 0 | 1 (20.0) | 1 (10.0) |
| Influenza like illness | 0 | 1 (20.0) | 1 (10.0) |
|  | | | |
| Musculoskeletal and connective tissue disorders | 3 (60.0) | 0 | 3 (30.0) |
| Myalgia | 2 (40.0) | 0 | 2 (20.0) |
| Pain in extremity | 1 (20.0) | 0 | 1 (10.0) |
|  | | | |
| Blood and lymphatic system disorders | 1 (20.0) | 1 (20.0) | 2 (20.0) |
| Anaemia | 1 (20.0) | 1 (20.0) | 2 (20.0) |
| Leukocytosis | 0 | 1 (20.0) | 1 (10.0) |
|  | | | |
| Respiratory, thoracic and mediastinal disorders | 0 | 2 (40.0) | 2 (20.0) |
| Cough | 0 | 1 (20.0) | 1 (10.0) |
| Hiccups | 0 | 1 (20.0) | 1 (10.0) |
| Productive cough | 0 | 1 (20.0) | 1 (10.0) |
|  | | | |
| Eye disorders | 1 (20.0) | 0 | 1 (10.0) |
| Periorbital pain | 1 (20.0) | 0 | 1 (10.0) |
|  | | | |
| Infections and infestations | 0 | 1 (20.0) | 1 (10.0) |
| Pneumonia | 0 | 1 (20.0) | 1 (10.0) |
|  | | | |
| Nervous system disorders | 1 (20.0) | 0 | 1 (10.0) |
| Hypoaesthesia | 1 (20.0) | 0 | 1 (10.0) |
|  | | | |
| Psychiatric disorders | 1 (20.0) | 0 | 1 (10.0) |
| Insomnia | 1 (20.0) | 0 | 1 (10.0) |
|  | | | |
| Skin and subcutaneous tissue disorders | 1 (20.0) | 0 | 1 (10.0) |
| Pruritus | 1 (20.0) | 0 | 1 (10.0) |
| Rash | 1 (20.0) | 0 | 1 (10.0) |

TEAE is defined as any AE that newly occurs or worsen after the first investigational drug administration and within end of safety follow up period (i.e., within 30 calendar days after the last administration of investigational drug or the start of new anti-cancer therapy (whichever occurs earlier)). If the timing of the AE cannot be established in relation to the first administration of investigational drug, it will be considered as TEAE to be more conservative.

D-1553 related TEAE is defined as the relationship with D-1553 as 'Definitely Related' or 'Probably Related' or 'Possibly Related' or 'Related/Reasonable Possibility'. To be conservative, if the relationship is missing, TEAE is still considered as D-1553 related TEAE.

Adverse events are coded with MedDRA 25.0.

Subjects with multiple occurrences of adverse events in the same preferred term are counted only once within that preferred term.

Subjects with multiple occurrences of adverse events in the same system organ class are counted only once within that system organ class.

Percentages are based on the number of subjects of each respective group in Safety Analysis Set.

Source Data: Listing 16.2.7.1

|  |  |  |
| --- | --- | --- |
| Program: t-ae-soc-pt.sas | DCO: 27APR2024 | Executed: 08JUL2024 17:16 |

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| **InxMed (Shanghai) Co., Ltd.  Protocol No. IN10018-602** |  |

**Table 14.3.1.3.2.6 Summary of D-1553 Related TEAEs by Grouped SOC and Grouped PT - Phase II part 2 - CRC (Safety Analysis Set)**

| System Organ Class  Preferred Term | Treatment Group (N = 5) n (%) | Control Group (N = 5) n (%) | Total (N = 10) n (%) |
| --- | --- | --- | --- |
| D-1553 Related TEAEs | 5 (100) | 5 (100) | 10 (100) |
|  | | | |
| Gastrointestinal disorders | 5 (100) | 3 (60.0) | 8 (80.0) |
| Diarrhoea | 5 (100) | 0 | 5 (50.0) |
| Nausea | 3 (60.0) | 2 (40.0) | 5 (50.0) |
| Abdominal distension | 2 (40.0) | 0 | 2 (20.0) |
| Vomiting | 1 (20.0) | 1 (20.0) | 2 (20.0) |
| Abdominal discomfort | 0 | 1 (20.0) | 1 (10.0) |
| Intestinal obstruction | 1 (20.0) | 0 | 1 (10.0) |
| Toothache | 0 | 1 (20.0) | 1 (10.0) |
|  | | | |
| Investigations | 4 (80.0) | 4 (80.0) | 8 (80.0) |
| Alanine aminotransferase increased | 2 (40.0) | 2 (40.0) | 4 (40.0) |
| Aspartate aminotransferase increased | 1 (20.0) | 2 (40.0) | 3 (30.0) |
| C-reactive protein increased | 1 (20.0) | 1 (20.0) | 2 (20.0) |
| Electrocardiogram QT prolonged | 1 (20.0) | 1 (20.0) | 2 (20.0) |
| Gamma-glutamyltransferase increased | 1 (20.0) | 1 (20.0) | 2 (20.0) |
| Lymphocyte count decreased | 0 | 2 (40.0) | 2 (20.0) |
| Neutrophil count decreased | 1 (20.0) | 1 (20.0) | 2 (20.0) |
| Platelet count decreased | 1 (20.0) | 1 (20.0) | 2 (20.0) |
| Weight decreased | 2 (40.0) | 0 | 2 (20.0) |
| White blood cell count decreased | 1 (20.0) | 1 (20.0) | 2 (20.0) |
| Blood alkaline phosphatase increased | 1 (20.0) | 0 | 1 (10.0) |
| Blood bilirubin increased | 0 | 1 (20.0) | 1 (10.0) |
| Blood creatine phosphokinase increased | 0 | 1 (20.0) | 1 (10.0) |
| Blood lactate dehydrogenase increased | 0 | 1 (20.0) | 1 (10.0) |
| Electrocardiogram PR prolongation | 1 (20.0) | 0 | 1 (10.0) |
| Electrocardiogram QRS complex prolonged | 0 | 1 (20.0) | 1 (10.0) |
| Neutrophil count increased | 0 | 1 (20.0) | 1 (10.0) |
| Serum amyloid A protein increased | 0 | 1 (20.0) | 1 (10.0) |
| Total bile acids increased | 0 | 1 (20.0) | 1 (10.0) |
|  | | | |
| Metabolism and nutrition disorders# | 4 (80.0) | 3 (60.0) | 7 (70.0) |
| Hypercholesterolaemia\* | 2 (40.0) | 1 (20.0) | 3 (30.0) |
| Hyperglycaemia | 1 (20.0) | 1 (20.0) | 2 (20.0) |
| Hypertriglyceridaemia | 1 (20.0) | 1 (20.0) | 2 (20.0) |
| Hypokalaemia | 1 (20.0) | 1 (20.0) | 2 (20.0) |
| Decreased appetite | 1 (20.0) | 0 | 1 (10.0) |
| Hypermagnesaemia | 0 | 1 (20.0) | 1 (10.0) |
| Hyperphosphataemia | 1 (20.0) | 0 | 1 (10.0) |
| Hypozincaemia | 0 | 1 (20.0) | 1 (10.0) |
|  | | | |
| Cardiac disorders | 2 (40.0) | 2 (40.0) | 4 (40.0) |
| Atrioventricular block first degree | 1 (20.0) | 0 | 1 (10.0) |
| Pericardial effusion | 0 | 1 (20.0) | 1 (10.0) |
| Sinus bradycardia | 1 (20.0) | 0 | 1 (10.0) |
| Supraventricular extrasystoles | 0 | 1 (20.0) | 1 (10.0) |
| Tachycardia | 0 | 1 (20.0) | 1 (10.0) |
|  | | | |
| Renal and urinary disorders# | 4 (80.0) | 0 | 4 (40.0) |
| Proteinuria\* | 3 (60.0) | 0 | 3 (30.0) |
| Haematuria\* | 2 (40.0) | 0 | 2 (20.0) |
| Acute kidney injury | 1 (20.0) | 0 | 1 (10.0) |
|  | | | |
| General disorders and administration site conditions# | 1 (20.0) | 2 (40.0) | 3 (30.0) |
| Fatigue\* | 1 (20.0) | 1 (20.0) | 2 (20.0) |
| Influenza like illness | 0 | 1 (20.0) | 1 (10.0) |
|  | | | |
| Musculoskeletal and connective tissue disorders | 3 (60.0) | 0 | 3 (30.0) |
| Myalgia | 2 (40.0) | 0 | 2 (20.0) |
| Pain in extremity | 1 (20.0) | 0 | 1 (10.0) |
|  | | | |
| Blood and lymphatic system disorders# | 1 (20.0) | 1 (20.0) | 2 (20.0) |
| Anaemia | 1 (20.0) | 1 (20.0) | 2 (20.0) |
| Leukocytosis\* | 0 | 1 (20.0) | 1 (10.0) |
|  | | | |
| Respiratory, thoracic and mediastinal disorders | 0 | 2 (40.0) | 2 (20.0) |
| Cough | 0 | 1 (20.0) | 1 (10.0) |
| Hiccups | 0 | 1 (20.0) | 1 (10.0) |
| Productive cough | 0 | 1 (20.0) | 1 (10.0) |
|  | | | |
| Eye disorders | 1 (20.0) | 0 | 1 (10.0) |
| Periorbital pain | 1 (20.0) | 0 | 1 (10.0) |
|  | | | |
| Infections and infestations | 0 | 1 (20.0) | 1 (10.0) |
| Pneumonia | 0 | 1 (20.0) | 1 (10.0) |
|  | | | |
| Nervous system disorders | 1 (20.0) | 0 | 1 (10.0) |
| Hypoaesthesia | 1 (20.0) | 0 | 1 (10.0) |
|  | | | |
| Psychiatric disorders | 1 (20.0) | 0 | 1 (10.0) |
| Insomnia | 1 (20.0) | 0 | 1 (10.0) |
|  | | | |
| Skin and subcutaneous tissue disorders | 1 (20.0) | 0 | 1 (10.0) |
| Pruritus | 1 (20.0) | 0 | 1 (10.0) |
| Rash | 1 (20.0) | 0 | 1 (10.0) |

TEAE is defined as any AE that newly occurs or worsen after the first investigational drug administration and within end of safety follow up period (i.e., within 30 calendar days after the last administration of investigational drug or the start of new anti-cancer therapy (whichever occurs earlier)). If the timing of the AE cannot be established in relation to the first administration of investigational drug, it will be considered as TEAE to be more conservative.

D-1553 related TEAE is defined as the relationship with D-1553 as 'Definitely Related' or 'Probably Related' or 'Possibly Related' or 'Related/Reasonable Possibility'. To be conservative, if the relationship is missing, TEAE is still considered as D-1553 related TEAE.

Adverse events are coded with MedDRA 25.0.

Subjects with multiple occurrences of adverse events in the same grouped preferred term are counted only once within that grouped preferred term.

Subjects with multiple occurrences of adverse events in the same grouped system organ class are counted only once within that grouped system organ class.

Percentages are based on the number of subjects of each respective group in Safety Analysis Set.

#: Grouped SOC. \*: Grouped PT.  
Source Data: Listing 16.2.7.1

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| --- | --- | --- |
| Program: t-ae-soc-pt.sas | DCO: 27APR2024 | Executed: 08JUL2024 17:16 |

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| **InxMed (Shanghai) Co., Ltd.  Protocol No. IN10018-602** |  |

**Table 14.3.1.3.2.11 Summary of IN10018 Related TEAEs by SOC and PT - Phase II part 2 - CRC (Safety Analysis Set)**

| System Organ Class  Preferred Term | Treatment Group (N = 5) n (%) | Control Group (N = 5) n (%) | Total (N = 10) n (%) |
| --- | --- | --- | --- |
| IN10018 Related TEAEs | 5 (100) | 1 (20.0) | 6 (60.0) |
|  | | | |
| Gastrointestinal disorders | 5 (100) | 0 | 5 (50.0) |
| Diarrhoea | 5 (100) | 0 | 5 (50.0) |
| Nausea | 3 (60.0) | 0 | 3 (30.0) |
| Abdominal distension | 2 (40.0) | 0 | 2 (20.0) |
| Intestinal obstruction | 1 (20.0) | 0 | 1 (10.0) |
| Vomiting | 1 (20.0) | 0 | 1 (10.0) |
|  | | | |
| Investigations | 4 (80.0) | 1 (20.0) | 5 (50.0) |
| Alanine aminotransferase increased | 2 (40.0) | 0 | 2 (20.0) |
| Weight decreased | 2 (40.0) | 0 | 2 (20.0) |
| Aspartate aminotransferase increased | 1 (20.0) | 0 | 1 (10.0) |
| Blood alkaline phosphatase increased | 1 (20.0) | 0 | 1 (10.0) |
| Blood lactate dehydrogenase increased | 0 | 1 (20.0) | 1 (10.0) |
| Blood urine | 1 (20.0) | 0 | 1 (10.0) |
| C-reactive protein increased | 1 (20.0) | 0 | 1 (10.0) |
| Electrocardiogram PR prolongation | 1 (20.0) | 0 | 1 (10.0) |
| Electrocardiogram QT prolonged | 1 (20.0) | 0 | 1 (10.0) |
| Gamma-glutamyltransferase increased | 1 (20.0) | 0 | 1 (10.0) |
| Neutrophil count decreased | 1 (20.0) | 0 | 1 (10.0) |
| Platelet count decreased | 1 (20.0) | 0 | 1 (10.0) |
| White blood cell count decreased | 1 (20.0) | 0 | 1 (10.0) |
|  | | | |
| Metabolism and nutrition disorders | 4 (80.0) | 1 (20.0) | 5 (50.0) |
| Hypercholesterolaemia | 2 (40.0) | 0 | 2 (20.0) |
| Decreased appetite | 1 (20.0) | 0 | 1 (10.0) |
| Hyperglycaemia | 1 (20.0) | 0 | 1 (10.0) |
| Hypermagnesaemia | 0 | 1 (20.0) | 1 (10.0) |
| Hyperphosphataemia | 1 (20.0) | 0 | 1 (10.0) |
| Hypertriglyceridaemia | 1 (20.0) | 0 | 1 (10.0) |
| Hypokalaemia | 1 (20.0) | 0 | 1 (10.0) |
|  | | | |
| Musculoskeletal and connective tissue disorders | 4 (80.0) | 0 | 4 (40.0) |
| Myalgia | 2 (40.0) | 0 | 2 (20.0) |
| Arthritis | 1 (20.0) | 0 | 1 (10.0) |
| Pain in extremity | 1 (20.0) | 0 | 1 (10.0) |
|  | | | |
| Renal and urinary disorders | 4 (80.0) | 0 | 4 (40.0) |
| Proteinuria | 3 (60.0) | 0 | 3 (30.0) |
| Haematuria | 2 (40.0) | 0 | 2 (20.0) |
| Acute kidney injury | 1 (20.0) | 0 | 1 (10.0) |
|  | | | |
| Cardiac disorders | 2 (40.0) | 0 | 2 (20.0) |
| Atrioventricular block first degree | 1 (20.0) | 0 | 1 (10.0) |
| Sinus bradycardia | 1 (20.0) | 0 | 1 (10.0) |
|  | | | |
| Blood and lymphatic system disorders | 1 (20.0) | 0 | 1 (10.0) |
| Anaemia | 1 (20.0) | 0 | 1 (10.0) |
|  | | | |
| Eye disorders | 1 (20.0) | 0 | 1 (10.0) |
| Periorbital pain | 1 (20.0) | 0 | 1 (10.0) |
|  | | | |
| General disorders and administration site conditions | 1 (20.0) | 0 | 1 (10.0) |
| Asthenia | 1 (20.0) | 0 | 1 (10.0) |
|  | | | |
| Nervous system disorders | 1 (20.0) | 0 | 1 (10.0) |
| Hypoaesthesia | 1 (20.0) | 0 | 1 (10.0) |
|  | | | |
| Psychiatric disorders | 1 (20.0) | 0 | 1 (10.0) |
| Insomnia | 1 (20.0) | 0 | 1 (10.0) |
|  | | | |
| Skin and subcutaneous tissue disorders | 1 (20.0) | 0 | 1 (10.0) |
| Pruritus | 1 (20.0) | 0 | 1 (10.0) |
| Rash | 1 (20.0) | 0 | 1 (10.0) |

TEAE is defined as any AE that newly occurs or worsen after the first investigational drug administration and within end of safety follow up period (i.e., within 30 calendar days after the last administration of investigational drug or the start of new anti-cancer therapy (whichever occurs earlier)). If the timing of the AE cannot be established in relation to the first administration of investigational drug, it will be considered as TEAE to be more conservative.

IN10018 related TEAE is defined as the relationship with IN10018 as 'Definitely Related' or 'Probably Related' or 'Possibly Related' or 'Related/Reasonable Possibility'. To be conservative, if the relationship is missing, TEAE is still considered as IN10018 related TEAE.

Adverse events are coded with MedDRA 25.0.

Subjects with multiple occurrences of adverse events in the same preferred term are counted only once within that preferred term.

Subjects with multiple occurrences of adverse events in the same system organ class are counted only once within that system organ class.

Percentages are based on the number of subjects of each respective group in Safety Analysis Set.

Source Data: Listing 16.2.7.1

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| --- | --- | --- |
| Program: t-ae-soc-pt.sas | DCO: 27APR2024 | Executed: 08JUL2024 17:16 |

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| **InxMed (Shanghai) Co., Ltd.  Protocol No. IN10018-602** |  |

**Table 14.3.1.3.2.12 Summary of IN10018 Related TEAEs by Grouped SOC and Grouped PT - Phase II part 2 - CRC (Safety Analysis Set)**

| System Organ Class  Preferred Term | Treatment Group (N = 5) n (%) | Control Group (N = 5) n (%) | Total (N = 10) n (%) |
| --- | --- | --- | --- |
| IN10018 Related TEAEs | 5 (100) | 1 (20.0) | 6 (60.0) |
|  | | | |
| Gastrointestinal disorders | 5 (100) | 0 | 5 (50.0) |
| Diarrhoea | 5 (100) | 0 | 5 (50.0) |
| Nausea | 3 (60.0) | 0 | 3 (30.0) |
| Abdominal distension | 2 (40.0) | 0 | 2 (20.0) |
| Intestinal obstruction | 1 (20.0) | 0 | 1 (10.0) |
| Vomiting | 1 (20.0) | 0 | 1 (10.0) |
|  | | | |
| Investigations | 4 (80.0) | 1 (20.0) | 5 (50.0) |
| Alanine aminotransferase increased | 2 (40.0) | 0 | 2 (20.0) |
| Weight decreased | 2 (40.0) | 0 | 2 (20.0) |
| Aspartate aminotransferase increased | 1 (20.0) | 0 | 1 (10.0) |
| Blood alkaline phosphatase increased | 1 (20.0) | 0 | 1 (10.0) |
| Blood lactate dehydrogenase increased | 0 | 1 (20.0) | 1 (10.0) |
| C-reactive protein increased | 1 (20.0) | 0 | 1 (10.0) |
| Electrocardiogram PR prolongation | 1 (20.0) | 0 | 1 (10.0) |
| Electrocardiogram QT prolonged | 1 (20.0) | 0 | 1 (10.0) |
| Gamma-glutamyltransferase increased | 1 (20.0) | 0 | 1 (10.0) |
| Neutrophil count decreased | 1 (20.0) | 0 | 1 (10.0) |
| Platelet count decreased | 1 (20.0) | 0 | 1 (10.0) |
| White blood cell count decreased | 1 (20.0) | 0 | 1 (10.0) |
|  | | | |
| Metabolism and nutrition disorders# | 4 (80.0) | 1 (20.0) | 5 (50.0) |
| Hypercholesterolaemia\* | 2 (40.0) | 0 | 2 (20.0) |
| Decreased appetite | 1 (20.0) | 0 | 1 (10.0) |
| Hyperglycaemia | 1 (20.0) | 0 | 1 (10.0) |
| Hypermagnesaemia | 0 | 1 (20.0) | 1 (10.0) |
| Hyperphosphataemia | 1 (20.0) | 0 | 1 (10.0) |
| Hypertriglyceridaemia | 1 (20.0) | 0 | 1 (10.0) |
| Hypokalaemia | 1 (20.0) | 0 | 1 (10.0) |
|  | | | |
| Musculoskeletal and connective tissue disorders | 4 (80.0) | 0 | 4 (40.0) |
| Myalgia | 2 (40.0) | 0 | 2 (20.0) |
| Arthritis | 1 (20.0) | 0 | 1 (10.0) |
| Pain in extremity | 1 (20.0) | 0 | 1 (10.0) |
|  | | | |
| Renal and urinary disorders# | 4 (80.0) | 0 | 4 (40.0) |
| Proteinuria\* | 3 (60.0) | 0 | 3 (30.0) |
| Haematuria\* | 2 (40.0) | 0 | 2 (20.0) |
| Acute kidney injury | 1 (20.0) | 0 | 1 (10.0) |
|  | | | |
| Cardiac disorders | 2 (40.0) | 0 | 2 (20.0) |
| Atrioventricular block first degree | 1 (20.0) | 0 | 1 (10.0) |
| Sinus bradycardia | 1 (20.0) | 0 | 1 (10.0) |
|  | | | |
| Blood and lymphatic system disorders# | 1 (20.0) | 0 | 1 (10.0) |
| Anaemia | 1 (20.0) | 0 | 1 (10.0) |
|  | | | |
| Eye disorders | 1 (20.0) | 0 | 1 (10.0) |
| Periorbital pain | 1 (20.0) | 0 | 1 (10.0) |
|  | | | |
| General disorders and administration site conditions# | 1 (20.0) | 0 | 1 (10.0) |
| Fatigue\* | 1 (20.0) | 0 | 1 (10.0) |
|  | | | |
| Nervous system disorders | 1 (20.0) | 0 | 1 (10.0) |
| Hypoaesthesia | 1 (20.0) | 0 | 1 (10.0) |
|  | | | |
| Psychiatric disorders | 1 (20.0) | 0 | 1 (10.0) |
| Insomnia | 1 (20.0) | 0 | 1 (10.0) |
|  | | | |
| Skin and subcutaneous tissue disorders | 1 (20.0) | 0 | 1 (10.0) |
| Pruritus | 1 (20.0) | 0 | 1 (10.0) |
| Rash | 1 (20.0) | 0 | 1 (10.0) |

TEAE is defined as any AE that newly occurs or worsen after the first investigational drug administration and within end of safety follow up period (i.e., within 30 calendar days after the last administration of investigational drug or the start of new anti-cancer therapy (whichever occurs earlier)). If the timing of the AE cannot be established in relation to the first administration of investigational drug, it will be considered as TEAE to be more conservative.

IN10018 related TEAE is defined as the relationship with IN10018 as 'Definitely Related' or 'Probably Related' or 'Possibly Related' or 'Related/Reasonable Possibility'. To be conservative, if the relationship is missing, TEAE is still considered as IN10018 related TEAE.

Adverse events are coded with MedDRA 25.0.

Subjects with multiple occurrences of adverse events in the same grouped preferred term are counted only once within that grouped preferred term.

Subjects with multiple occurrences of adverse events in the same grouped system organ class are counted only once within that grouped system organ class.

Percentages are based on the number of subjects of each respective group in Safety Analysis Set.

#: Grouped SOC. \*: Grouped PT.  
Source Data: Listing 16.2.7.1

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| --- | --- | --- |
| Program: t-ae-soc-pt.sas | DCO: 27APR2024 | Executed: 08JUL2024 17:16 |

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| **InxMed (Shanghai) Co., Ltd.  Protocol No. IN10018-602** |  |

**Table 14.3.1.3.3.5 Summary of TEAEs by SOC, PT and Severity - Phase II part 2 - CRC (Safety Analysis Set)**

|  | | Total n (%) | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Group | System Organ Class  Preferred Term | Grade 1 | Grade 2 | Grade 3 | Grade 4 | Grade 5 | Total |
| Treatment Group (N = 5) | All TEAEs | 1 (20.0) | 2 (40.0) | 2 (40.0) | 0 | 0 | 5 (100) |
|  | | | | | | | |
|  | Gastrointestinal disorders | 2 (40.0) | 1 (20.0) | 2 (40.0) | 0 | 0 | 5 (100) |
|  | Diarrhoea | 2 (40.0) | 1 (20.0) | 2 (40.0) | 0 | 0 | 5 (100) |
|  | Nausea | 3 (60.0) | 0 | 0 | 0 | 0 | 3 (60.0) |
|  | Abdominal distension | 2 (40.0) | 0 | 0 | 0 | 0 | 2 (40.0) |
|  | Intestinal obstruction | 0 | 0 | 1 (20.0) | 0 | 0 | 1 (20.0) |
|  | Vomiting | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | | | | | | | |
|  | Investigations | 2 (40.0) | 1 (20.0) | 1 (20.0) | 0 | 0 | 4 (80.0) |
|  | Alanine aminotransferase increased | 2 (40.0) | 0 | 0 | 0 | 0 | 2 (40.0) |
|  | C-reactive protein increased | 1 (20.0) | 0 | 1 (20.0) | 0 | 0 | 2 (40.0) |
|  | Weight decreased | 2 (40.0) | 0 | 0 | 0 | 0 | 2 (40.0) |
|  | Aspartate aminotransferase increased | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | Blood alkaline phosphatase increased | 0 | 1 (20.0) | 0 | 0 | 0 | 1 (20.0) |
|  | Blood urine | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | Electrocardiogram PR prolongation | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | Electrocardiogram QT prolonged | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | Gamma-glutamyltransferase increased | 0 | 1 (20.0) | 0 | 0 | 0 | 1 (20.0) |
|  | Neutrophil count decreased | 0 | 1 (20.0) | 0 | 0 | 0 | 1 (20.0) |
|  | Platelet count decreased | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | Procalcitonin increased | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | Red blood cell sedimentation rate increased | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | White blood cell count decreased | 0 | 1 (20.0) | 0 | 0 | 0 | 1 (20.0) |
|  | | | | | | | |
|  | Metabolism and nutrition disorders | 2 (40.0) | 2 (40.0) | 0 | 0 | 0 | 4 (80.0) |
|  | Hypercholesterolaemia | 2 (40.0) | 0 | 0 | 0 | 0 | 2 (40.0) |
|  | Hypertriglyceridaemia | 1 (20.0) | 1 (20.0) | 0 | 0 | 0 | 2 (40.0) |
|  | Hypoalbuminaemia | 2 (40.0) | 0 | 0 | 0 | 0 | 2 (40.0) |
|  | Decreased appetite | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | Hyperglycaemia | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | Hyperphosphataemia | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | Hypokalaemia | 0 | 1 (20.0) | 0 | 0 | 0 | 1 (20.0) |
|  | Hyponatraemia | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | | | | | | | |
|  | Musculoskeletal and connective tissue disorders | 3 (60.0) | 1 (20.0) | 0 | 0 | 0 | 4 (80.0) |
|  | Myalgia | 2 (40.0) | 0 | 0 | 0 | 0 | 2 (40.0) |
|  | Arthritis | 0 | 1 (20.0) | 0 | 0 | 0 | 1 (20.0) |
|  | Pain in extremity | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | | | | | | | |
|  | Renal and urinary disorders | 2 (40.0) | 1 (20.0) | 1 (20.0) | 0 | 0 | 4 (80.0) |
|  | Proteinuria | 2 (40.0) | 1 (20.0) | 0 | 0 | 0 | 3 (60.0) |
|  | Haematuria | 2 (40.0) | 0 | 0 | 0 | 0 | 2 (40.0) |
|  | Acute kidney injury | 0 | 0 | 1 (20.0) | 0 | 0 | 1 (20.0) |
|  | | | | | | | |
|  | Blood and lymphatic system disorders | 2 (40.0) | 0 | 0 | 0 | 0 | 2 (40.0) |
|  | Anaemia | 2 (40.0) | 0 | 0 | 0 | 0 | 2 (40.0) |
|  | | | | | | | |
|  | Cardiac disorders | 2 (40.0) | 0 | 0 | 0 | 0 | 2 (40.0) |
|  | Sinus bradycardia | 2 (40.0) | 0 | 0 | 0 | 0 | 2 (40.0) |
|  | Atrioventricular block first degree | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | | | | | | | |
|  | General disorders and administration site conditions | 2 (40.0) | 0 | 0 | 0 | 0 | 2 (40.0) |
|  | Asthenia | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | Influenza like illness | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | | | | | | | |
|  | Eye disorders | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | Periorbital pain | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | | | | | | | |
|  | Nervous system disorders | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | Hypoaesthesia | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | | | | | | | |
|  | Psychiatric disorders | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | Insomnia | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | | | | | | | |
|  | Respiratory, thoracic and mediastinal disorders | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | Productive cough | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | | | | | | | |
|  | Skin and subcutaneous tissue disorders | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | Pruritus | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | Rash | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | | | | | | | |
| Control Group (N = 5) | All TEAEs | 2 (40.0) | 2 (40.0) | 1 (20.0) | 0 | 0 | 5 (100) |
|  | | | | | | | |
|  | Investigations | 2 (40.0) | 1 (20.0) | 1 (20.0) | 0 | 0 | 4 (80.0) |
|  | Alanine aminotransferase increased | 2 (40.0) | 0 | 0 | 0 | 0 | 2 (40.0) |
|  | Aspartate aminotransferase increased | 2 (40.0) | 0 | 0 | 0 | 0 | 2 (40.0) |
|  | Lymphocyte count decreased | 1 (20.0) | 0 | 1 (20.0) | 0 | 0 | 2 (40.0) |
|  | Blood bilirubin increased | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | Blood creatine phosphokinase increased | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | Blood lactate dehydrogenase increased | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | C-reactive protein increased | 0 | 0 | 1 (20.0) | 0 | 0 | 1 (20.0) |
|  | Electrocardiogram QRS complex prolonged | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | Electrocardiogram QT prolonged | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | Gamma-glutamyltransferase increased | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | Leukocyte alkaline phosphatase increased | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | Neutrophil count decreased | 0 | 1 (20.0) | 0 | 0 | 0 | 1 (20.0) |
|  | Neutrophil count increased | 0 | 0 | 1 (20.0) | 0 | 0 | 1 (20.0) |
|  | Platelet count decreased | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | Serum amyloid A protein increased | 0 | 0 | 1 (20.0) | 0 | 0 | 1 (20.0) |
|  | Serum ferritin increased | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | Total bile acids increased | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | White blood cell count decreased | 0 | 1 (20.0) | 0 | 0 | 0 | 1 (20.0) |
|  | | | | | | | |
|  | Gastrointestinal disorders | 3 (60.0) | 0 | 0 | 0 | 0 | 3 (60.0) |
|  | Nausea | 2 (40.0) | 0 | 0 | 0 | 0 | 2 (40.0) |
|  | Abdominal discomfort | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | Toothache | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | Vomiting | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | | | | | | | |
|  | Metabolism and nutrition disorders | 2 (40.0) | 1 (20.0) | 0 | 0 | 0 | 3 (60.0) |
|  | Hyperglycaemia | 2 (40.0) | 0 | 0 | 0 | 0 | 2 (40.0) |
|  | Hypertriglyceridaemia | 2 (40.0) | 0 | 0 | 0 | 0 | 2 (40.0) |
|  | Hypokalaemia | 2 (40.0) | 0 | 0 | 0 | 0 | 2 (40.0) |
|  | Hypercholesterolaemia | 0 | 1 (20.0) | 0 | 0 | 0 | 1 (20.0) |
|  | Hypermagnesaemia | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | Hypozincaemia | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | | | | | | | |
|  | Respiratory, thoracic and mediastinal disorders | 2 (40.0) | 1 (20.0) | 0 | 0 | 0 | 3 (60.0) |
|  | Cough | 0 | 1 (20.0) | 0 | 0 | 0 | 1 (20.0) |
|  | Hiccups | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | Pleural effusion | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | Productive cough | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | Rhinorrhoea | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | | | | | | | |
|  | Cardiac disorders | 2 (40.0) | 0 | 0 | 0 | 0 | 2 (40.0) |
|  | Pericardial effusion | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | Supraventricular extrasystoles | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | Tachycardia | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | | | | | | | |
|  | General disorders and administration site conditions | 1 (20.0) | 1 (20.0) | 0 | 0 | 0 | 2 (40.0) |
|  | Fatigue | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | Influenza like illness | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | Pyrexia | 0 | 1 (20.0) | 0 | 0 | 0 | 1 (20.0) |
|  | | | | | | | |
|  | Infections and infestations | 0 | 1 (20.0) | 1 (20.0) | 0 | 0 | 2 (40.0) |
|  | COVID-19 | 0 | 1 (20.0) | 0 | 0 | 0 | 1 (20.0) |
|  | Laryngopharyngitis | 0 | 1 (20.0) | 0 | 0 | 0 | 1 (20.0) |
|  | Pneumonia | 0 | 0 | 1 (20.0) | 0 | 0 | 1 (20.0) |
|  | | | | | | | |
|  | Blood and lymphatic system disorders | 0 | 0 | 1 (20.0) | 0 | 0 | 1 (20.0) |
|  | Anaemia | 0 | 0 | 1 (20.0) | 0 | 0 | 1 (20.0) |
|  | Leukocytosis | 0 | 0 | 1 (20.0) | 0 | 0 | 1 (20.0) |
|  | | | | | | | |
|  | Musculoskeletal and connective tissue disorders | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | Joint swelling | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | | | | | | | |
| Total (N = 10) | All TEAEs | 3 (30.0) | 4 (40.0) | 3 (30.0) | 0 | 0 | 10 (100) |
|  | | | | | | | |
|  | Gastrointestinal disorders | 5 (50.0) | 1 (10.0) | 2 (20.0) | 0 | 0 | 8 (80.0) |
|  | Diarrhoea | 2 (20.0) | 1 (10.0) | 2 (20.0) | 0 | 0 | 5 (50.0) |
|  | Nausea | 5 (50.0) | 0 | 0 | 0 | 0 | 5 (50.0) |
|  | Abdominal distension | 2 (20.0) | 0 | 0 | 0 | 0 | 2 (20.0) |
|  | Vomiting | 2 (20.0) | 0 | 0 | 0 | 0 | 2 (20.0) |
|  | Abdominal discomfort | 1 (10.0) | 0 | 0 | 0 | 0 | 1 (10.0) |
|  | Intestinal obstruction | 0 | 0 | 1 (10.0) | 0 | 0 | 1 (10.0) |
|  | Toothache | 1 (10.0) | 0 | 0 | 0 | 0 | 1 (10.0) |
|  | | | | | | | |
|  | Investigations | 4 (40.0) | 2 (20.0) | 2 (20.0) | 0 | 0 | 8 (80.0) |
|  | Alanine aminotransferase increased | 4 (40.0) | 0 | 0 | 0 | 0 | 4 (40.0) |
|  | Aspartate aminotransferase increased | 3 (30.0) | 0 | 0 | 0 | 0 | 3 (30.0) |
|  | C-reactive protein increased | 1 (10.0) | 0 | 2 (20.0) | 0 | 0 | 3 (30.0) |
|  | Electrocardiogram QT prolonged | 2 (20.0) | 0 | 0 | 0 | 0 | 2 (20.0) |
|  | Gamma-glutamyltransferase increased | 1 (10.0) | 1 (10.0) | 0 | 0 | 0 | 2 (20.0) |
|  | Lymphocyte count decreased | 1 (10.0) | 0 | 1 (10.0) | 0 | 0 | 2 (20.0) |
|  | Neutrophil count decreased | 0 | 2 (20.0) | 0 | 0 | 0 | 2 (20.0) |
|  | Platelet count decreased | 2 (20.0) | 0 | 0 | 0 | 0 | 2 (20.0) |
|  | Weight decreased | 2 (20.0) | 0 | 0 | 0 | 0 | 2 (20.0) |
|  | White blood cell count decreased | 0 | 2 (20.0) | 0 | 0 | 0 | 2 (20.0) |
|  | Blood alkaline phosphatase increased | 0 | 1 (10.0) | 0 | 0 | 0 | 1 (10.0) |
|  | Blood bilirubin increased | 1 (10.0) | 0 | 0 | 0 | 0 | 1 (10.0) |
|  | Blood creatine phosphokinase increased | 1 (10.0) | 0 | 0 | 0 | 0 | 1 (10.0) |
|  | Blood lactate dehydrogenase increased | 1 (10.0) | 0 | 0 | 0 | 0 | 1 (10.0) |
|  | Blood urine | 1 (10.0) | 0 | 0 | 0 | 0 | 1 (10.0) |
|  | Electrocardiogram PR prolongation | 1 (10.0) | 0 | 0 | 0 | 0 | 1 (10.0) |
|  | Electrocardiogram QRS complex prolonged | 1 (10.0) | 0 | 0 | 0 | 0 | 1 (10.0) |
|  | Leukocyte alkaline phosphatase increased | 1 (10.0) | 0 | 0 | 0 | 0 | 1 (10.0) |
|  | Neutrophil count increased | 0 | 0 | 1 (10.0) | 0 | 0 | 1 (10.0) |
|  | Procalcitonin increased | 1 (10.0) | 0 | 0 | 0 | 0 | 1 (10.0) |
|  | Red blood cell sedimentation rate increased | 1 (10.0) | 0 | 0 | 0 | 0 | 1 (10.0) |
|  | Serum amyloid A protein increased | 0 | 0 | 1 (10.0) | 0 | 0 | 1 (10.0) |
|  | Serum ferritin increased | 1 (10.0) | 0 | 0 | 0 | 0 | 1 (10.0) |
|  | Total bile acids increased | 1 (10.0) | 0 | 0 | 0 | 0 | 1 (10.0) |
|  | | | | | | | |
|  | Metabolism and nutrition disorders | 4 (40.0) | 3 (30.0) | 0 | 0 | 0 | 7 (70.0) |
|  | Hypertriglyceridaemia | 3 (30.0) | 1 (10.0) | 0 | 0 | 0 | 4 (40.0) |
|  | Hypercholesterolaemia | 2 (20.0) | 1 (10.0) | 0 | 0 | 0 | 3 (30.0) |
|  | Hyperglycaemia | 3 (30.0) | 0 | 0 | 0 | 0 | 3 (30.0) |
|  | Hypokalaemia | 2 (20.0) | 1 (10.0) | 0 | 0 | 0 | 3 (30.0) |
|  | Hypoalbuminaemia | 2 (20.0) | 0 | 0 | 0 | 0 | 2 (20.0) |
|  | Decreased appetite | 1 (10.0) | 0 | 0 | 0 | 0 | 1 (10.0) |
|  | Hypermagnesaemia | 1 (10.0) | 0 | 0 | 0 | 0 | 1 (10.0) |
|  | Hyperphosphataemia | 1 (10.0) | 0 | 0 | 0 | 0 | 1 (10.0) |
|  | Hyponatraemia | 1 (10.0) | 0 | 0 | 0 | 0 | 1 (10.0) |
|  | Hypozincaemia | 1 (10.0) | 0 | 0 | 0 | 0 | 1 (10.0) |
|  | | | | | | | |
|  | Musculoskeletal and connective tissue disorders | 4 (40.0) | 1 (10.0) | 0 | 0 | 0 | 5 (50.0) |
|  | Myalgia | 2 (20.0) | 0 | 0 | 0 | 0 | 2 (20.0) |
|  | Arthritis | 0 | 1 (10.0) | 0 | 0 | 0 | 1 (10.0) |
|  | Joint swelling | 1 (10.0) | 0 | 0 | 0 | 0 | 1 (10.0) |
|  | Pain in extremity | 1 (10.0) | 0 | 0 | 0 | 0 | 1 (10.0) |
|  | | | | | | | |
|  | Cardiac disorders | 4 (40.0) | 0 | 0 | 0 | 0 | 4 (40.0) |
|  | Sinus bradycardia | 2 (20.0) | 0 | 0 | 0 | 0 | 2 (20.0) |
|  | Atrioventricular block first degree | 1 (10.0) | 0 | 0 | 0 | 0 | 1 (10.0) |
|  | Pericardial effusion | 1 (10.0) | 0 | 0 | 0 | 0 | 1 (10.0) |
|  | Supraventricular extrasystoles | 1 (10.0) | 0 | 0 | 0 | 0 | 1 (10.0) |
|  | Tachycardia | 1 (10.0) | 0 | 0 | 0 | 0 | 1 (10.0) |
|  | | | | | | | |
|  | General disorders and administration site conditions | 3 (30.0) | 1 (10.0) | 0 | 0 | 0 | 4 (40.0) |
|  | Influenza like illness | 2 (20.0) | 0 | 0 | 0 | 0 | 2 (20.0) |
|  | Asthenia | 1 (10.0) | 0 | 0 | 0 | 0 | 1 (10.0) |
|  | Fatigue | 1 (10.0) | 0 | 0 | 0 | 0 | 1 (10.0) |
|  | Pyrexia | 0 | 1 (10.0) | 0 | 0 | 0 | 1 (10.0) |
|  | | | | | | | |
|  | Renal and urinary disorders | 2 (20.0) | 1 (10.0) | 1 (10.0) | 0 | 0 | 4 (40.0) |
|  | Proteinuria | 2 (20.0) | 1 (10.0) | 0 | 0 | 0 | 3 (30.0) |
|  | Haematuria | 2 (20.0) | 0 | 0 | 0 | 0 | 2 (20.0) |
|  | Acute kidney injury | 0 | 0 | 1 (10.0) | 0 | 0 | 1 (10.0) |
|  | | | | | | | |
|  | Respiratory, thoracic and mediastinal disorders | 3 (30.0) | 1 (10.0) | 0 | 0 | 0 | 4 (40.0) |
|  | Productive cough | 2 (20.0) | 0 | 0 | 0 | 0 | 2 (20.0) |
|  | Cough | 0 | 1 (10.0) | 0 | 0 | 0 | 1 (10.0) |
|  | Hiccups | 1 (10.0) | 0 | 0 | 0 | 0 | 1 (10.0) |
|  | Pleural effusion | 1 (10.0) | 0 | 0 | 0 | 0 | 1 (10.0) |
|  | Rhinorrhoea | 1 (10.0) | 0 | 0 | 0 | 0 | 1 (10.0) |
|  | | | | | | | |
|  | Blood and lymphatic system disorders | 2 (20.0) | 0 | 1 (10.0) | 0 | 0 | 3 (30.0) |
|  | Anaemia | 2 (20.0) | 0 | 1 (10.0) | 0 | 0 | 3 (30.0) |
|  | Leukocytosis | 0 | 0 | 1 (10.0) | 0 | 0 | 1 (10.0) |
|  | | | | | | | |
|  | Infections and infestations | 0 | 1 (10.0) | 1 (10.0) | 0 | 0 | 2 (20.0) |
|  | COVID-19 | 0 | 1 (10.0) | 0 | 0 | 0 | 1 (10.0) |
|  | Laryngopharyngitis | 0 | 1 (10.0) | 0 | 0 | 0 | 1 (10.0) |
|  | Pneumonia | 0 | 0 | 1 (10.0) | 0 | 0 | 1 (10.0) |
|  | | | | | | | |
|  | Eye disorders | 1 (10.0) | 0 | 0 | 0 | 0 | 1 (10.0) |
|  | Periorbital pain | 1 (10.0) | 0 | 0 | 0 | 0 | 1 (10.0) |
|  | | | | | | | |
|  | Nervous system disorders | 1 (10.0) | 0 | 0 | 0 | 0 | 1 (10.0) |
|  | Hypoaesthesia | 1 (10.0) | 0 | 0 | 0 | 0 | 1 (10.0) |
|  | | | | | | | |
|  | Psychiatric disorders | 1 (10.0) | 0 | 0 | 0 | 0 | 1 (10.0) |
|  | Insomnia | 1 (10.0) | 0 | 0 | 0 | 0 | 1 (10.0) |
|  | | | | | | | |
|  | Skin and subcutaneous tissue disorders | 1 (10.0) | 0 | 0 | 0 | 0 | 1 (10.0) |
|  | Pruritus | 1 (10.0) | 0 | 0 | 0 | 0 | 1 (10.0) |
|  | Rash | 1 (10.0) | 0 | 0 | 0 | 0 | 1 (10.0) |

Grade 1: Mild, Grade 2: Moderate, Grade 3: Severe, Grade 4: Life threatening, Grade 5: Death related to AE.

TEAE is defined as any AE that newly occurs or worsen after the first investigational drug administration and within end of safety follow up period (i.e., within 30 calendar days after the last administration of investigational drug or the start of new anti-cancer therapy (whichever occurs earlier)). If the timing of the AE cannot be established in relation to the first administration of investigational drug, it will be considered as TEAE to be more conservative.

Adverse events are coded with MedDRA 25.0.

Subjects with multiple occurrences of adverse events in the same preferred term are counted only once within that preferred term at the maximum severity.

Subjects with multiple occurrences of adverse events in the same system organ class are counted only once within that system organ class at the maximum severity.

Percentages are based on the number of subjects of each respective group in the Safety Analysis Set.

Source Data: Listing 16.2.7.1

|  |  |  |
| --- | --- | --- |
| Program: t-ae-soc-pt-sev.sas | DCO: 27APR2024 | Executed: 08JUL2024 17:16 |

|  |  |
| --- | --- |
| **InxMed (Shanghai) Co., Ltd.  Protocol No. IN10018-602** |  |

**Table 14.3.1.3.3.6 Summary of TEAEs by Grouped SOC and Grouped PT and Severity - Phase II part 2 - CRC (Safety Analysis Set)**

|  | | Total n (%) | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Group | System Organ Class  Preferred Term | Grade 1 | Grade 2 | Grade 3 | Grade 4 | Grade 5 | Total |
| Treatment Group (N = 5) | All TEAEs | 1 (20.0) | 2 (40.0) | 2 (40.0) | 0 | 0 | 5 (100) |
|  | | | | | | | |
|  | Gastrointestinal disorders | 2 (40.0) | 1 (20.0) | 2 (40.0) | 0 | 0 | 5 (100) |
|  | Diarrhoea | 2 (40.0) | 1 (20.0) | 2 (40.0) | 0 | 0 | 5 (100) |
|  | Nausea | 3 (60.0) | 0 | 0 | 0 | 0 | 3 (60.0) |
|  | Abdominal distension | 2 (40.0) | 0 | 0 | 0 | 0 | 2 (40.0) |
|  | Intestinal obstruction | 0 | 0 | 1 (20.0) | 0 | 0 | 1 (20.0) |
|  | Vomiting | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | | | | | | | |
|  | Investigations | 2 (40.0) | 1 (20.0) | 1 (20.0) | 0 | 0 | 4 (80.0) |
|  | Alanine aminotransferase increased | 2 (40.0) | 0 | 0 | 0 | 0 | 2 (40.0) |
|  | C-reactive protein increased | 1 (20.0) | 0 | 1 (20.0) | 0 | 0 | 2 (40.0) |
|  | Weight decreased | 2 (40.0) | 0 | 0 | 0 | 0 | 2 (40.0) |
|  | Aspartate aminotransferase increased | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | Blood alkaline phosphatase increased | 0 | 1 (20.0) | 0 | 0 | 0 | 1 (20.0) |
|  | Electrocardiogram PR prolongation | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | Electrocardiogram QT prolonged | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | Gamma-glutamyltransferase increased | 0 | 1 (20.0) | 0 | 0 | 0 | 1 (20.0) |
|  | Neutrophil count decreased | 0 | 1 (20.0) | 0 | 0 | 0 | 1 (20.0) |
|  | Platelet count decreased | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | Procalcitonin increased | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | Red blood cell sedimentation rate increased | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | White blood cell count decreased | 0 | 1 (20.0) | 0 | 0 | 0 | 1 (20.0) |
|  | | | | | | | |
|  | Metabolism and nutrition disorders# | 2 (40.0) | 2 (40.0) | 0 | 0 | 0 | 4 (80.0) |
|  | Hypercholesterolaemia\* | 2 (40.0) | 0 | 0 | 0 | 0 | 2 (40.0) |
|  | Hypertriglyceridaemia | 1 (20.0) | 1 (20.0) | 0 | 0 | 0 | 2 (40.0) |
|  | Hypoalbuminaemia | 2 (40.0) | 0 | 0 | 0 | 0 | 2 (40.0) |
|  | Decreased appetite | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | Hyperglycaemia | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | Hyperphosphataemia | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | Hypokalaemia | 0 | 1 (20.0) | 0 | 0 | 0 | 1 (20.0) |
|  | Hyponatraemia | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | | | | | | | |
|  | Musculoskeletal and connective tissue disorders | 3 (60.0) | 1 (20.0) | 0 | 0 | 0 | 4 (80.0) |
|  | Myalgia | 2 (40.0) | 0 | 0 | 0 | 0 | 2 (40.0) |
|  | Arthritis | 0 | 1 (20.0) | 0 | 0 | 0 | 1 (20.0) |
|  | Pain in extremity | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | | | | | | | |
|  | Renal and urinary disorders# | 2 (40.0) | 1 (20.0) | 1 (20.0) | 0 | 0 | 4 (80.0) |
|  | Proteinuria\* | 2 (40.0) | 1 (20.0) | 0 | 0 | 0 | 3 (60.0) |
|  | Haematuria\* | 2 (40.0) | 0 | 0 | 0 | 0 | 2 (40.0) |
|  | Acute kidney injury | 0 | 0 | 1 (20.0) | 0 | 0 | 1 (20.0) |
|  | | | | | | | |
|  | Blood and lymphatic system disorders# | 2 (40.0) | 0 | 0 | 0 | 0 | 2 (40.0) |
|  | Anaemia | 2 (40.0) | 0 | 0 | 0 | 0 | 2 (40.0) |
|  | | | | | | | |
|  | Cardiac disorders | 2 (40.0) | 0 | 0 | 0 | 0 | 2 (40.0) |
|  | Sinus bradycardia | 2 (40.0) | 0 | 0 | 0 | 0 | 2 (40.0) |
|  | Atrioventricular block first degree | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | | | | | | | |
|  | General disorders and administration site conditions# | 2 (40.0) | 0 | 0 | 0 | 0 | 2 (40.0) |
|  | Fatigue\* | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | Influenza like illness | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | | | | | | | |
|  | Eye disorders | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | Periorbital pain | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | | | | | | | |
|  | Nervous system disorders | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | Hypoaesthesia | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | | | | | | | |
|  | Psychiatric disorders | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | Insomnia | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | | | | | | | |
|  | Respiratory, thoracic and mediastinal disorders | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | Productive cough | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | | | | | | | |
|  | Skin and subcutaneous tissue disorders | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | Pruritus | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | Rash | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | | | | | | | |
| Control Group (N = 5) | All TEAEs | 2 (40.0) | 2 (40.0) | 1 (20.0) | 0 | 0 | 5 (100) |
|  | | | | | | | |
|  | Investigations | 2 (40.0) | 1 (20.0) | 1 (20.0) | 0 | 0 | 4 (80.0) |
|  | Alanine aminotransferase increased | 2 (40.0) | 0 | 0 | 0 | 0 | 2 (40.0) |
|  | Aspartate aminotransferase increased | 2 (40.0) | 0 | 0 | 0 | 0 | 2 (40.0) |
|  | Lymphocyte count decreased | 1 (20.0) | 0 | 1 (20.0) | 0 | 0 | 2 (40.0) |
|  | Blood bilirubin increased | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | Blood creatine phosphokinase increased | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | Blood lactate dehydrogenase increased | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | C-reactive protein increased | 0 | 0 | 1 (20.0) | 0 | 0 | 1 (20.0) |
|  | Electrocardiogram QRS complex prolonged | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | Electrocardiogram QT prolonged | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | Gamma-glutamyltransferase increased | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | Leukocyte alkaline phosphatase increased | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | Neutrophil count decreased | 0 | 1 (20.0) | 0 | 0 | 0 | 1 (20.0) |
|  | Neutrophil count increased | 0 | 0 | 1 (20.0) | 0 | 0 | 1 (20.0) |
|  | Platelet count decreased | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | Serum amyloid A protein increased | 0 | 0 | 1 (20.0) | 0 | 0 | 1 (20.0) |
|  | Serum ferritin increased | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | Total bile acids increased | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | White blood cell count decreased | 0 | 1 (20.0) | 0 | 0 | 0 | 1 (20.0) |
|  | | | | | | | |
|  | Gastrointestinal disorders | 3 (60.0) | 0 | 0 | 0 | 0 | 3 (60.0) |
|  | Nausea | 2 (40.0) | 0 | 0 | 0 | 0 | 2 (40.0) |
|  | Abdominal discomfort | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | Toothache | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | Vomiting | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | | | | | | | |
|  | Metabolism and nutrition disorders# | 2 (40.0) | 1 (20.0) | 0 | 0 | 0 | 3 (60.0) |
|  | Hyperglycaemia | 2 (40.0) | 0 | 0 | 0 | 0 | 2 (40.0) |
|  | Hypertriglyceridaemia | 2 (40.0) | 0 | 0 | 0 | 0 | 2 (40.0) |
|  | Hypokalaemia | 2 (40.0) | 0 | 0 | 0 | 0 | 2 (40.0) |
|  | Hypercholesterolaemia\* | 0 | 1 (20.0) | 0 | 0 | 0 | 1 (20.0) |
|  | Hypermagnesaemia | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | Hypozincaemia | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | | | | | | | |
|  | Respiratory, thoracic and mediastinal disorders | 2 (40.0) | 1 (20.0) | 0 | 0 | 0 | 3 (60.0) |
|  | Cough | 0 | 1 (20.0) | 0 | 0 | 0 | 1 (20.0) |
|  | Hiccups | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | Pleural effusion | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | Productive cough | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | Rhinorrhoea | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | | | | | | | |
|  | Cardiac disorders | 2 (40.0) | 0 | 0 | 0 | 0 | 2 (40.0) |
|  | Pericardial effusion | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | Supraventricular extrasystoles | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | Tachycardia | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | | | | | | | |
|  | General disorders and administration site conditions# | 1 (20.0) | 1 (20.0) | 0 | 0 | 0 | 2 (40.0) |
|  | Fatigue\* | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | Influenza like illness | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | Pyrexia | 0 | 1 (20.0) | 0 | 0 | 0 | 1 (20.0) |
|  | | | | | | | |
|  | Infections and infestations | 0 | 1 (20.0) | 1 (20.0) | 0 | 0 | 2 (40.0) |
|  | COVID-19 | 0 | 1 (20.0) | 0 | 0 | 0 | 1 (20.0) |
|  | Laryngopharyngitis | 0 | 1 (20.0) | 0 | 0 | 0 | 1 (20.0) |
|  | Pneumonia | 0 | 0 | 1 (20.0) | 0 | 0 | 1 (20.0) |
|  | | | | | | | |
|  | Blood and lymphatic system disorders# | 0 | 0 | 1 (20.0) | 0 | 0 | 1 (20.0) |
|  | Anaemia | 0 | 0 | 1 (20.0) | 0 | 0 | 1 (20.0) |
|  | Leukocytosis\* | 0 | 0 | 1 (20.0) | 0 | 0 | 1 (20.0) |
|  | | | | | | | |
|  | Musculoskeletal and connective tissue disorders | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | Joint swelling | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | | | | | | | |
| Total (N = 10) | All TEAEs | 3 (30.0) | 4 (40.0) | 3 (30.0) | 0 | 0 | 10 (100) |
|  | | | | | | | |
|  | Gastrointestinal disorders | 5 (50.0) | 1 (10.0) | 2 (20.0) | 0 | 0 | 8 (80.0) |
|  | Diarrhoea | 2 (20.0) | 1 (10.0) | 2 (20.0) | 0 | 0 | 5 (50.0) |
|  | Nausea | 5 (50.0) | 0 | 0 | 0 | 0 | 5 (50.0) |
|  | Abdominal distension | 2 (20.0) | 0 | 0 | 0 | 0 | 2 (20.0) |
|  | Vomiting | 2 (20.0) | 0 | 0 | 0 | 0 | 2 (20.0) |
|  | Abdominal discomfort | 1 (10.0) | 0 | 0 | 0 | 0 | 1 (10.0) |
|  | Intestinal obstruction | 0 | 0 | 1 (10.0) | 0 | 0 | 1 (10.0) |
|  | Toothache | 1 (10.0) | 0 | 0 | 0 | 0 | 1 (10.0) |
|  | | | | | | | |
|  | Investigations | 4 (40.0) | 2 (20.0) | 2 (20.0) | 0 | 0 | 8 (80.0) |
|  | Alanine aminotransferase increased | 4 (40.0) | 0 | 0 | 0 | 0 | 4 (40.0) |
|  | Aspartate aminotransferase increased | 3 (30.0) | 0 | 0 | 0 | 0 | 3 (30.0) |
|  | C-reactive protein increased | 1 (10.0) | 0 | 2 (20.0) | 0 | 0 | 3 (30.0) |
|  | Electrocardiogram QT prolonged | 2 (20.0) | 0 | 0 | 0 | 0 | 2 (20.0) |
|  | Gamma-glutamyltransferase increased | 1 (10.0) | 1 (10.0) | 0 | 0 | 0 | 2 (20.0) |
|  | Lymphocyte count decreased | 1 (10.0) | 0 | 1 (10.0) | 0 | 0 | 2 (20.0) |
|  | Neutrophil count decreased | 0 | 2 (20.0) | 0 | 0 | 0 | 2 (20.0) |
|  | Platelet count decreased | 2 (20.0) | 0 | 0 | 0 | 0 | 2 (20.0) |
|  | Weight decreased | 2 (20.0) | 0 | 0 | 0 | 0 | 2 (20.0) |
|  | White blood cell count decreased | 0 | 2 (20.0) | 0 | 0 | 0 | 2 (20.0) |
|  | Blood alkaline phosphatase increased | 0 | 1 (10.0) | 0 | 0 | 0 | 1 (10.0) |
|  | Blood bilirubin increased | 1 (10.0) | 0 | 0 | 0 | 0 | 1 (10.0) |
|  | Blood creatine phosphokinase increased | 1 (10.0) | 0 | 0 | 0 | 0 | 1 (10.0) |
|  | Blood lactate dehydrogenase increased | 1 (10.0) | 0 | 0 | 0 | 0 | 1 (10.0) |
|  | Electrocardiogram PR prolongation | 1 (10.0) | 0 | 0 | 0 | 0 | 1 (10.0) |
|  | Electrocardiogram QRS complex prolonged | 1 (10.0) | 0 | 0 | 0 | 0 | 1 (10.0) |
|  | Leukocyte alkaline phosphatase increased | 1 (10.0) | 0 | 0 | 0 | 0 | 1 (10.0) |
|  | Neutrophil count increased | 0 | 0 | 1 (10.0) | 0 | 0 | 1 (10.0) |
|  | Procalcitonin increased | 1 (10.0) | 0 | 0 | 0 | 0 | 1 (10.0) |
|  | Red blood cell sedimentation rate increased | 1 (10.0) | 0 | 0 | 0 | 0 | 1 (10.0) |
|  | Serum amyloid A protein increased | 0 | 0 | 1 (10.0) | 0 | 0 | 1 (10.0) |
|  | Serum ferritin increased | 1 (10.0) | 0 | 0 | 0 | 0 | 1 (10.0) |
|  | Total bile acids increased | 1 (10.0) | 0 | 0 | 0 | 0 | 1 (10.0) |
|  | | | | | | | |
|  | Metabolism and nutrition disorders# | 4 (40.0) | 3 (30.0) | 0 | 0 | 0 | 7 (70.0) |
|  | Hypertriglyceridaemia | 3 (30.0) | 1 (10.0) | 0 | 0 | 0 | 4 (40.0) |
|  | Hypercholesterolaemia\* | 2 (20.0) | 1 (10.0) | 0 | 0 | 0 | 3 (30.0) |
|  | Hyperglycaemia | 3 (30.0) | 0 | 0 | 0 | 0 | 3 (30.0) |
|  | Hypokalaemia | 2 (20.0) | 1 (10.0) | 0 | 0 | 0 | 3 (30.0) |
|  | Hypoalbuminaemia | 2 (20.0) | 0 | 0 | 0 | 0 | 2 (20.0) |
|  | Decreased appetite | 1 (10.0) | 0 | 0 | 0 | 0 | 1 (10.0) |
|  | Hypermagnesaemia | 1 (10.0) | 0 | 0 | 0 | 0 | 1 (10.0) |
|  | Hyperphosphataemia | 1 (10.0) | 0 | 0 | 0 | 0 | 1 (10.0) |
|  | Hyponatraemia | 1 (10.0) | 0 | 0 | 0 | 0 | 1 (10.0) |
|  | Hypozincaemia | 1 (10.0) | 0 | 0 | 0 | 0 | 1 (10.0) |
|  | | | | | | | |
|  | Musculoskeletal and connective tissue disorders | 4 (40.0) | 1 (10.0) | 0 | 0 | 0 | 5 (50.0) |
|  | Myalgia | 2 (20.0) | 0 | 0 | 0 | 0 | 2 (20.0) |
|  | Arthritis | 0 | 1 (10.0) | 0 | 0 | 0 | 1 (10.0) |
|  | Joint swelling | 1 (10.0) | 0 | 0 | 0 | 0 | 1 (10.0) |
|  | Pain in extremity | 1 (10.0) | 0 | 0 | 0 | 0 | 1 (10.0) |
|  | | | | | | | |
|  | Cardiac disorders | 4 (40.0) | 0 | 0 | 0 | 0 | 4 (40.0) |
|  | Sinus bradycardia | 2 (20.0) | 0 | 0 | 0 | 0 | 2 (20.0) |
|  | Atrioventricular block first degree | 1 (10.0) | 0 | 0 | 0 | 0 | 1 (10.0) |
|  | Pericardial effusion | 1 (10.0) | 0 | 0 | 0 | 0 | 1 (10.0) |
|  | Supraventricular extrasystoles | 1 (10.0) | 0 | 0 | 0 | 0 | 1 (10.0) |
|  | Tachycardia | 1 (10.0) | 0 | 0 | 0 | 0 | 1 (10.0) |
|  | | | | | | | |
|  | General disorders and administration site conditions# | 3 (30.0) | 1 (10.0) | 0 | 0 | 0 | 4 (40.0) |
|  | Fatigue\* | 2 (20.0) | 0 | 0 | 0 | 0 | 2 (20.0) |
|  | Influenza like illness | 2 (20.0) | 0 | 0 | 0 | 0 | 2 (20.0) |
|  | Pyrexia | 0 | 1 (10.0) | 0 | 0 | 0 | 1 (10.0) |
|  | | | | | | | |
|  | Renal and urinary disorders# | 2 (20.0) | 1 (10.0) | 1 (10.0) | 0 | 0 | 4 (40.0) |
|  | Proteinuria\* | 2 (20.0) | 1 (10.0) | 0 | 0 | 0 | 3 (30.0) |
|  | Haematuria\* | 2 (20.0) | 0 | 0 | 0 | 0 | 2 (20.0) |
|  | Acute kidney injury | 0 | 0 | 1 (10.0) | 0 | 0 | 1 (10.0) |
|  | | | | | | | |
|  | Respiratory, thoracic and mediastinal disorders | 3 (30.0) | 1 (10.0) | 0 | 0 | 0 | 4 (40.0) |
|  | Productive cough | 2 (20.0) | 0 | 0 | 0 | 0 | 2 (20.0) |
|  | Cough | 0 | 1 (10.0) | 0 | 0 | 0 | 1 (10.0) |
|  | Hiccups | 1 (10.0) | 0 | 0 | 0 | 0 | 1 (10.0) |
|  | Pleural effusion | 1 (10.0) | 0 | 0 | 0 | 0 | 1 (10.0) |
|  | Rhinorrhoea | 1 (10.0) | 0 | 0 | 0 | 0 | 1 (10.0) |
|  | | | | | | | |
|  | Blood and lymphatic system disorders# | 2 (20.0) | 0 | 1 (10.0) | 0 | 0 | 3 (30.0) |
|  | Anaemia | 2 (20.0) | 0 | 1 (10.0) | 0 | 0 | 3 (30.0) |
|  | Leukocytosis\* | 0 | 0 | 1 (10.0) | 0 | 0 | 1 (10.0) |
|  | | | | | | | |
|  | Infections and infestations | 0 | 1 (10.0) | 1 (10.0) | 0 | 0 | 2 (20.0) |
|  | COVID-19 | 0 | 1 (10.0) | 0 | 0 | 0 | 1 (10.0) |
|  | Laryngopharyngitis | 0 | 1 (10.0) | 0 | 0 | 0 | 1 (10.0) |
|  | Pneumonia | 0 | 0 | 1 (10.0) | 0 | 0 | 1 (10.0) |
|  | | | | | | | |
|  | Eye disorders | 1 (10.0) | 0 | 0 | 0 | 0 | 1 (10.0) |
|  | Periorbital pain | 1 (10.0) | 0 | 0 | 0 | 0 | 1 (10.0) |
|  | | | | | | | |
|  | Nervous system disorders | 1 (10.0) | 0 | 0 | 0 | 0 | 1 (10.0) |
|  | Hypoaesthesia | 1 (10.0) | 0 | 0 | 0 | 0 | 1 (10.0) |
|  | | | | | | | |
|  | Psychiatric disorders | 1 (10.0) | 0 | 0 | 0 | 0 | 1 (10.0) |
|  | Insomnia | 1 (10.0) | 0 | 0 | 0 | 0 | 1 (10.0) |
|  | | | | | | | |
|  | Skin and subcutaneous tissue disorders | 1 (10.0) | 0 | 0 | 0 | 0 | 1 (10.0) |
|  | Pruritus | 1 (10.0) | 0 | 0 | 0 | 0 | 1 (10.0) |
|  | Rash | 1 (10.0) | 0 | 0 | 0 | 0 | 1 (10.0) |

Grade 1: Mild, Grade 2: Moderate, Grade 3: Severe, Grade 4: Life threatening, Grade 5: Death related to AE.

TEAE is defined as any AE that newly occurs or worsen after the first investigational drug administration and within end of safety follow up period (i.e., within 30 calendar days after the last administration of investigational drug or the start of new anti-cancer therapy (whichever occurs earlier)). If the timing of the AE cannot be established in relation to the first administration of investigational drug, it will be considered as TEAE to be more conservative.

Adverse events are coded with MedDRA 25.0.

Subjects with multiple occurrences of adverse events in the same grouped preferred term are counted only once within that grouped preferred term at the maximum severity.

Subjects with multiple occurrences of adverse events in the same grouped system organ class are counted only once within that grouped system organ class at the maximum severity.

Percentages are based on the number of subjects of each respective group in the Safety Analysis Set.

#: Grouped SOC. \*: Grouped PT.  
Source Data: Listing 16.2.7.1

|  |  |  |
| --- | --- | --- |
| Program: t-ae-soc-pt-sev.sas | DCO: 27APR2024 | Executed: 08JUL2024 17:16 |

|  |  |
| --- | --- |
| **InxMed (Shanghai) Co., Ltd.  Protocol No. IN10018-602** |  |

**Table 14.3.1.3.4.5 Summary of D-1553 Related TEAEs by SOC, PT and Severity - Phase II part 2 - CRC (Safety Analysis Set)**

|  | | Total n (%) | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Group | System Organ Class  Preferred Term | Grade 1 | Grade 2 | Grade 3 | Grade 4 | Grade 5 | Total |
| Treatment Group (N = 5) | All TEAEs | 1 (20.0) | 2 (40.0) | 2 (40.0) | 0 | 0 | 5 (100) |
|  | | | | | | | |
|  | Gastrointestinal disorders | 2 (40.0) | 1 (20.0) | 2 (40.0) | 0 | 0 | 5 (100) |
|  | Diarrhoea | 2 (40.0) | 1 (20.0) | 2 (40.0) | 0 | 0 | 5 (100) |
|  | Nausea | 3 (60.0) | 0 | 0 | 0 | 0 | 3 (60.0) |
|  | Abdominal distension | 2 (40.0) | 0 | 0 | 0 | 0 | 2 (40.0) |
|  | Intestinal obstruction | 0 | 0 | 1 (20.0) | 0 | 0 | 1 (20.0) |
|  | Vomiting | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | | | | | | | |
|  | Investigations | 2 (40.0) | 1 (20.0) | 1 (20.0) | 0 | 0 | 4 (80.0) |
|  | Alanine aminotransferase increased | 2 (40.0) | 0 | 0 | 0 | 0 | 2 (40.0) |
|  | Weight decreased | 2 (40.0) | 0 | 0 | 0 | 0 | 2 (40.0) |
|  | Aspartate aminotransferase increased | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | Blood alkaline phosphatase increased | 0 | 1 (20.0) | 0 | 0 | 0 | 1 (20.0) |
|  | Blood urine | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | C-reactive protein increased | 0 | 0 | 1 (20.0) | 0 | 0 | 1 (20.0) |
|  | Electrocardiogram PR prolongation | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | Electrocardiogram QT prolonged | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | Gamma-glutamyltransferase increased | 0 | 1 (20.0) | 0 | 0 | 0 | 1 (20.0) |
|  | Neutrophil count decreased | 0 | 1 (20.0) | 0 | 0 | 0 | 1 (20.0) |
|  | Platelet count decreased | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | White blood cell count decreased | 0 | 1 (20.0) | 0 | 0 | 0 | 1 (20.0) |
|  | | | | | | | |
|  | Metabolism and nutrition disorders | 3 (60.0) | 1 (20.0) | 0 | 0 | 0 | 4 (80.0) |
|  | Hypercholesterolaemia | 2 (40.0) | 0 | 0 | 0 | 0 | 2 (40.0) |
|  | Decreased appetite | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | Hyperglycaemia | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | Hyperphosphataemia | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | Hypertriglyceridaemia | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | Hypokalaemia | 0 | 1 (20.0) | 0 | 0 | 0 | 1 (20.0) |
|  | | | | | | | |
|  | Renal and urinary disorders | 2 (40.0) | 1 (20.0) | 1 (20.0) | 0 | 0 | 4 (80.0) |
|  | Proteinuria | 2 (40.0) | 1 (20.0) | 0 | 0 | 0 | 3 (60.0) |
|  | Haematuria | 2 (40.0) | 0 | 0 | 0 | 0 | 2 (40.0) |
|  | Acute kidney injury | 0 | 0 | 1 (20.0) | 0 | 0 | 1 (20.0) |
|  | | | | | | | |
|  | Musculoskeletal and connective tissue disorders | 3 (60.0) | 0 | 0 | 0 | 0 | 3 (60.0) |
|  | Myalgia | 2 (40.0) | 0 | 0 | 0 | 0 | 2 (40.0) |
|  | Pain in extremity | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | | | | | | | |
|  | Cardiac disorders | 2 (40.0) | 0 | 0 | 0 | 0 | 2 (40.0) |
|  | Atrioventricular block first degree | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | Sinus bradycardia | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | | | | | | | |
|  | Blood and lymphatic system disorders | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | Anaemia | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | | | | | | | |
|  | Eye disorders | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | Periorbital pain | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | | | | | | | |
|  | General disorders and administration site conditions | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | Asthenia | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | | | | | | | |
|  | Nervous system disorders | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | Hypoaesthesia | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | | | | | | | |
|  | Psychiatric disorders | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | Insomnia | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | | | | | | | |
|  | Skin and subcutaneous tissue disorders | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | Pruritus | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | Rash | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | | | | | | | |
| Control Group (N = 5) | All TEAEs | 3 (60.0) | 1 (20.0) | 1 (20.0) | 0 | 0 | 5 (100) |
|  | | | | | | | |
|  | Investigations | 2 (40.0) | 1 (20.0) | 1 (20.0) | 0 | 0 | 4 (80.0) |
|  | Alanine aminotransferase increased | 2 (40.0) | 0 | 0 | 0 | 0 | 2 (40.0) |
|  | Aspartate aminotransferase increased | 2 (40.0) | 0 | 0 | 0 | 0 | 2 (40.0) |
|  | Lymphocyte count decreased | 1 (20.0) | 0 | 1 (20.0) | 0 | 0 | 2 (40.0) |
|  | Blood bilirubin increased | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | Blood creatine phosphokinase increased | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | Blood lactate dehydrogenase increased | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | C-reactive protein increased | 0 | 0 | 1 (20.0) | 0 | 0 | 1 (20.0) |
|  | Electrocardiogram QRS complex prolonged | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | Electrocardiogram QT prolonged | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | Gamma-glutamyltransferase increased | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | Neutrophil count decreased | 0 | 1 (20.0) | 0 | 0 | 0 | 1 (20.0) |
|  | Neutrophil count increased | 0 | 0 | 1 (20.0) | 0 | 0 | 1 (20.0) |
|  | Platelet count decreased | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | Serum amyloid A protein increased | 0 | 0 | 1 (20.0) | 0 | 0 | 1 (20.0) |
|  | Total bile acids increased | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | White blood cell count decreased | 0 | 1 (20.0) | 0 | 0 | 0 | 1 (20.0) |
|  | | | | | | | |
|  | Gastrointestinal disorders | 3 (60.0) | 0 | 0 | 0 | 0 | 3 (60.0) |
|  | Nausea | 2 (40.0) | 0 | 0 | 0 | 0 | 2 (40.0) |
|  | Abdominal discomfort | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | Toothache | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | Vomiting | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | | | | | | | |
|  | Metabolism and nutrition disorders | 2 (40.0) | 1 (20.0) | 0 | 0 | 0 | 3 (60.0) |
|  | Hypercholesterolaemia | 0 | 1 (20.0) | 0 | 0 | 0 | 1 (20.0) |
|  | Hyperglycaemia | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | Hypermagnesaemia | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | Hypertriglyceridaemia | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | Hypokalaemia | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | Hypozincaemia | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | | | | | | | |
|  | Cardiac disorders | 2 (40.0) | 0 | 0 | 0 | 0 | 2 (40.0) |
|  | Pericardial effusion | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | Supraventricular extrasystoles | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | Tachycardia | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | | | | | | | |
|  | General disorders and administration site conditions | 2 (40.0) | 0 | 0 | 0 | 0 | 2 (40.0) |
|  | Fatigue | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | Influenza like illness | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | | | | | | | |
|  | Respiratory, thoracic and mediastinal disorders | 1 (20.0) | 1 (20.0) | 0 | 0 | 0 | 2 (40.0) |
|  | Cough | 0 | 1 (20.0) | 0 | 0 | 0 | 1 (20.0) |
|  | Hiccups | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | Productive cough | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | | | | | | | |
|  | Blood and lymphatic system disorders | 0 | 0 | 1 (20.0) | 0 | 0 | 1 (20.0) |
|  | Anaemia | 0 | 0 | 1 (20.0) | 0 | 0 | 1 (20.0) |
|  | Leukocytosis | 0 | 0 | 1 (20.0) | 0 | 0 | 1 (20.0) |
|  | | | | | | | |
|  | Infections and infestations | 0 | 0 | 1 (20.0) | 0 | 0 | 1 (20.0) |
|  | Pneumonia | 0 | 0 | 1 (20.0) | 0 | 0 | 1 (20.0) |
|  | | | | | | | |
| Total (N = 10) | All TEAEs | 4 (40.0) | 3 (30.0) | 3 (30.0) | 0 | 0 | 10 (100) |
|  | | | | | | | |
|  | Gastrointestinal disorders | 5 (50.0) | 1 (10.0) | 2 (20.0) | 0 | 0 | 8 (80.0) |
|  | Diarrhoea | 2 (20.0) | 1 (10.0) | 2 (20.0) | 0 | 0 | 5 (50.0) |
|  | Nausea | 5 (50.0) | 0 | 0 | 0 | 0 | 5 (50.0) |
|  | Abdominal distension | 2 (20.0) | 0 | 0 | 0 | 0 | 2 (20.0) |
|  | Vomiting | 2 (20.0) | 0 | 0 | 0 | 0 | 2 (20.0) |
|  | Abdominal discomfort | 1 (10.0) | 0 | 0 | 0 | 0 | 1 (10.0) |
|  | Intestinal obstruction | 0 | 0 | 1 (10.0) | 0 | 0 | 1 (10.0) |
|  | Toothache | 1 (10.0) | 0 | 0 | 0 | 0 | 1 (10.0) |
|  | | | | | | | |
|  | Investigations | 4 (40.0) | 2 (20.0) | 2 (20.0) | 0 | 0 | 8 (80.0) |
|  | Alanine aminotransferase increased | 4 (40.0) | 0 | 0 | 0 | 0 | 4 (40.0) |
|  | Aspartate aminotransferase increased | 3 (30.0) | 0 | 0 | 0 | 0 | 3 (30.0) |
|  | C-reactive protein increased | 0 | 0 | 2 (20.0) | 0 | 0 | 2 (20.0) |
|  | Electrocardiogram QT prolonged | 2 (20.0) | 0 | 0 | 0 | 0 | 2 (20.0) |
|  | Gamma-glutamyltransferase increased | 1 (10.0) | 1 (10.0) | 0 | 0 | 0 | 2 (20.0) |
|  | Lymphocyte count decreased | 1 (10.0) | 0 | 1 (10.0) | 0 | 0 | 2 (20.0) |
|  | Neutrophil count decreased | 0 | 2 (20.0) | 0 | 0 | 0 | 2 (20.0) |
|  | Platelet count decreased | 2 (20.0) | 0 | 0 | 0 | 0 | 2 (20.0) |
|  | Weight decreased | 2 (20.0) | 0 | 0 | 0 | 0 | 2 (20.0) |
|  | White blood cell count decreased | 0 | 2 (20.0) | 0 | 0 | 0 | 2 (20.0) |
|  | Blood alkaline phosphatase increased | 0 | 1 (10.0) | 0 | 0 | 0 | 1 (10.0) |
|  | Blood bilirubin increased | 1 (10.0) | 0 | 0 | 0 | 0 | 1 (10.0) |
|  | Blood creatine phosphokinase increased | 1 (10.0) | 0 | 0 | 0 | 0 | 1 (10.0) |
|  | Blood lactate dehydrogenase increased | 1 (10.0) | 0 | 0 | 0 | 0 | 1 (10.0) |
|  | Blood urine | 1 (10.0) | 0 | 0 | 0 | 0 | 1 (10.0) |
|  | Electrocardiogram PR prolongation | 1 (10.0) | 0 | 0 | 0 | 0 | 1 (10.0) |
|  | Electrocardiogram QRS complex prolonged | 1 (10.0) | 0 | 0 | 0 | 0 | 1 (10.0) |
|  | Neutrophil count increased | 0 | 0 | 1 (10.0) | 0 | 0 | 1 (10.0) |
|  | Serum amyloid A protein increased | 0 | 0 | 1 (10.0) | 0 | 0 | 1 (10.0) |
|  | Total bile acids increased | 1 (10.0) | 0 | 0 | 0 | 0 | 1 (10.0) |
|  | | | | | | | |
|  | Metabolism and nutrition disorders | 5 (50.0) | 2 (20.0) | 0 | 0 | 0 | 7 (70.0) |
|  | Hypercholesterolaemia | 2 (20.0) | 1 (10.0) | 0 | 0 | 0 | 3 (30.0) |
|  | Hyperglycaemia | 2 (20.0) | 0 | 0 | 0 | 0 | 2 (20.0) |
|  | Hypertriglyceridaemia | 2 (20.0) | 0 | 0 | 0 | 0 | 2 (20.0) |
|  | Hypokalaemia | 1 (10.0) | 1 (10.0) | 0 | 0 | 0 | 2 (20.0) |
|  | Decreased appetite | 1 (10.0) | 0 | 0 | 0 | 0 | 1 (10.0) |
|  | Hypermagnesaemia | 1 (10.0) | 0 | 0 | 0 | 0 | 1 (10.0) |
|  | Hyperphosphataemia | 1 (10.0) | 0 | 0 | 0 | 0 | 1 (10.0) |
|  | Hypozincaemia | 1 (10.0) | 0 | 0 | 0 | 0 | 1 (10.0) |
|  | | | | | | | |
|  | Cardiac disorders | 4 (40.0) | 0 | 0 | 0 | 0 | 4 (40.0) |
|  | Atrioventricular block first degree | 1 (10.0) | 0 | 0 | 0 | 0 | 1 (10.0) |
|  | Pericardial effusion | 1 (10.0) | 0 | 0 | 0 | 0 | 1 (10.0) |
|  | Sinus bradycardia | 1 (10.0) | 0 | 0 | 0 | 0 | 1 (10.0) |
|  | Supraventricular extrasystoles | 1 (10.0) | 0 | 0 | 0 | 0 | 1 (10.0) |
|  | Tachycardia | 1 (10.0) | 0 | 0 | 0 | 0 | 1 (10.0) |
|  | | | | | | | |
|  | Renal and urinary disorders | 2 (20.0) | 1 (10.0) | 1 (10.0) | 0 | 0 | 4 (40.0) |
|  | Proteinuria | 2 (20.0) | 1 (10.0) | 0 | 0 | 0 | 3 (30.0) |
|  | Haematuria | 2 (20.0) | 0 | 0 | 0 | 0 | 2 (20.0) |
|  | Acute kidney injury | 0 | 0 | 1 (10.0) | 0 | 0 | 1 (10.0) |
|  | | | | | | | |
|  | General disorders and administration site conditions | 3 (30.0) | 0 | 0 | 0 | 0 | 3 (30.0) |
|  | Asthenia | 1 (10.0) | 0 | 0 | 0 | 0 | 1 (10.0) |
|  | Fatigue | 1 (10.0) | 0 | 0 | 0 | 0 | 1 (10.0) |
|  | Influenza like illness | 1 (10.0) | 0 | 0 | 0 | 0 | 1 (10.0) |
|  | | | | | | | |
|  | Musculoskeletal and connective tissue disorders | 3 (30.0) | 0 | 0 | 0 | 0 | 3 (30.0) |
|  | Myalgia | 2 (20.0) | 0 | 0 | 0 | 0 | 2 (20.0) |
|  | Pain in extremity | 1 (10.0) | 0 | 0 | 0 | 0 | 1 (10.0) |
|  | | | | | | | |
|  | Blood and lymphatic system disorders | 1 (10.0) | 0 | 1 (10.0) | 0 | 0 | 2 (20.0) |
|  | Anaemia | 1 (10.0) | 0 | 1 (10.0) | 0 | 0 | 2 (20.0) |
|  | Leukocytosis | 0 | 0 | 1 (10.0) | 0 | 0 | 1 (10.0) |
|  | | | | | | | |
|  | Respiratory, thoracic and mediastinal disorders | 1 (10.0) | 1 (10.0) | 0 | 0 | 0 | 2 (20.0) |
|  | Cough | 0 | 1 (10.0) | 0 | 0 | 0 | 1 (10.0) |
|  | Hiccups | 1 (10.0) | 0 | 0 | 0 | 0 | 1 (10.0) |
|  | Productive cough | 1 (10.0) | 0 | 0 | 0 | 0 | 1 (10.0) |
|  | | | | | | | |
|  | Eye disorders | 1 (10.0) | 0 | 0 | 0 | 0 | 1 (10.0) |
|  | Periorbital pain | 1 (10.0) | 0 | 0 | 0 | 0 | 1 (10.0) |
|  | | | | | | | |
|  | Infections and infestations | 0 | 0 | 1 (10.0) | 0 | 0 | 1 (10.0) |
|  | Pneumonia | 0 | 0 | 1 (10.0) | 0 | 0 | 1 (10.0) |
|  | | | | | | | |
|  | Nervous system disorders | 1 (10.0) | 0 | 0 | 0 | 0 | 1 (10.0) |
|  | Hypoaesthesia | 1 (10.0) | 0 | 0 | 0 | 0 | 1 (10.0) |
|  | | | | | | | |
|  | Psychiatric disorders | 1 (10.0) | 0 | 0 | 0 | 0 | 1 (10.0) |
|  | Insomnia | 1 (10.0) | 0 | 0 | 0 | 0 | 1 (10.0) |
|  | | | | | | | |
|  | Skin and subcutaneous tissue disorders | 1 (10.0) | 0 | 0 | 0 | 0 | 1 (10.0) |
|  | Pruritus | 1 (10.0) | 0 | 0 | 0 | 0 | 1 (10.0) |
|  | Rash | 1 (10.0) | 0 | 0 | 0 | 0 | 1 (10.0) |

Grade 1: Mild, Grade 2: Moderate, Grade 3: Severe, Grade 4: Life threatening, Grade 5: Death related to AE.

D-1553 related TEAE is defined as the relationship with D-1553 as 'Definitely Related' or 'Probably Related' or 'Possibly Related' or 'Related/Reasonable Possibility'. To be conservative, if the relationship is missing, TEAE is still considered as D-1553 related TEAE.

TEAE is defined as any AE that newly occurs or worsen after the first investigational drug administration and within end of safety follow up period (i.e., within 30 calendar days after the last administration of investigational drug or the start of new anti-cancer therapy (whichever occurs earlier)). If the timing of the AE cannot be established in relation to the first administration of investigational drug, it will be considered as TEAE to be more conservative.

Adverse events are coded with MedDRA 25.0.

Subjects with multiple occurrences of adverse events in the same preferred term are counted only once within that preferred term at the maximum severity.

Subjects with multiple occurrences of adverse events in the same system organ class are counted only once within that system organ class at the maximum severity.

Percentages are based on the number of subjects of each respective group in the Safety Analysis Set.

Source Data: Listing 16.2.7.1

|  |  |  |
| --- | --- | --- |
| Program: t-ae-soc-pt-sev.sas | DCO: 27APR2024 | Executed: 08JUL2024 17:16 |

|  |  |
| --- | --- |
| **InxMed (Shanghai) Co., Ltd.  Protocol No. IN10018-602** |  |

**Table 14.3.1.3.4.6 Summary of D-1553 Related TEAEs by Grouped SOC and Grouped PT and Severity - Phase II part 2 - CRC (Safety Analysis Set)**

|  | | Total n (%) | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Group | System Organ Class  Preferred Term | Grade 1 | Grade 2 | Grade 3 | Grade 4 | Grade 5 | Total |
| Treatment Group (N = 5) | All TEAEs | 1 (20.0) | 2 (40.0) | 2 (40.0) | 0 | 0 | 5 (100) |
|  | | | | | | | |
|  | Gastrointestinal disorders | 2 (40.0) | 1 (20.0) | 2 (40.0) | 0 | 0 | 5 (100) |
|  | Diarrhoea | 2 (40.0) | 1 (20.0) | 2 (40.0) | 0 | 0 | 5 (100) |
|  | Nausea | 3 (60.0) | 0 | 0 | 0 | 0 | 3 (60.0) |
|  | Abdominal distension | 2 (40.0) | 0 | 0 | 0 | 0 | 2 (40.0) |
|  | Intestinal obstruction | 0 | 0 | 1 (20.0) | 0 | 0 | 1 (20.0) |
|  | Vomiting | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | | | | | | | |
|  | Investigations | 2 (40.0) | 1 (20.0) | 1 (20.0) | 0 | 0 | 4 (80.0) |
|  | Alanine aminotransferase increased | 2 (40.0) | 0 | 0 | 0 | 0 | 2 (40.0) |
|  | Weight decreased | 2 (40.0) | 0 | 0 | 0 | 0 | 2 (40.0) |
|  | Aspartate aminotransferase increased | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | Blood alkaline phosphatase increased | 0 | 1 (20.0) | 0 | 0 | 0 | 1 (20.0) |
|  | C-reactive protein increased | 0 | 0 | 1 (20.0) | 0 | 0 | 1 (20.0) |
|  | Electrocardiogram PR prolongation | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | Electrocardiogram QT prolonged | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | Gamma-glutamyltransferase increased | 0 | 1 (20.0) | 0 | 0 | 0 | 1 (20.0) |
|  | Neutrophil count decreased | 0 | 1 (20.0) | 0 | 0 | 0 | 1 (20.0) |
|  | Platelet count decreased | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | White blood cell count decreased | 0 | 1 (20.0) | 0 | 0 | 0 | 1 (20.0) |
|  | | | | | | | |
|  | Metabolism and nutrition disorders# | 3 (60.0) | 1 (20.0) | 0 | 0 | 0 | 4 (80.0) |
|  | Hypercholesterolaemia\* | 2 (40.0) | 0 | 0 | 0 | 0 | 2 (40.0) |
|  | Decreased appetite | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | Hyperglycaemia | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | Hyperphosphataemia | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | Hypertriglyceridaemia | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | Hypokalaemia | 0 | 1 (20.0) | 0 | 0 | 0 | 1 (20.0) |
|  | | | | | | | |
|  | Renal and urinary disorders# | 2 (40.0) | 1 (20.0) | 1 (20.0) | 0 | 0 | 4 (80.0) |
|  | Proteinuria\* | 2 (40.0) | 1 (20.0) | 0 | 0 | 0 | 3 (60.0) |
|  | Haematuria\* | 2 (40.0) | 0 | 0 | 0 | 0 | 2 (40.0) |
|  | Acute kidney injury | 0 | 0 | 1 (20.0) | 0 | 0 | 1 (20.0) |
|  | | | | | | | |
|  | Musculoskeletal and connective tissue disorders | 3 (60.0) | 0 | 0 | 0 | 0 | 3 (60.0) |
|  | Myalgia | 2 (40.0) | 0 | 0 | 0 | 0 | 2 (40.0) |
|  | Pain in extremity | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | | | | | | | |
|  | Cardiac disorders | 2 (40.0) | 0 | 0 | 0 | 0 | 2 (40.0) |
|  | Atrioventricular block first degree | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | Sinus bradycardia | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | | | | | | | |
|  | Blood and lymphatic system disorders# | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | Anaemia | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | | | | | | | |
|  | Eye disorders | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | Periorbital pain | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | | | | | | | |
|  | General disorders and administration site conditions# | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | Fatigue\* | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | | | | | | | |
|  | Nervous system disorders | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | Hypoaesthesia | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | | | | | | | |
|  | Psychiatric disorders | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | Insomnia | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | | | | | | | |
|  | Skin and subcutaneous tissue disorders | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | Pruritus | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | Rash | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | | | | | | | |
| Control Group (N = 5) | All TEAEs | 3 (60.0) | 1 (20.0) | 1 (20.0) | 0 | 0 | 5 (100) |
|  | | | | | | | |
|  | Investigations | 2 (40.0) | 1 (20.0) | 1 (20.0) | 0 | 0 | 4 (80.0) |
|  | Alanine aminotransferase increased | 2 (40.0) | 0 | 0 | 0 | 0 | 2 (40.0) |
|  | Aspartate aminotransferase increased | 2 (40.0) | 0 | 0 | 0 | 0 | 2 (40.0) |
|  | Lymphocyte count decreased | 1 (20.0) | 0 | 1 (20.0) | 0 | 0 | 2 (40.0) |
|  | Blood bilirubin increased | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | Blood creatine phosphokinase increased | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | Blood lactate dehydrogenase increased | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | C-reactive protein increased | 0 | 0 | 1 (20.0) | 0 | 0 | 1 (20.0) |
|  | Electrocardiogram QRS complex prolonged | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | Electrocardiogram QT prolonged | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | Gamma-glutamyltransferase increased | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | Neutrophil count decreased | 0 | 1 (20.0) | 0 | 0 | 0 | 1 (20.0) |
|  | Neutrophil count increased | 0 | 0 | 1 (20.0) | 0 | 0 | 1 (20.0) |
|  | Platelet count decreased | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | Serum amyloid A protein increased | 0 | 0 | 1 (20.0) | 0 | 0 | 1 (20.0) |
|  | Total bile acids increased | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | White blood cell count decreased | 0 | 1 (20.0) | 0 | 0 | 0 | 1 (20.0) |
|  | | | | | | | |
|  | Gastrointestinal disorders | 3 (60.0) | 0 | 0 | 0 | 0 | 3 (60.0) |
|  | Nausea | 2 (40.0) | 0 | 0 | 0 | 0 | 2 (40.0) |
|  | Abdominal discomfort | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | Toothache | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | Vomiting | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | | | | | | | |
|  | Metabolism and nutrition disorders# | 2 (40.0) | 1 (20.0) | 0 | 0 | 0 | 3 (60.0) |
|  | Hypercholesterolaemia\* | 0 | 1 (20.0) | 0 | 0 | 0 | 1 (20.0) |
|  | Hyperglycaemia | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | Hypermagnesaemia | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | Hypertriglyceridaemia | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | Hypokalaemia | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | Hypozincaemia | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | | | | | | | |
|  | Cardiac disorders | 2 (40.0) | 0 | 0 | 0 | 0 | 2 (40.0) |
|  | Pericardial effusion | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | Supraventricular extrasystoles | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | Tachycardia | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | | | | | | | |
|  | General disorders and administration site conditions# | 2 (40.0) | 0 | 0 | 0 | 0 | 2 (40.0) |
|  | Fatigue\* | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | Influenza like illness | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | | | | | | | |
|  | Respiratory, thoracic and mediastinal disorders | 1 (20.0) | 1 (20.0) | 0 | 0 | 0 | 2 (40.0) |
|  | Cough | 0 | 1 (20.0) | 0 | 0 | 0 | 1 (20.0) |
|  | Hiccups | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | Productive cough | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | | | | | | | |
|  | Blood and lymphatic system disorders# | 0 | 0 | 1 (20.0) | 0 | 0 | 1 (20.0) |
|  | Anaemia | 0 | 0 | 1 (20.0) | 0 | 0 | 1 (20.0) |
|  | Leukocytosis\* | 0 | 0 | 1 (20.0) | 0 | 0 | 1 (20.0) |
|  | | | | | | | |
|  | Infections and infestations | 0 | 0 | 1 (20.0) | 0 | 0 | 1 (20.0) |
|  | Pneumonia | 0 | 0 | 1 (20.0) | 0 | 0 | 1 (20.0) |
|  | | | | | | | |
| Total (N = 10) | All TEAEs | 4 (40.0) | 3 (30.0) | 3 (30.0) | 0 | 0 | 10 (100) |
|  | | | | | | | |
|  | Gastrointestinal disorders | 5 (50.0) | 1 (10.0) | 2 (20.0) | 0 | 0 | 8 (80.0) |
|  | Diarrhoea | 2 (20.0) | 1 (10.0) | 2 (20.0) | 0 | 0 | 5 (50.0) |
|  | Nausea | 5 (50.0) | 0 | 0 | 0 | 0 | 5 (50.0) |
|  | Abdominal distension | 2 (20.0) | 0 | 0 | 0 | 0 | 2 (20.0) |
|  | Vomiting | 2 (20.0) | 0 | 0 | 0 | 0 | 2 (20.0) |
|  | Abdominal discomfort | 1 (10.0) | 0 | 0 | 0 | 0 | 1 (10.0) |
|  | Intestinal obstruction | 0 | 0 | 1 (10.0) | 0 | 0 | 1 (10.0) |
|  | Toothache | 1 (10.0) | 0 | 0 | 0 | 0 | 1 (10.0) |
|  | | | | | | | |
|  | Investigations | 4 (40.0) | 2 (20.0) | 2 (20.0) | 0 | 0 | 8 (80.0) |
|  | Alanine aminotransferase increased | 4 (40.0) | 0 | 0 | 0 | 0 | 4 (40.0) |
|  | Aspartate aminotransferase increased | 3 (30.0) | 0 | 0 | 0 | 0 | 3 (30.0) |
|  | C-reactive protein increased | 0 | 0 | 2 (20.0) | 0 | 0 | 2 (20.0) |
|  | Electrocardiogram QT prolonged | 2 (20.0) | 0 | 0 | 0 | 0 | 2 (20.0) |
|  | Gamma-glutamyltransferase increased | 1 (10.0) | 1 (10.0) | 0 | 0 | 0 | 2 (20.0) |
|  | Lymphocyte count decreased | 1 (10.0) | 0 | 1 (10.0) | 0 | 0 | 2 (20.0) |
|  | Neutrophil count decreased | 0 | 2 (20.0) | 0 | 0 | 0 | 2 (20.0) |
|  | Platelet count decreased | 2 (20.0) | 0 | 0 | 0 | 0 | 2 (20.0) |
|  | Weight decreased | 2 (20.0) | 0 | 0 | 0 | 0 | 2 (20.0) |
|  | White blood cell count decreased | 0 | 2 (20.0) | 0 | 0 | 0 | 2 (20.0) |
|  | Blood alkaline phosphatase increased | 0 | 1 (10.0) | 0 | 0 | 0 | 1 (10.0) |
|  | Blood bilirubin increased | 1 (10.0) | 0 | 0 | 0 | 0 | 1 (10.0) |
|  | Blood creatine phosphokinase increased | 1 (10.0) | 0 | 0 | 0 | 0 | 1 (10.0) |
|  | Blood lactate dehydrogenase increased | 1 (10.0) | 0 | 0 | 0 | 0 | 1 (10.0) |
|  | Electrocardiogram PR prolongation | 1 (10.0) | 0 | 0 | 0 | 0 | 1 (10.0) |
|  | Electrocardiogram QRS complex prolonged | 1 (10.0) | 0 | 0 | 0 | 0 | 1 (10.0) |
|  | Neutrophil count increased | 0 | 0 | 1 (10.0) | 0 | 0 | 1 (10.0) |
|  | Serum amyloid A protein increased | 0 | 0 | 1 (10.0) | 0 | 0 | 1 (10.0) |
|  | Total bile acids increased | 1 (10.0) | 0 | 0 | 0 | 0 | 1 (10.0) |
|  | | | | | | | |
|  | Metabolism and nutrition disorders# | 5 (50.0) | 2 (20.0) | 0 | 0 | 0 | 7 (70.0) |
|  | Hypercholesterolaemia\* | 2 (20.0) | 1 (10.0) | 0 | 0 | 0 | 3 (30.0) |
|  | Hyperglycaemia | 2 (20.0) | 0 | 0 | 0 | 0 | 2 (20.0) |
|  | Hypertriglyceridaemia | 2 (20.0) | 0 | 0 | 0 | 0 | 2 (20.0) |
|  | Hypokalaemia | 1 (10.0) | 1 (10.0) | 0 | 0 | 0 | 2 (20.0) |
|  | Decreased appetite | 1 (10.0) | 0 | 0 | 0 | 0 | 1 (10.0) |
|  | Hypermagnesaemia | 1 (10.0) | 0 | 0 | 0 | 0 | 1 (10.0) |
|  | Hyperphosphataemia | 1 (10.0) | 0 | 0 | 0 | 0 | 1 (10.0) |
|  | Hypozincaemia | 1 (10.0) | 0 | 0 | 0 | 0 | 1 (10.0) |
|  | | | | | | | |
|  | Cardiac disorders | 4 (40.0) | 0 | 0 | 0 | 0 | 4 (40.0) |
|  | Atrioventricular block first degree | 1 (10.0) | 0 | 0 | 0 | 0 | 1 (10.0) |
|  | Pericardial effusion | 1 (10.0) | 0 | 0 | 0 | 0 | 1 (10.0) |
|  | Sinus bradycardia | 1 (10.0) | 0 | 0 | 0 | 0 | 1 (10.0) |
|  | Supraventricular extrasystoles | 1 (10.0) | 0 | 0 | 0 | 0 | 1 (10.0) |
|  | Tachycardia | 1 (10.0) | 0 | 0 | 0 | 0 | 1 (10.0) |
|  | | | | | | | |
|  | Renal and urinary disorders# | 2 (20.0) | 1 (10.0) | 1 (10.0) | 0 | 0 | 4 (40.0) |
|  | Proteinuria\* | 2 (20.0) | 1 (10.0) | 0 | 0 | 0 | 3 (30.0) |
|  | Haematuria\* | 2 (20.0) | 0 | 0 | 0 | 0 | 2 (20.0) |
|  | Acute kidney injury | 0 | 0 | 1 (10.0) | 0 | 0 | 1 (10.0) |
|  | | | | | | | |
|  | General disorders and administration site conditions# | 3 (30.0) | 0 | 0 | 0 | 0 | 3 (30.0) |
|  | Fatigue\* | 2 (20.0) | 0 | 0 | 0 | 0 | 2 (20.0) |
|  | Influenza like illness | 1 (10.0) | 0 | 0 | 0 | 0 | 1 (10.0) |
|  | | | | | | | |
|  | Musculoskeletal and connective tissue disorders | 3 (30.0) | 0 | 0 | 0 | 0 | 3 (30.0) |
|  | Myalgia | 2 (20.0) | 0 | 0 | 0 | 0 | 2 (20.0) |
|  | Pain in extremity | 1 (10.0) | 0 | 0 | 0 | 0 | 1 (10.0) |
|  | | | | | | | |
|  | Blood and lymphatic system disorders# | 1 (10.0) | 0 | 1 (10.0) | 0 | 0 | 2 (20.0) |
|  | Anaemia | 1 (10.0) | 0 | 1 (10.0) | 0 | 0 | 2 (20.0) |
|  | Leukocytosis\* | 0 | 0 | 1 (10.0) | 0 | 0 | 1 (10.0) |
|  | | | | | | | |
|  | Respiratory, thoracic and mediastinal disorders | 1 (10.0) | 1 (10.0) | 0 | 0 | 0 | 2 (20.0) |
|  | Cough | 0 | 1 (10.0) | 0 | 0 | 0 | 1 (10.0) |
|  | Hiccups | 1 (10.0) | 0 | 0 | 0 | 0 | 1 (10.0) |
|  | Productive cough | 1 (10.0) | 0 | 0 | 0 | 0 | 1 (10.0) |
|  | | | | | | | |
|  | Eye disorders | 1 (10.0) | 0 | 0 | 0 | 0 | 1 (10.0) |
|  | Periorbital pain | 1 (10.0) | 0 | 0 | 0 | 0 | 1 (10.0) |
|  | | | | | | | |
|  | Infections and infestations | 0 | 0 | 1 (10.0) | 0 | 0 | 1 (10.0) |
|  | Pneumonia | 0 | 0 | 1 (10.0) | 0 | 0 | 1 (10.0) |
|  | | | | | | | |
|  | Nervous system disorders | 1 (10.0) | 0 | 0 | 0 | 0 | 1 (10.0) |
|  | Hypoaesthesia | 1 (10.0) | 0 | 0 | 0 | 0 | 1 (10.0) |
|  | | | | | | | |
|  | Psychiatric disorders | 1 (10.0) | 0 | 0 | 0 | 0 | 1 (10.0) |
|  | Insomnia | 1 (10.0) | 0 | 0 | 0 | 0 | 1 (10.0) |
|  | | | | | | | |
|  | Skin and subcutaneous tissue disorders | 1 (10.0) | 0 | 0 | 0 | 0 | 1 (10.0) |
|  | Pruritus | 1 (10.0) | 0 | 0 | 0 | 0 | 1 (10.0) |
|  | Rash | 1 (10.0) | 0 | 0 | 0 | 0 | 1 (10.0) |

Grade 1: Mild, Grade 2: Moderate, Grade 3: Severe, Grade 4: Life threatening, Grade 5: Death related to AE.

D-1553 related TEAE is defined as the relationship with D-1553 as 'Definitely Related' or 'Probably Related' or 'Possibly Related' or 'Related/Reasonable Possibility'. To be conservative, if the relationship is missing, TEAE is still considered as D-1553 related TEAE.

TEAE is defined as any AE that newly occurs or worsen after the first investigational drug administration and within end of safety follow up period (i.e., within 30 calendar days after the last administration of investigational drug or the start of new anti-cancer therapy (whichever occurs earlier)). If the timing of the AE cannot be established in relation to the first administration of investigational drug, it will be considered as TEAE to be more conservative.

Adverse events are coded with MedDRA 25.0.

Subjects with multiple occurrences of adverse events in the same grouped preferred term are counted only once within that grouped preferred term at the maximum severity.

Subjects with multiple occurrences of adverse events in the same grouped system organ class are counted only once within that grouped system organ class at the maximum severity.

Percentages are based on the number of subjects of each respective group in the Safety Analysis Set.

#: Grouped SOC. \*: Grouped PT.  
Source Data: Listing 16.2.7.1

|  |  |  |
| --- | --- | --- |
| Program: t-ae-soc-pt-sev.sas | DCO: 27APR2024 | Executed: 08JUL2024 17:16 |

|  |  |
| --- | --- |
| **InxMed (Shanghai) Co., Ltd.  Protocol No. IN10018-602** |  |

**Table 14.3.1.3.4.11 Summary of IN10018 Related TEAEs by SOC, PT and Severity - Phase II part 2 - CRC (Safety Analysis Set)**

|  | | Total n (%) | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Group | System Organ Class  Preferred Term | Grade 1 | Grade 2 | Grade 3 | Grade 4 | Grade 5 | Total |
| Treatment Group (N = 5) | All TEAEs | 1 (20.0) | 2 (40.0) | 2 (40.0) | 0 | 0 | 5 (100) |
|  | | | | | | | |
|  | Gastrointestinal disorders | 2 (40.0) | 1 (20.0) | 2 (40.0) | 0 | 0 | 5 (100) |
|  | Diarrhoea | 2 (40.0) | 1 (20.0) | 2 (40.0) | 0 | 0 | 5 (100) |
|  | Nausea | 3 (60.0) | 0 | 0 | 0 | 0 | 3 (60.0) |
|  | Abdominal distension | 2 (40.0) | 0 | 0 | 0 | 0 | 2 (40.0) |
|  | Intestinal obstruction | 0 | 0 | 1 (20.0) | 0 | 0 | 1 (20.0) |
|  | Vomiting | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | | | | | | | |
|  | Investigations | 2 (40.0) | 1 (20.0) | 1 (20.0) | 0 | 0 | 4 (80.0) |
|  | Alanine aminotransferase increased | 2 (40.0) | 0 | 0 | 0 | 0 | 2 (40.0) |
|  | Weight decreased | 2 (40.0) | 0 | 0 | 0 | 0 | 2 (40.0) |
|  | Aspartate aminotransferase increased | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | Blood alkaline phosphatase increased | 0 | 1 (20.0) | 0 | 0 | 0 | 1 (20.0) |
|  | Blood urine | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | C-reactive protein increased | 0 | 0 | 1 (20.0) | 0 | 0 | 1 (20.0) |
|  | Electrocardiogram PR prolongation | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | Electrocardiogram QT prolonged | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | Gamma-glutamyltransferase increased | 0 | 1 (20.0) | 0 | 0 | 0 | 1 (20.0) |
|  | Neutrophil count decreased | 0 | 1 (20.0) | 0 | 0 | 0 | 1 (20.0) |
|  | Platelet count decreased | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | White blood cell count decreased | 0 | 1 (20.0) | 0 | 0 | 0 | 1 (20.0) |
|  | | | | | | | |
|  | Metabolism and nutrition disorders | 3 (60.0) | 1 (20.0) | 0 | 0 | 0 | 4 (80.0) |
|  | Hypercholesterolaemia | 2 (40.0) | 0 | 0 | 0 | 0 | 2 (40.0) |
|  | Decreased appetite | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | Hyperglycaemia | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | Hyperphosphataemia | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | Hypertriglyceridaemia | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | Hypokalaemia | 0 | 1 (20.0) | 0 | 0 | 0 | 1 (20.0) |
|  | | | | | | | |
|  | Musculoskeletal and connective tissue disorders | 3 (60.0) | 1 (20.0) | 0 | 0 | 0 | 4 (80.0) |
|  | Myalgia | 2 (40.0) | 0 | 0 | 0 | 0 | 2 (40.0) |
|  | Arthritis | 0 | 1 (20.0) | 0 | 0 | 0 | 1 (20.0) |
|  | Pain in extremity | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | | | | | | | |
|  | Renal and urinary disorders | 2 (40.0) | 1 (20.0) | 1 (20.0) | 0 | 0 | 4 (80.0) |
|  | Proteinuria | 2 (40.0) | 1 (20.0) | 0 | 0 | 0 | 3 (60.0) |
|  | Haematuria | 2 (40.0) | 0 | 0 | 0 | 0 | 2 (40.0) |
|  | Acute kidney injury | 0 | 0 | 1 (20.0) | 0 | 0 | 1 (20.0) |
|  | | | | | | | |
|  | Cardiac disorders | 2 (40.0) | 0 | 0 | 0 | 0 | 2 (40.0) |
|  | Atrioventricular block first degree | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | Sinus bradycardia | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | | | | | | | |
|  | Blood and lymphatic system disorders | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | Anaemia | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | | | | | | | |
|  | Eye disorders | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | Periorbital pain | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | | | | | | | |
|  | General disorders and administration site conditions | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | Asthenia | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | | | | | | | |
|  | Nervous system disorders | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | Hypoaesthesia | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | | | | | | | |
|  | Psychiatric disorders | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | Insomnia | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | | | | | | | |
|  | Skin and subcutaneous tissue disorders | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | Pruritus | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | Rash | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | | | | | | | |
| Control Group (N = 5) | All TEAEs | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | | | | | | | |
|  | Investigations | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | Blood lactate dehydrogenase increased | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | | | | | | | |
|  | Metabolism and nutrition disorders | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | Hypermagnesaemia | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | | | | | | | |
| Total (N = 10) | All TEAEs | 2 (20.0) | 2 (20.0) | 2 (20.0) | 0 | 0 | 6 (60.0) |
|  | | | | | | | |
|  | Gastrointestinal disorders | 2 (20.0) | 1 (10.0) | 2 (20.0) | 0 | 0 | 5 (50.0) |
|  | Diarrhoea | 2 (20.0) | 1 (10.0) | 2 (20.0) | 0 | 0 | 5 (50.0) |
|  | Nausea | 3 (30.0) | 0 | 0 | 0 | 0 | 3 (30.0) |
|  | Abdominal distension | 2 (20.0) | 0 | 0 | 0 | 0 | 2 (20.0) |
|  | Intestinal obstruction | 0 | 0 | 1 (10.0) | 0 | 0 | 1 (10.0) |
|  | Vomiting | 1 (10.0) | 0 | 0 | 0 | 0 | 1 (10.0) |
|  | | | | | | | |
|  | Investigations | 3 (30.0) | 1 (10.0) | 1 (10.0) | 0 | 0 | 5 (50.0) |
|  | Alanine aminotransferase increased | 2 (20.0) | 0 | 0 | 0 | 0 | 2 (20.0) |
|  | Weight decreased | 2 (20.0) | 0 | 0 | 0 | 0 | 2 (20.0) |
|  | Aspartate aminotransferase increased | 1 (10.0) | 0 | 0 | 0 | 0 | 1 (10.0) |
|  | Blood alkaline phosphatase increased | 0 | 1 (10.0) | 0 | 0 | 0 | 1 (10.0) |
|  | Blood lactate dehydrogenase increased | 1 (10.0) | 0 | 0 | 0 | 0 | 1 (10.0) |
|  | Blood urine | 1 (10.0) | 0 | 0 | 0 | 0 | 1 (10.0) |
|  | C-reactive protein increased | 0 | 0 | 1 (10.0) | 0 | 0 | 1 (10.0) |
|  | Electrocardiogram PR prolongation | 1 (10.0) | 0 | 0 | 0 | 0 | 1 (10.0) |
|  | Electrocardiogram QT prolonged | 1 (10.0) | 0 | 0 | 0 | 0 | 1 (10.0) |
|  | Gamma-glutamyltransferase increased | 0 | 1 (10.0) | 0 | 0 | 0 | 1 (10.0) |
|  | Neutrophil count decreased | 0 | 1 (10.0) | 0 | 0 | 0 | 1 (10.0) |
|  | Platelet count decreased | 1 (10.0) | 0 | 0 | 0 | 0 | 1 (10.0) |
|  | White blood cell count decreased | 0 | 1 (10.0) | 0 | 0 | 0 | 1 (10.0) |
|  | | | | | | | |
|  | Metabolism and nutrition disorders | 4 (40.0) | 1 (10.0) | 0 | 0 | 0 | 5 (50.0) |
|  | Hypercholesterolaemia | 2 (20.0) | 0 | 0 | 0 | 0 | 2 (20.0) |
|  | Decreased appetite | 1 (10.0) | 0 | 0 | 0 | 0 | 1 (10.0) |
|  | Hyperglycaemia | 1 (10.0) | 0 | 0 | 0 | 0 | 1 (10.0) |
|  | Hypermagnesaemia | 1 (10.0) | 0 | 0 | 0 | 0 | 1 (10.0) |
|  | Hyperphosphataemia | 1 (10.0) | 0 | 0 | 0 | 0 | 1 (10.0) |
|  | Hypertriglyceridaemia | 1 (10.0) | 0 | 0 | 0 | 0 | 1 (10.0) |
|  | Hypokalaemia | 0 | 1 (10.0) | 0 | 0 | 0 | 1 (10.0) |
|  | | | | | | | |
|  | Musculoskeletal and connective tissue disorders | 3 (30.0) | 1 (10.0) | 0 | 0 | 0 | 4 (40.0) |
|  | Myalgia | 2 (20.0) | 0 | 0 | 0 | 0 | 2 (20.0) |
|  | Arthritis | 0 | 1 (10.0) | 0 | 0 | 0 | 1 (10.0) |
|  | Pain in extremity | 1 (10.0) | 0 | 0 | 0 | 0 | 1 (10.0) |
|  | | | | | | | |
|  | Renal and urinary disorders | 2 (20.0) | 1 (10.0) | 1 (10.0) | 0 | 0 | 4 (40.0) |
|  | Proteinuria | 2 (20.0) | 1 (10.0) | 0 | 0 | 0 | 3 (30.0) |
|  | Haematuria | 2 (20.0) | 0 | 0 | 0 | 0 | 2 (20.0) |
|  | Acute kidney injury | 0 | 0 | 1 (10.0) | 0 | 0 | 1 (10.0) |
|  | | | | | | | |
|  | Cardiac disorders | 2 (20.0) | 0 | 0 | 0 | 0 | 2 (20.0) |
|  | Atrioventricular block first degree | 1 (10.0) | 0 | 0 | 0 | 0 | 1 (10.0) |
|  | Sinus bradycardia | 1 (10.0) | 0 | 0 | 0 | 0 | 1 (10.0) |
|  | | | | | | | |
|  | Blood and lymphatic system disorders | 1 (10.0) | 0 | 0 | 0 | 0 | 1 (10.0) |
|  | Anaemia | 1 (10.0) | 0 | 0 | 0 | 0 | 1 (10.0) |
|  | | | | | | | |
|  | Eye disorders | 1 (10.0) | 0 | 0 | 0 | 0 | 1 (10.0) |
|  | Periorbital pain | 1 (10.0) | 0 | 0 | 0 | 0 | 1 (10.0) |
|  | | | | | | | |
|  | General disorders and administration site conditions | 1 (10.0) | 0 | 0 | 0 | 0 | 1 (10.0) |
|  | Asthenia | 1 (10.0) | 0 | 0 | 0 | 0 | 1 (10.0) |
|  | | | | | | | |
|  | Nervous system disorders | 1 (10.0) | 0 | 0 | 0 | 0 | 1 (10.0) |
|  | Hypoaesthesia | 1 (10.0) | 0 | 0 | 0 | 0 | 1 (10.0) |
|  | | | | | | | |
|  | Psychiatric disorders | 1 (10.0) | 0 | 0 | 0 | 0 | 1 (10.0) |
|  | Insomnia | 1 (10.0) | 0 | 0 | 0 | 0 | 1 (10.0) |
|  | | | | | | | |
|  | Skin and subcutaneous tissue disorders | 1 (10.0) | 0 | 0 | 0 | 0 | 1 (10.0) |
|  | Pruritus | 1 (10.0) | 0 | 0 | 0 | 0 | 1 (10.0) |
|  | Rash | 1 (10.0) | 0 | 0 | 0 | 0 | 1 (10.0) |

Grade 1: Mild, Grade 2: Moderate, Grade 3: Severe, Grade 4: Life threatening, Grade 5: Death related to AE.

IN10018 related TEAE is defined as the relationship with IN10018 as 'Definitely Related' or 'Probably Related' or 'Possibly Related' or 'Related/Reasonable Possibility'. To be conservative, if the relationship is missing, TEAE is still considered as IN10018 related TEAE.

TEAE is defined as any AE that newly occurs or worsen after the first investigational drug administration and within end of safety follow up period (i.e., within 30 calendar days after the last administration of investigational drug or the start of new anti-cancer therapy (whichever occurs earlier)). If the timing of the AE cannot be established in relation to the first administration of investigational drug, it will be considered as TEAE to be more conservative.

Adverse events are coded with MedDRA 25.0.

Subjects with multiple occurrences of adverse events in the same preferred term are counted only once within that preferred term at the maximum severity.

Subjects with multiple occurrences of adverse events in the same system organ class are counted only once within that system organ class at the maximum severity.

Percentages are based on the number of subjects of each respective group in the Safety Analysis Set.

Source Data: Listing 16.2.7.1

|  |  |  |
| --- | --- | --- |
| Program: t-ae-soc-pt-sev.sas | DCO: 27APR2024 | Executed: 08JUL2024 17:16 |

|  |  |
| --- | --- |
| **InxMed (Shanghai) Co., Ltd.  Protocol No. IN10018-602** |  |

**Table 14.3.1.3.4.12 Summary of IN10018 Related TEAEs by Grouped SOC and Grouped PT and Severity - Phase II part 2 - CRC (Safety Analysis Set)**

|  | | Total n (%) | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Group | System Organ Class  Preferred Term | Grade 1 | Grade 2 | Grade 3 | Grade 4 | Grade 5 | Total |
| Treatment Group (N = 5) | All TEAEs | 1 (20.0) | 2 (40.0) | 2 (40.0) | 0 | 0 | 5 (100) |
|  | | | | | | | |
|  | Gastrointestinal disorders | 2 (40.0) | 1 (20.0) | 2 (40.0) | 0 | 0 | 5 (100) |
|  | Diarrhoea | 2 (40.0) | 1 (20.0) | 2 (40.0) | 0 | 0 | 5 (100) |
|  | Nausea | 3 (60.0) | 0 | 0 | 0 | 0 | 3 (60.0) |
|  | Abdominal distension | 2 (40.0) | 0 | 0 | 0 | 0 | 2 (40.0) |
|  | Intestinal obstruction | 0 | 0 | 1 (20.0) | 0 | 0 | 1 (20.0) |
|  | Vomiting | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | | | | | | | |
|  | Investigations | 2 (40.0) | 1 (20.0) | 1 (20.0) | 0 | 0 | 4 (80.0) |
|  | Alanine aminotransferase increased | 2 (40.0) | 0 | 0 | 0 | 0 | 2 (40.0) |
|  | Weight decreased | 2 (40.0) | 0 | 0 | 0 | 0 | 2 (40.0) |
|  | Aspartate aminotransferase increased | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | Blood alkaline phosphatase increased | 0 | 1 (20.0) | 0 | 0 | 0 | 1 (20.0) |
|  | C-reactive protein increased | 0 | 0 | 1 (20.0) | 0 | 0 | 1 (20.0) |
|  | Electrocardiogram PR prolongation | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | Electrocardiogram QT prolonged | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | Gamma-glutamyltransferase increased | 0 | 1 (20.0) | 0 | 0 | 0 | 1 (20.0) |
|  | Neutrophil count decreased | 0 | 1 (20.0) | 0 | 0 | 0 | 1 (20.0) |
|  | Platelet count decreased | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | White blood cell count decreased | 0 | 1 (20.0) | 0 | 0 | 0 | 1 (20.0) |
|  | | | | | | | |
|  | Metabolism and nutrition disorders# | 3 (60.0) | 1 (20.0) | 0 | 0 | 0 | 4 (80.0) |
|  | Hypercholesterolaemia\* | 2 (40.0) | 0 | 0 | 0 | 0 | 2 (40.0) |
|  | Decreased appetite | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | Hyperglycaemia | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | Hyperphosphataemia | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | Hypertriglyceridaemia | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | Hypokalaemia | 0 | 1 (20.0) | 0 | 0 | 0 | 1 (20.0) |
|  | | | | | | | |
|  | Musculoskeletal and connective tissue disorders | 3 (60.0) | 1 (20.0) | 0 | 0 | 0 | 4 (80.0) |
|  | Myalgia | 2 (40.0) | 0 | 0 | 0 | 0 | 2 (40.0) |
|  | Arthritis | 0 | 1 (20.0) | 0 | 0 | 0 | 1 (20.0) |
|  | Pain in extremity | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | | | | | | | |
|  | Renal and urinary disorders# | 2 (40.0) | 1 (20.0) | 1 (20.0) | 0 | 0 | 4 (80.0) |
|  | Proteinuria\* | 2 (40.0) | 1 (20.0) | 0 | 0 | 0 | 3 (60.0) |
|  | Haematuria\* | 2 (40.0) | 0 | 0 | 0 | 0 | 2 (40.0) |
|  | Acute kidney injury | 0 | 0 | 1 (20.0) | 0 | 0 | 1 (20.0) |
|  | | | | | | | |
|  | Cardiac disorders | 2 (40.0) | 0 | 0 | 0 | 0 | 2 (40.0) |
|  | Atrioventricular block first degree | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | Sinus bradycardia | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | | | | | | | |
|  | Blood and lymphatic system disorders# | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | Anaemia | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | | | | | | | |
|  | Eye disorders | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | Periorbital pain | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | | | | | | | |
|  | General disorders and administration site conditions# | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | Fatigue\* | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | | | | | | | |
|  | Nervous system disorders | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | Hypoaesthesia | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | | | | | | | |
|  | Psychiatric disorders | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | Insomnia | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | | | | | | | |
|  | Skin and subcutaneous tissue disorders | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | Pruritus | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | Rash | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | | | | | | | |
| Control Group (N = 5) | All TEAEs | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | | | | | | | |
|  | Investigations | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | Blood lactate dehydrogenase increased | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | | | | | | | |
|  | Metabolism and nutrition disorders# | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | Hypermagnesaemia | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | | | | | | | |
| Total (N = 10) | All TEAEs | 2 (20.0) | 2 (20.0) | 2 (20.0) | 0 | 0 | 6 (60.0) |
|  | | | | | | | |
|  | Gastrointestinal disorders | 2 (20.0) | 1 (10.0) | 2 (20.0) | 0 | 0 | 5 (50.0) |
|  | Diarrhoea | 2 (20.0) | 1 (10.0) | 2 (20.0) | 0 | 0 | 5 (50.0) |
|  | Nausea | 3 (30.0) | 0 | 0 | 0 | 0 | 3 (30.0) |
|  | Abdominal distension | 2 (20.0) | 0 | 0 | 0 | 0 | 2 (20.0) |
|  | Intestinal obstruction | 0 | 0 | 1 (10.0) | 0 | 0 | 1 (10.0) |
|  | Vomiting | 1 (10.0) | 0 | 0 | 0 | 0 | 1 (10.0) |
|  | | | | | | | |
|  | Investigations | 3 (30.0) | 1 (10.0) | 1 (10.0) | 0 | 0 | 5 (50.0) |
|  | Alanine aminotransferase increased | 2 (20.0) | 0 | 0 | 0 | 0 | 2 (20.0) |
|  | Weight decreased | 2 (20.0) | 0 | 0 | 0 | 0 | 2 (20.0) |
|  | Aspartate aminotransferase increased | 1 (10.0) | 0 | 0 | 0 | 0 | 1 (10.0) |
|  | Blood alkaline phosphatase increased | 0 | 1 (10.0) | 0 | 0 | 0 | 1 (10.0) |
|  | Blood lactate dehydrogenase increased | 1 (10.0) | 0 | 0 | 0 | 0 | 1 (10.0) |
|  | C-reactive protein increased | 0 | 0 | 1 (10.0) | 0 | 0 | 1 (10.0) |
|  | Electrocardiogram PR prolongation | 1 (10.0) | 0 | 0 | 0 | 0 | 1 (10.0) |
|  | Electrocardiogram QT prolonged | 1 (10.0) | 0 | 0 | 0 | 0 | 1 (10.0) |
|  | Gamma-glutamyltransferase increased | 0 | 1 (10.0) | 0 | 0 | 0 | 1 (10.0) |
|  | Neutrophil count decreased | 0 | 1 (10.0) | 0 | 0 | 0 | 1 (10.0) |
|  | Platelet count decreased | 1 (10.0) | 0 | 0 | 0 | 0 | 1 (10.0) |
|  | White blood cell count decreased | 0 | 1 (10.0) | 0 | 0 | 0 | 1 (10.0) |
|  | | | | | | | |
|  | Metabolism and nutrition disorders# | 4 (40.0) | 1 (10.0) | 0 | 0 | 0 | 5 (50.0) |
|  | Hypercholesterolaemia\* | 2 (20.0) | 0 | 0 | 0 | 0 | 2 (20.0) |
|  | Decreased appetite | 1 (10.0) | 0 | 0 | 0 | 0 | 1 (10.0) |
|  | Hyperglycaemia | 1 (10.0) | 0 | 0 | 0 | 0 | 1 (10.0) |
|  | Hypermagnesaemia | 1 (10.0) | 0 | 0 | 0 | 0 | 1 (10.0) |
|  | Hyperphosphataemia | 1 (10.0) | 0 | 0 | 0 | 0 | 1 (10.0) |
|  | Hypertriglyceridaemia | 1 (10.0) | 0 | 0 | 0 | 0 | 1 (10.0) |
|  | Hypokalaemia | 0 | 1 (10.0) | 0 | 0 | 0 | 1 (10.0) |
|  | | | | | | | |
|  | Musculoskeletal and connective tissue disorders | 3 (30.0) | 1 (10.0) | 0 | 0 | 0 | 4 (40.0) |
|  | Myalgia | 2 (20.0) | 0 | 0 | 0 | 0 | 2 (20.0) |
|  | Arthritis | 0 | 1 (10.0) | 0 | 0 | 0 | 1 (10.0) |
|  | Pain in extremity | 1 (10.0) | 0 | 0 | 0 | 0 | 1 (10.0) |
|  | | | | | | | |
|  | Renal and urinary disorders# | 2 (20.0) | 1 (10.0) | 1 (10.0) | 0 | 0 | 4 (40.0) |
|  | Proteinuria\* | 2 (20.0) | 1 (10.0) | 0 | 0 | 0 | 3 (30.0) |
|  | Haematuria\* | 2 (20.0) | 0 | 0 | 0 | 0 | 2 (20.0) |
|  | Acute kidney injury | 0 | 0 | 1 (10.0) | 0 | 0 | 1 (10.0) |
|  | | | | | | | |
|  | Cardiac disorders | 2 (20.0) | 0 | 0 | 0 | 0 | 2 (20.0) |
|  | Atrioventricular block first degree | 1 (10.0) | 0 | 0 | 0 | 0 | 1 (10.0) |
|  | Sinus bradycardia | 1 (10.0) | 0 | 0 | 0 | 0 | 1 (10.0) |
|  | | | | | | | |
|  | Blood and lymphatic system disorders# | 1 (10.0) | 0 | 0 | 0 | 0 | 1 (10.0) |
|  | Anaemia | 1 (10.0) | 0 | 0 | 0 | 0 | 1 (10.0) |
|  | | | | | | | |
|  | Eye disorders | 1 (10.0) | 0 | 0 | 0 | 0 | 1 (10.0) |
|  | Periorbital pain | 1 (10.0) | 0 | 0 | 0 | 0 | 1 (10.0) |
|  | | | | | | | |
|  | General disorders and administration site conditions# | 1 (10.0) | 0 | 0 | 0 | 0 | 1 (10.0) |
|  | Fatigue\* | 1 (10.0) | 0 | 0 | 0 | 0 | 1 (10.0) |
|  | | | | | | | |
|  | Nervous system disorders | 1 (10.0) | 0 | 0 | 0 | 0 | 1 (10.0) |
|  | Hypoaesthesia | 1 (10.0) | 0 | 0 | 0 | 0 | 1 (10.0) |
|  | | | | | | | |
|  | Psychiatric disorders | 1 (10.0) | 0 | 0 | 0 | 0 | 1 (10.0) |
|  | Insomnia | 1 (10.0) | 0 | 0 | 0 | 0 | 1 (10.0) |
|  | | | | | | | |
|  | Skin and subcutaneous tissue disorders | 1 (10.0) | 0 | 0 | 0 | 0 | 1 (10.0) |
|  | Pruritus | 1 (10.0) | 0 | 0 | 0 | 0 | 1 (10.0) |
|  | Rash | 1 (10.0) | 0 | 0 | 0 | 0 | 1 (10.0) |

Grade 1: Mild, Grade 2: Moderate, Grade 3: Severe, Grade 4: Life threatening, Grade 5: Death related to AE.

IN10018 related TEAE is defined as the relationship with IN10018 as 'Definitely Related' or 'Probably Related' or 'Possibly Related' or 'Related/Reasonable Possibility'. To be conservative, if the relationship is missing, TEAE is still considered as IN10018 related TEAE.

TEAE is defined as any AE that newly occurs or worsen after the first investigational drug administration and within end of safety follow up period (i.e., within 30 calendar days after the last administration of investigational drug or the start of new anti-cancer therapy (whichever occurs earlier)). If the timing of the AE cannot be established in relation to the first administration of investigational drug, it will be considered as TEAE to be more conservative.

Adverse events are coded with MedDRA 25.0.

Subjects with multiple occurrences of adverse events in the same grouped preferred term are counted only once within that grouped preferred term at the maximum severity.

Subjects with multiple occurrences of adverse events in the same grouped system organ class are counted only once within that grouped system organ class at the maximum severity.

Percentages are based on the number of subjects of each respective group in the Safety Analysis Set.

#: Grouped SOC. \*: Grouped PT.  
Source Data: Listing 16.2.7.1

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| Program: t-ae-soc-pt-sev.sas | DCO: 27APR2024 | Executed: 08JUL2024 17:16 |

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| **InxMed (Shanghai) Co., Ltd.  Protocol No. IN10018-602** |  |

**Table 14.3.1.4.1.5 Summary of CTCAE Grade 3/4 TEAEs by SOC and PT - Phase II part 2 - CRC (Safety Analysis Set)**

| System Organ Class  Preferred Term | Treatment Group (N = 5) n (%) | Control Group (N = 5) n (%) | Total (N = 10) n (%) |
| --- | --- | --- | --- |
| CTCAE Grade 3/4 TEAEs | 2 (40.0) | 1 (20.0) | 3 (30.0) |
|  | | | |
| Gastrointestinal disorders | 2 (40.0) | 0 | 2 (20.0) |
| Diarrhoea | 2 (40.0) | 0 | 2 (20.0) |
| Intestinal obstruction | 1 (20.0) | 0 | 1 (10.0) |
|  | | | |
| Investigations | 1 (20.0) | 1 (20.0) | 2 (20.0) |
| C-reactive protein increased | 1 (20.0) | 1 (20.0) | 2 (20.0) |
| Lymphocyte count decreased | 0 | 1 (20.0) | 1 (10.0) |
| Neutrophil count increased | 0 | 1 (20.0) | 1 (10.0) |
| Serum amyloid A protein increased | 0 | 1 (20.0) | 1 (10.0) |
|  | | | |
| Blood and lymphatic system disorders | 0 | 1 (20.0) | 1 (10.0) |
| Anaemia | 0 | 1 (20.0) | 1 (10.0) |
| Leukocytosis | 0 | 1 (20.0) | 1 (10.0) |
|  | | | |
| Infections and infestations | 0 | 1 (20.0) | 1 (10.0) |
| Pneumonia | 0 | 1 (20.0) | 1 (10.0) |
|  | | | |
| Renal and urinary disorders | 1 (20.0) | 0 | 1 (10.0) |
| Acute kidney injury | 1 (20.0) | 0 | 1 (10.0) |

TEAE is defined as any AE that newly occurs or worsen after the first investigational drug administration and within end of safety follow up period (i.e., within 30 calendar days after the last administration of investigational drug or the start of new anti-cancer therapy (whichever occurs earlier)). If the timing of the AE cannot be established in relation to the first administration of investigational drug, it will be considered as TEAE to be more conservative.

Adverse events are coded with MedDRA 25.0.

Subjects with multiple occurrences of adverse events in the same preferred term are counted only once within that preferred term.

Subjects with multiple occurrences of adverse events in the same system organ class are counted only once within that system organ class.

Subjects with multiple occurrences of adverse events in the same category are counted only once in that category at the maximum severity.

Percentages are based on the number of subjects of each respective group in Safety Analysis Set.

Source Data: Listing 16.2.7.1

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| Program: t-ae-soc-pt.sas | DCO: 27APR2024 | Executed: 08JUL2024 17:16 |

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| **InxMed (Shanghai) Co., Ltd.  Protocol No. IN10018-602** |  |

**Table 14.3.1.4.1.6 Summary of CTCAE Grade 3/4 TEAEs by Grouped SOC and Grouped PT - Phase II part 2 - CRC (Safety Analysis Set)**

| System Organ Class  Preferred Term | Treatment Group (N = 5) n (%) | Control Group (N = 5) n (%) | Total (N = 10) n (%) |
| --- | --- | --- | --- |
| CTCAE Grade 3/4 TEAEs | 2 (40.0) | 1 (20.0) | 3 (30.0) |
|  | | | |
| Gastrointestinal disorders | 2 (40.0) | 0 | 2 (20.0) |
| Diarrhoea | 2 (40.0) | 0 | 2 (20.0) |
| Intestinal obstruction | 1 (20.0) | 0 | 1 (10.0) |
|  | | | |
| Investigations | 1 (20.0) | 1 (20.0) | 2 (20.0) |
| C-reactive protein increased | 1 (20.0) | 1 (20.0) | 2 (20.0) |
| Lymphocyte count decreased | 0 | 1 (20.0) | 1 (10.0) |
| Neutrophil count increased | 0 | 1 (20.0) | 1 (10.0) |
| Serum amyloid A protein increased | 0 | 1 (20.0) | 1 (10.0) |
|  | | | |
| Blood and lymphatic system disorders# | 0 | 1 (20.0) | 1 (10.0) |
| Anaemia | 0 | 1 (20.0) | 1 (10.0) |
| Leukocytosis\* | 0 | 1 (20.0) | 1 (10.0) |
|  | | | |
| Infections and infestations | 0 | 1 (20.0) | 1 (10.0) |
| Pneumonia | 0 | 1 (20.0) | 1 (10.0) |
|  | | | |
| Renal and urinary disorders# | 1 (20.0) | 0 | 1 (10.0) |
| Acute kidney injury | 1 (20.0) | 0 | 1 (10.0) |

TEAE is defined as any AE that newly occurs or worsen after the first investigational drug administration and within end of safety follow up period (i.e., within 30 calendar days after the last administration of investigational drug or the start of new anti-cancer therapy (whichever occurs earlier)). If the timing of the AE cannot be established in relation to the first administration of investigational drug, it will be considered as TEAE to be more conservative.

Adverse events are coded with MedDRA 25.0.

Subjects with multiple occurrences of adverse events in the same grouped preferred term are counted only once within that grouped preferred term.

Subjects with multiple occurrences of adverse events in the same grouped system organ class are counted only once within that grouped system organ class.

Subjects with multiple occurrences of adverse events in the same category are counted only once in that category at the maximum severity.

Percentages are based on the number of subjects of each respective group in Safety Analysis Set.

#: Grouped SOC. \*: Grouped PT.  
Source Data: Listing 16.2.7.1

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| Program: t-ae-soc-pt.sas | DCO: 27APR2024 | Executed: 08JUL2024 17:16 |

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| **InxMed (Shanghai) Co., Ltd.  Protocol No. IN10018-602** |  |

**Table 14.3.1.4.2.5 Summary of D-1553 Related CTCAE Grade 3/4 TEAEs by SOC and PT - Phase II part 2 - CRC (Safety Analysis Set)**

| System Organ Class  Preferred Term | Treatment Group (N = 5) n (%) | Control Group (N = 5) n (%) | Total (N = 10) n (%) |
| --- | --- | --- | --- |
| D-1553 Related CTCAE Grade 3/4 TEAEs | 2 (40.0) | 1 (20.0) | 3 (30.0) |
|  | | | |
| Gastrointestinal disorders | 2 (40.0) | 0 | 2 (20.0) |
| Diarrhoea | 2 (40.0) | 0 | 2 (20.0) |
| Intestinal obstruction | 1 (20.0) | 0 | 1 (10.0) |
|  | | | |
| Investigations | 1 (20.0) | 1 (20.0) | 2 (20.0) |
| C-reactive protein increased | 1 (20.0) | 1 (20.0) | 2 (20.0) |
| Lymphocyte count decreased | 0 | 1 (20.0) | 1 (10.0) |
| Neutrophil count increased | 0 | 1 (20.0) | 1 (10.0) |
| Serum amyloid A protein increased | 0 | 1 (20.0) | 1 (10.0) |
|  | | | |
| Blood and lymphatic system disorders | 0 | 1 (20.0) | 1 (10.0) |
| Anaemia | 0 | 1 (20.0) | 1 (10.0) |
| Leukocytosis | 0 | 1 (20.0) | 1 (10.0) |
|  | | | |
| Infections and infestations | 0 | 1 (20.0) | 1 (10.0) |
| Pneumonia | 0 | 1 (20.0) | 1 (10.0) |
|  | | | |
| Renal and urinary disorders | 1 (20.0) | 0 | 1 (10.0) |
| Acute kidney injury | 1 (20.0) | 0 | 1 (10.0) |

TEAE is defined as any AE that newly occurs or worsen after the first investigational drug administration and within end of safety follow up period (i.e., within 30 calendar days after the last administration of investigational drug or the start of new anti-cancer therapy (whichever occurs earlier)). If the timing of the AE cannot be established in relation to the first administration of investigational drug, it will be considered as TEAE to be more conservative.

D-1553 related TEAE is defined as the relationship with D-1553 as 'Definitely Related' or 'Probably Related' or 'Possibly Related' or 'Related/Reasonable Possibility'. To be conservative, if the relationship is missing, TEAE is still considered as D-1553 related TEAE.

Adverse events are coded with MedDRA 25.0.

Subjects with multiple occurrences of adverse events in the same preferred term are counted only once within that preferred term.

Subjects with multiple occurrences of adverse events in the same system organ class are counted only once within that system organ class.

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| **InxMed (Shanghai) Co., Ltd.  Protocol No. IN10018-602** |  |

**Table 14.3.1.4.2.6 Summary of D-1553 Related CTCAE Grade 3/4 TEAEs by Grouped SOC and Grouped PT - Phase II part 2 - CRC (Safety Analysis Set)**

| System Organ Class  Preferred Term | Treatment Group (N = 5) n (%) | Control Group (N = 5) n (%) | Total (N = 10) n (%) |
| --- | --- | --- | --- |
| D-1553 Related CTCAE Grade 3/4 TEAEs | 2 (40.0) | 1 (20.0) | 3 (30.0) |
|  | | | |
| Gastrointestinal disorders | 2 (40.0) | 0 | 2 (20.0) |
| Diarrhoea | 2 (40.0) | 0 | 2 (20.0) |
| Intestinal obstruction | 1 (20.0) | 0 | 1 (10.0) |
|  | | | |
| Investigations | 1 (20.0) | 1 (20.0) | 2 (20.0) |
| C-reactive protein increased | 1 (20.0) | 1 (20.0) | 2 (20.0) |
| Lymphocyte count decreased | 0 | 1 (20.0) | 1 (10.0) |
| Neutrophil count increased | 0 | 1 (20.0) | 1 (10.0) |
| Serum amyloid A protein increased | 0 | 1 (20.0) | 1 (10.0) |
|  | | | |
| Blood and lymphatic system disorders# | 0 | 1 (20.0) | 1 (10.0) |
| Anaemia | 0 | 1 (20.0) | 1 (10.0) |
| Leukocytosis\* | 0 | 1 (20.0) | 1 (10.0) |
|  | | | |
| Infections and infestations | 0 | 1 (20.0) | 1 (10.0) |
| Pneumonia | 0 | 1 (20.0) | 1 (10.0) |
|  | | | |
| Renal and urinary disorders# | 1 (20.0) | 0 | 1 (10.0) |
| Acute kidney injury | 1 (20.0) | 0 | 1 (10.0) |

TEAE is defined as any AE that newly occurs or worsen after the first investigational drug administration and within end of safety follow up period (i.e., within 30 calendar days after the last administration of investigational drug or the start of new anti-cancer therapy (whichever occurs earlier)). If the timing of the AE cannot be established in relation to the first administration of investigational drug, it will be considered as TEAE to be more conservative.

D-1553 related TEAE is defined as the relationship with D-1553 as 'Definitely Related' or 'Probably Related' or 'Possibly Related' or 'Related/Reasonable Possibility'. To be conservative, if the relationship is missing, TEAE is still considered as D-1553 related TEAE.

Adverse events are coded with MedDRA 25.0.

Subjects with multiple occurrences of adverse events in the same grouped preferred term are counted only once within that grouped preferred term.

Subjects with multiple occurrences of adverse events in the same grouped system organ class are counted only once within that grouped system organ class.

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| **InxMed (Shanghai) Co., Ltd.  Protocol No. IN10018-602** |  |

**Table 14.3.1.4.2.11 Summary of IN10018 Related CTCAE Grade 3/4 TEAEs by SOC and PT - Phase II part 2 - CRC (Safety Analysis Set)**

| System Organ Class  Preferred Term | Treatment Group (N = 5) n (%) | Control Group (N = 5) n (%) | Total (N = 10) n (%) |
| --- | --- | --- | --- |
| IN10018 Related CTCAE Grade 3/4 TEAEs | 2 (40.0) | 0 | 2 (20.0) |
|  | | | |
| Gastrointestinal disorders | 2 (40.0) | 0 | 2 (20.0) |
| Diarrhoea | 2 (40.0) | 0 | 2 (20.0) |
| Intestinal obstruction | 1 (20.0) | 0 | 1 (10.0) |
|  | | | |
| Investigations | 1 (20.0) | 0 | 1 (10.0) |
| C-reactive protein increased | 1 (20.0) | 0 | 1 (10.0) |
|  | | | |
| Renal and urinary disorders | 1 (20.0) | 0 | 1 (10.0) |
| Acute kidney injury | 1 (20.0) | 0 | 1 (10.0) |

TEAE is defined as any AE that newly occurs or worsen after the first investigational drug administration and within end of safety follow up period (i.e., within 30 calendar days after the last administration of investigational drug or the start of new anti-cancer therapy (whichever occurs earlier)). If the timing of the AE cannot be established in relation to the first administration of investigational drug, it will be considered as TEAE to be more conservative.

IN10018 related TEAE is defined as the relationship with IN10018 as 'Definitely Related' or 'Probably Related' or 'Possibly Related' or 'Related/Reasonable Possibility'. To be conservative, if the relationship is missing, TEAE is still considered as IN10018 related TEAE.

Adverse events are coded with MedDRA 25.0.

Subjects with multiple occurrences of adverse events in the same preferred term are counted only once within that preferred term.

Subjects with multiple occurrences of adverse events in the same system organ class are counted only once within that system organ class.

Subjects with multiple occurrences of adverse events in the same category are counted only once in that category at the maximum severity.

Percentages are based on the number of subjects of each respective group in Safety Analysis Set.

Source Data: Listing 16.2.7.1

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| Program: t-ae-soc-pt.sas | DCO: 27APR2024 | Executed: 08JUL2024 17:16 |

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| **InxMed (Shanghai) Co., Ltd.  Protocol No. IN10018-602** |  |

**Table 14.3.1.4.2.12 Summary of IN10018 Related CTCAE Grade 3/4 TEAEs by Grouped SOC and Grouped PT - Phase II part 2 - CRC (Safety Analysis Set)**

| System Organ Class  Preferred Term | Treatment Group (N = 5) n (%) | Control Group (N = 5) n (%) | Total (N = 10) n (%) |
| --- | --- | --- | --- |
| IN10018 Related CTCAE Grade 3/4 TEAEs | 2 (40.0) | 0 | 2 (20.0) |
|  | | | |
| Gastrointestinal disorders | 2 (40.0) | 0 | 2 (20.0) |
| Diarrhoea | 2 (40.0) | 0 | 2 (20.0) |
| Intestinal obstruction | 1 (20.0) | 0 | 1 (10.0) |
|  | | | |
| Investigations | 1 (20.0) | 0 | 1 (10.0) |
| C-reactive protein increased | 1 (20.0) | 0 | 1 (10.0) |
|  | | | |
| Renal and urinary disorders# | 1 (20.0) | 0 | 1 (10.0) |
| Acute kidney injury | 1 (20.0) | 0 | 1 (10.0) |

TEAE is defined as any AE that newly occurs or worsen after the first investigational drug administration and within end of safety follow up period (i.e., within 30 calendar days after the last administration of investigational drug or the start of new anti-cancer therapy (whichever occurs earlier)). If the timing of the AE cannot be established in relation to the first administration of investigational drug, it will be considered as TEAE to be more conservative.

IN10018 related TEAE is defined as the relationship with IN10018 as 'Definitely Related' or 'Probably Related' or 'Possibly Related' or 'Related/Reasonable Possibility'. To be conservative, if the relationship is missing, TEAE is still considered as IN10018 related TEAE.

Adverse events are coded with MedDRA 25.0.

Subjects with multiple occurrences of adverse events in the same grouped preferred term are counted only once within that grouped preferred term.

Subjects with multiple occurrences of adverse events in the same grouped system organ class are counted only once within that grouped system organ class.

Subjects with multiple occurrences of adverse events in the same category are counted only once in that category at the maximum severity.

Percentages are based on the number of subjects of each respective group in Safety Analysis Set.

#: Grouped SOC. \*: Grouped PT.  
Source Data: Listing 16.2.7.1

|  |  |  |
| --- | --- | --- |
| Program: t-ae-soc-pt.sas | DCO: 27APR2024 | Executed: 08JUL2024 17:16 |

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| --- | --- |
| **InxMed (Shanghai) Co., Ltd.  Protocol No. IN10018-602** |  |

**Table 14.3.1.5.1.5 Summary of TEAEs Leading to D-1553 Dose Reduction by SOC and PT - Phase II part 2 - CRC (Safety Analysis Set)**

| System Organ Class  Preferred Term | Treatment Group (N = 5) n (%) | Control Group (N = 5) n (%) | Total (N = 10) n (%) |
| --- | --- | --- | --- |
| TEAEs Leading to D-1553 Dose Reduction | 0 | 0 | 0 |

TEAE is defined as any AE that newly occurs or worsen after the first investigational drug administration and within end of safety follow up period (i.e., within 30 calendar days after the last administration of investigational drug or the start of new anti-cancer therapy (whichever occurs earlier)). If the timing of the AE cannot be established in relation to the first administration of investigational drug, it will be considered as TEAE to be more conservative.

Adverse events are coded with MedDRA 25.0.

Subjects with multiple occurrences of adverse events in the same preferred term are counted only once within that preferred term.

Subjects with multiple occurrences of adverse events in the same system organ class are counted only once within that system organ class.

Percentages are based on the number of subjects of each respective group in Safety Analysis Set.

Source Data: Listing 16.2.7.1

|  |  |  |
| --- | --- | --- |
| Program: t-ae-soc-pt.sas | DCO: 27APR2024 | Executed: 08JUL2024 17:16 |

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| --- | --- |
| **InxMed (Shanghai) Co., Ltd.  Protocol No. IN10018-602** |  |

**Table 14.3.1.5.1.6 Summary of TEAEs Leading to D-1553 Dose Reduction by Grouped SOC and Grouped PT - Phase II part 2 - CRC (Safety Analysis Set)**

| System Organ Class  Preferred Term | Treatment Group (N = 5) n (%) | Control Group (N = 5) n (%) | Total (N = 10) n (%) |
| --- | --- | --- | --- |
| TEAEs Leading to D-1553 Dose Reduction | 0 | 0 | 0 |

TEAE is defined as any AE that newly occurs or worsen after the first investigational drug administration and within end of safety follow up period (i.e., within 30 calendar days after the last administration of investigational drug or the start of new anti-cancer therapy (whichever occurs earlier)). If the timing of the AE cannot be established in relation to the first administration of investigational drug, it will be considered as TEAE to be more conservative.

Adverse events are coded with MedDRA 25.0.

Subjects with multiple occurrences of adverse events in the same grouped preferred term are counted only once within that grouped preferred term.

Subjects with multiple occurrences of adverse events in the same grouped system organ class are counted only once within that grouped system organ class.

Percentages are based on the number of subjects of each respective group in Safety Analysis Set.

Source Data: Listing 16.2.7.1

|  |  |  |
| --- | --- | --- |
| Program: t-ae-soc-pt.sas | DCO: 27APR2024 | Executed: 08JUL2024 17:16 |

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| --- | --- |
| **InxMed (Shanghai) Co., Ltd.  Protocol No. IN10018-602** |  |

**Table 14.3.1.5.1.11 Summary of TEAEs Leading to IN10018 Dose Reduction by SOC and PT - Phase II part 2 - CRC (Safety Analysis Set)**

| System Organ Class  Preferred Term | Treatment Group (N = 5) n (%) | Control Group (N = 5) n (%) | Total (N = 10) n (%) |
| --- | --- | --- | --- |
| TEAEs Leading to IN10018 Dose Reduction | 1 (20.0) | 0 | 1 (10.0) |
|  | | | |
| Renal and urinary disorders | 1 (20.0) | 0 | 1 (10.0) |
| Acute kidney injury | 1 (20.0) | 0 | 1 (10.0) |

TEAE is defined as any AE that newly occurs or worsen after the first investigational drug administration and within end of safety follow up period (i.e., within 30 calendar days after the last administration of investigational drug or the start of new anti-cancer therapy (whichever occurs earlier)). If the timing of the AE cannot be established in relation to the first administration of investigational drug, it will be considered as TEAE to be more conservative.

Adverse events are coded with MedDRA 25.0.

Subjects with multiple occurrences of adverse events in the same preferred term are counted only once within that preferred term.

Subjects with multiple occurrences of adverse events in the same system organ class are counted only once within that system organ class.

Percentages are based on the number of subjects of each respective group in Safety Analysis Set.

Source Data: Listing 16.2.7.1

|  |  |  |
| --- | --- | --- |
| Program: t-ae-soc-pt.sas | DCO: 27APR2024 | Executed: 08JUL2024 17:16 |

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| --- | --- |
| **InxMed (Shanghai) Co., Ltd.  Protocol No. IN10018-602** |  |

**Table 14.3.1.5.1.12 Summary of TEAEs Leading to IN10018 Dose Reduction by Grouped SOC and Grouped PT - Phase II part 2 - CRC (Safety Analysis Set)**

| System Organ Class  Preferred Term | Treatment Group (N = 5) n (%) | Control Group (N = 5) n (%) | Total (N = 10) n (%) |
| --- | --- | --- | --- |
| TEAEs Leading to IN10018 Dose Reduction | 1 (20.0) | 0 | 1 (10.0) |
|  | | | |
| Renal and urinary disorders# | 1 (20.0) | 0 | 1 (10.0) |
| Acute kidney injury | 1 (20.0) | 0 | 1 (10.0) |

TEAE is defined as any AE that newly occurs or worsen after the first investigational drug administration and within end of safety follow up period (i.e., within 30 calendar days after the last administration of investigational drug or the start of new anti-cancer therapy (whichever occurs earlier)). If the timing of the AE cannot be established in relation to the first administration of investigational drug, it will be considered as TEAE to be more conservative.

Adverse events are coded with MedDRA 25.0.

Subjects with multiple occurrences of adverse events in the same grouped preferred term are counted only once within that grouped preferred term.

Subjects with multiple occurrences of adverse events in the same grouped system organ class are counted only once within that grouped system organ class.

Percentages are based on the number of subjects of each respective group in Safety Analysis Set.

#: Grouped SOC. \*: Grouped PT.  
Source Data: Listing 16.2.7.1

|  |  |  |
| --- | --- | --- |
| Program: t-ae-soc-pt.sas | DCO: 27APR2024 | Executed: 08JUL2024 17:16 |

|  |  |
| --- | --- |
| **InxMed (Shanghai) Co., Ltd.  Protocol No. IN10018-602** |  |

**Table 14.3.1.5.2.5 Summary of D-1553 Related TEAEs Leading to D-1553 Dose Reduction by SOC and PT - Phase II part 2 - CRC (Safety Analysis Set)**

| System Organ Class  Preferred Term | Treatment Group (N = 5) n (%) | Control Group (N = 5) n (%) | Total (N = 10) n (%) |
| --- | --- | --- | --- |
| D-1553 Related TEAEs Leading to D-1553 Dose Reduction | 0 | 0 | 0 |

TEAE is defined as any AE that newly occurs or worsen after the first investigational drug administration and within end of safety follow up period (i.e., within 30 calendar days after the last administration of investigational drug or the start of new anti-cancer therapy (whichever occurs earlier)). If the timing of the AE cannot be established in relation to the first administration of investigational drug, it will be considered as TEAE to be more conservative.

D-1553 related TEAE is defined as the relationship with D-1553 as 'Definitely Related' or 'Probably Related' or 'Possibly Related' or 'Related/Reasonable Possibility'. To be conservative, if the relationship is missing, TEAE is still considered as D-1553 related TEAE.

Adverse events are coded with MedDRA 25.0.

Subjects with multiple occurrences of adverse events in the same preferred term are counted only once within that preferred term.

Subjects with multiple occurrences of adverse events in the same system organ class are counted only once within that system organ class.

Percentages are based on the number of subjects of each respective group in Safety Analysis Set.

Source Data: Listing 16.2.7.1

|  |  |  |
| --- | --- | --- |
| Program: t-ae-soc-pt.sas | DCO: 27APR2024 | Executed: 08JUL2024 17:16 |

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| --- | --- |
| **InxMed (Shanghai) Co., Ltd.  Protocol No. IN10018-602** |  |

**Table 14.3.1.5.2.6 Summary of D-1553 Related TEAEs Leading to D-1553 Dose Reduction by Grouped SOC and Grouped PT - Phase II part 2 - CRC (Safety Analysis Set)**

| System Organ Class  Preferred Term | Treatment Group (N = 5) n (%) | Control Group (N = 5) n (%) | Total (N = 10) n (%) |
| --- | --- | --- | --- |
| D-1553 Related TEAEs Leading to D-1553 Dose Reduction | 0 | 0 | 0 |

TEAE is defined as any AE that newly occurs or worsen after the first investigational drug administration and within end of safety follow up period (i.e., within 30 calendar days after the last administration of investigational drug or the start of new anti-cancer therapy (whichever occurs earlier)). If the timing of the AE cannot be established in relation to the first administration of investigational drug, it will be considered as TEAE to be more conservative.

D-1553 related TEAE is defined as the relationship with D-1553 as 'Definitely Related' or 'Probably Related' or 'Possibly Related' or 'Related/Reasonable Possibility'. To be conservative, if the relationship is missing, TEAE is still considered as D-1553 related TEAE.

Adverse events are coded with MedDRA 25.0.

Subjects with multiple occurrences of adverse events in the same grouped preferred term are counted only once within that grouped preferred term.

Subjects with multiple occurrences of adverse events in the same grouped system organ class are counted only once within that grouped system organ class.

Percentages are based on the number of subjects of each respective group in Safety Analysis Set.

Source Data: Listing 16.2.7.1

|  |  |  |
| --- | --- | --- |
| Program: t-ae-soc-pt.sas | DCO: 27APR2024 | Executed: 08JUL2024 17:16 |

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| --- | --- |
| **InxMed (Shanghai) Co., Ltd.  Protocol No. IN10018-602** |  |

**Table 14.3.1.5.2.11 Summary of IN10018 Related TEAEs Leading to IN10018 Dose Reduction by SOC and PT - Phase II part 2 - CRC (Safety Analysis Set)**

| System Organ Class  Preferred Term | Treatment Group (N = 5) n (%) | Control Group (N = 5) n (%) | Total (N = 10) n (%) |
| --- | --- | --- | --- |
| IN10018 Related TEAEs Leading to IN10018 Dose Reduction | 1 (20.0) | 0 | 1 (10.0) |
|  | | | |
| Renal and urinary disorders | 1 (20.0) | 0 | 1 (10.0) |
| Acute kidney injury | 1 (20.0) | 0 | 1 (10.0) |

TEAE is defined as any AE that newly occurs or worsen after the first investigational drug administration and within end of safety follow up period (i.e., within 30 calendar days after the last administration of investigational drug or the start of new anti-cancer therapy (whichever occurs earlier)). If the timing of the AE cannot be established in relation to the first administration of investigational drug, it will be considered as TEAE to be more conservative.

IN10018 related TEAE is defined as the relationship with IN10018 as 'Definitely Related' or 'Probably Related' or 'Possibly Related' or 'Related/Reasonable Possibility'. To be conservative, if the relationship is missing, TEAE is still considered as IN10018 related TEAE.

Adverse events are coded with MedDRA 25.0.

Subjects with multiple occurrences of adverse events in the same preferred term are counted only once within that preferred term.

Subjects with multiple occurrences of adverse events in the same system organ class are counted only once within that system organ class.

Percentages are based on the number of subjects of each respective group in Safety Analysis Set.

Source Data: Listing 16.2.7.1

|  |  |  |
| --- | --- | --- |
| Program: t-ae-soc-pt.sas | DCO: 27APR2024 | Executed: 08JUL2024 17:16 |

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| --- | --- |
| **InxMed (Shanghai) Co., Ltd.  Protocol No. IN10018-602** |  |

**Table 14.3.1.5.2.12 Summary of IN10018 Related TEAEs Leading to IN10018 Dose Reduction by Grouped SOC and Grouped PT - Phase II part 2 - CRC (Safety Analysis Set)**

| System Organ Class  Preferred Term | Treatment Group (N = 5) n (%) | Control Group (N = 5) n (%) | Total (N = 10) n (%) |
| --- | --- | --- | --- |
| IN10018 Related TEAEs Leading to IN10018 Dose Reduction | 1 (20.0) | 0 | 1 (10.0) |
|  | | | |
| Renal and urinary disorders# | 1 (20.0) | 0 | 1 (10.0) |
| Acute kidney injury | 1 (20.0) | 0 | 1 (10.0) |

TEAE is defined as any AE that newly occurs or worsen after the first investigational drug administration and within end of safety follow up period (i.e., within 30 calendar days after the last administration of investigational drug or the start of new anti-cancer therapy (whichever occurs earlier)). If the timing of the AE cannot be established in relation to the first administration of investigational drug, it will be considered as TEAE to be more conservative.

IN10018 related TEAE is defined as the relationship with IN10018 as 'Definitely Related' or 'Probably Related' or 'Possibly Related' or 'Related/Reasonable Possibility'. To be conservative, if the relationship is missing, TEAE is still considered as IN10018 related TEAE.

Adverse events are coded with MedDRA 25.0.

Subjects with multiple occurrences of adverse events in the same grouped preferred term are counted only once within that grouped preferred term.

Subjects with multiple occurrences of adverse events in the same grouped system organ class are counted only once within that grouped system organ class.

Percentages are based on the number of subjects of each respective group in Safety Analysis Set.

#: Grouped SOC. \*: Grouped PT.  
Source Data: Listing 16.2.7.1

|  |  |  |
| --- | --- | --- |
| Program: t-ae-soc-pt.sas | DCO: 27APR2024 | Executed: 08JUL2024 17:16 |

|  |  |
| --- | --- |
| **InxMed (Shanghai) Co., Ltd.  Protocol No. IN10018-602** |  |

**Table 14.3.1.6.1.5 Summary of TEAEs Leading to D-1553 Drug Interruption by SOC and PT - Phase II part 2 - CRC (Safety Analysis Set)**

| System Organ Class  Preferred Term | Treatment Group (N = 5) n (%) | Control Group (N = 5) n (%) | Total (N = 10) n (%) |
| --- | --- | --- | --- |
| TEAEs Leading to D-1553 Drug Interruption | 2 (40.0) | 2 (40.0) | 4 (40.0) |
|  | | | |
| Gastrointestinal disorders | 1 (20.0) | 1 (20.0) | 2 (20.0) |
| Intestinal obstruction | 1 (20.0) | 0 | 1 (10.0) |
| Toothache | 0 | 1 (20.0) | 1 (10.0) |
|  | | | |
| Blood and lymphatic system disorders | 0 | 1 (20.0) | 1 (10.0) |
| Anaemia | 0 | 1 (20.0) | 1 (10.0) |
|  | | | |
| Renal and urinary disorders | 1 (20.0) | 0 | 1 (10.0) |
| Acute kidney injury | 1 (20.0) | 0 | 1 (10.0) |

TEAE is defined as any AE that newly occurs or worsen after the first investigational drug administration and within end of safety follow up period (i.e., within 30 calendar days after the last administration of investigational drug or the start of new anti-cancer therapy (whichever occurs earlier)). If the timing of the AE cannot be established in relation to the first administration of investigational drug, it will be considered as TEAE to be more conservative.

Adverse events are coded with MedDRA 25.0.

Subjects with multiple occurrences of adverse events in the same preferred term are counted only once within that preferred term.

Subjects with multiple occurrences of adverse events in the same system organ class are counted only once within that system organ class.

Percentages are based on the number of subjects of each respective group in Safety Analysis Set.

Source Data: Listing 16.2.7.1

|  |  |  |
| --- | --- | --- |
| Program: t-ae-soc-pt.sas | DCO: 27APR2024 | Executed: 08JUL2024 17:16 |

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| --- | --- |
| **InxMed (Shanghai) Co., Ltd.  Protocol No. IN10018-602** |  |

**Table 14.3.1.6.1.6 Summary of TEAEs Leading to D-1553 Drug Interruption by Grouped SOC and Grouped PT - Phase II part 2 - CRC (Safety Analysis Set)**

| System Organ Class  Preferred Term | Treatment Group (N = 5) n (%) | Control Group (N = 5) n (%) | Total (N = 10) n (%) |
| --- | --- | --- | --- |
| TEAEs Leading to D-1553 Drug Interruption | 2 (40.0) | 2 (40.0) | 4 (40.0) |
|  | | | |
| Gastrointestinal disorders | 1 (20.0) | 1 (20.0) | 2 (20.0) |
| Intestinal obstruction | 1 (20.0) | 0 | 1 (10.0) |
| Toothache | 0 | 1 (20.0) | 1 (10.0) |
|  | | | |
| Blood and lymphatic system disorders# | 0 | 1 (20.0) | 1 (10.0) |
| Anaemia | 0 | 1 (20.0) | 1 (10.0) |
|  | | | |
| Renal and urinary disorders# | 1 (20.0) | 0 | 1 (10.0) |
| Acute kidney injury | 1 (20.0) | 0 | 1 (10.0) |

TEAE is defined as any AE that newly occurs or worsen after the first investigational drug administration and within end of safety follow up period (i.e., within 30 calendar days after the last administration of investigational drug or the start of new anti-cancer therapy (whichever occurs earlier)). If the timing of the AE cannot be established in relation to the first administration of investigational drug, it will be considered as TEAE to be more conservative.

Adverse events are coded with MedDRA 25.0.

Subjects with multiple occurrences of adverse events in the same grouped preferred term are counted only once within that grouped preferred term.

Subjects with multiple occurrences of adverse events in the same grouped system organ class are counted only once within that grouped system organ class.

Percentages are based on the number of subjects of each respective group in Safety Analysis Set.

#: Grouped SOC. \*: Grouped PT.  
Source Data: Listing 16.2.7.1

|  |  |  |
| --- | --- | --- |
| Program: t-ae-soc-pt.sas | DCO: 27APR2024 | Executed: 08JUL2024 17:16 |

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| --- | --- |
| **InxMed (Shanghai) Co., Ltd.  Protocol No. IN10018-602** |  |

**Table 14.3.1.6.1.11 Summary of TEAEs Leading to IN10018 Drug Interruption by SOC and PT - Phase II part 2 - CRC (Safety Analysis Set)**

| System Organ Class  Preferred Term | Treatment Group (N = 5) n (%) | Control Group (N = 5) n (%) | Total (N = 10) n (%) |
| --- | --- | --- | --- |
| TEAEs Leading to IN10018 Drug Interruption | 2 (40.0) | 0 | 2 (20.0) |
|  | | | |
| Gastrointestinal disorders | 1 (20.0) | 0 | 1 (10.0) |
| Intestinal obstruction | 1 (20.0) | 0 | 1 (10.0) |
|  | | | |
| Musculoskeletal and connective tissue disorders | 1 (20.0) | 0 | 1 (10.0) |
| Arthritis | 1 (20.0) | 0 | 1 (10.0) |

TEAE is defined as any AE that newly occurs or worsen after the first investigational drug administration and within end of safety follow up period (i.e., within 30 calendar days after the last administration of investigational drug or the start of new anti-cancer therapy (whichever occurs earlier)). If the timing of the AE cannot be established in relation to the first administration of investigational drug, it will be considered as TEAE to be more conservative.

Adverse events are coded with MedDRA 25.0.

Subjects with multiple occurrences of adverse events in the same preferred term are counted only once within that preferred term.

Subjects with multiple occurrences of adverse events in the same system organ class are counted only once within that system organ class.

Percentages are based on the number of subjects of each respective group in Safety Analysis Set.

Source Data: Listing 16.2.7.1

|  |  |  |
| --- | --- | --- |
| Program: t-ae-soc-pt.sas | DCO: 27APR2024 | Executed: 08JUL2024 17:16 |

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| --- | --- |
| **InxMed (Shanghai) Co., Ltd.  Protocol No. IN10018-602** |  |

**Table 14.3.1.6.1.12 Summary of TEAEs Leading to IN10018 Drug Interruption by Grouped SOC and Grouped PT - Phase II part 2 - CRC (Safety Analysis Set)**

| System Organ Class  Preferred Term | Treatment Group (N = 5) n (%) | Control Group (N = 5) n (%) | Total (N = 10) n (%) |
| --- | --- | --- | --- |
| TEAEs Leading to IN10018 Drug Interruption | 2 (40.0) | 0 | 2 (20.0) |
|  | | | |
| Gastrointestinal disorders | 1 (20.0) | 0 | 1 (10.0) |
| Intestinal obstruction | 1 (20.0) | 0 | 1 (10.0) |
|  | | | |
| Musculoskeletal and connective tissue disorders | 1 (20.0) | 0 | 1 (10.0) |
| Arthritis | 1 (20.0) | 0 | 1 (10.0) |

TEAE is defined as any AE that newly occurs or worsen after the first investigational drug administration and within end of safety follow up period (i.e., within 30 calendar days after the last administration of investigational drug or the start of new anti-cancer therapy (whichever occurs earlier)). If the timing of the AE cannot be established in relation to the first administration of investigational drug, it will be considered as TEAE to be more conservative.

Adverse events are coded with MedDRA 25.0.

Subjects with multiple occurrences of adverse events in the same grouped preferred term are counted only once within that grouped preferred term.

Subjects with multiple occurrences of adverse events in the same grouped system organ class are counted only once within that grouped system organ class.

Percentages are based on the number of subjects of each respective group in Safety Analysis Set.

Source Data: Listing 16.2.7.1

|  |  |  |
| --- | --- | --- |
| Program: t-ae-soc-pt.sas | DCO: 27APR2024 | Executed: 08JUL2024 17:16 |

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| --- | --- |
| **InxMed (Shanghai) Co., Ltd.  Protocol No. IN10018-602** |  |

**Table 14.3.1.6.2.5 Summary of D-1553 Related TEAEs Leading to D-1553 Drug Interruption by SOC and PT - Phase II part 2 - CRC (Safety Analysis Set)**

| System Organ Class  Preferred Term | Treatment Group (N = 5) n (%) | Control Group (N = 5) n (%) | Total (N = 10) n (%) |
| --- | --- | --- | --- |
| D-1553 Related TEAEs Leading to D-1553 Drug Interruption | 2 (40.0) | 2 (40.0) | 4 (40.0) |
|  | | | |
| Gastrointestinal disorders | 1 (20.0) | 1 (20.0) | 2 (20.0) |
| Intestinal obstruction | 1 (20.0) | 0 | 1 (10.0) |
| Toothache | 0 | 1 (20.0) | 1 (10.0) |
|  | | | |
| Blood and lymphatic system disorders | 0 | 1 (20.0) | 1 (10.0) |
| Anaemia | 0 | 1 (20.0) | 1 (10.0) |
|  | | | |
| Renal and urinary disorders | 1 (20.0) | 0 | 1 (10.0) |
| Acute kidney injury | 1 (20.0) | 0 | 1 (10.0) |

TEAE is defined as any AE that newly occurs or worsen after the first investigational drug administration and within end of safety follow up period (i.e., within 30 calendar days after the last administration of investigational drug or the start of new anti-cancer therapy (whichever occurs earlier)). If the timing of the AE cannot be established in relation to the first administration of investigational drug, it will be considered as TEAE to be more conservative.

D-1553 related TEAE is defined as the relationship with D-1553 as 'Definitely Related' or 'Probably Related' or 'Possibly Related' or 'Related/Reasonable Possibility'. To be conservative, if the relationship is missing, TEAE is still considered as D-1553 related TEAE.

Adverse events are coded with MedDRA 25.0.

Subjects with multiple occurrences of adverse events in the same preferred term are counted only once within that preferred term.

Subjects with multiple occurrences of adverse events in the same system organ class are counted only once within that system organ class.

Percentages are based on the number of subjects of each respective group in Safety Analysis Set.

Source Data: Listing 16.2.7.1

|  |  |  |
| --- | --- | --- |
| Program: t-ae-soc-pt.sas | DCO: 27APR2024 | Executed: 08JUL2024 17:16 |

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| --- | --- |
| **InxMed (Shanghai) Co., Ltd.  Protocol No. IN10018-602** |  |

**Table 14.3.1.6.2.6 Summary of D-1553 Related TEAEs Leading to D-1553 Drug Interruption by Grouped SOC and Grouped PT - Phase II part 2 - CRC (Safety Analysis Set)**

| System Organ Class  Preferred Term | Treatment Group (N = 5) n (%) | Control Group (N = 5) n (%) | Total (N = 10) n (%) |
| --- | --- | --- | --- |
| D-1553 Related TEAEs Leading to D-1553 Drug Interruption | 2 (40.0) | 2 (40.0) | 4 (40.0) |
|  | | | |
| Gastrointestinal disorders | 1 (20.0) | 1 (20.0) | 2 (20.0) |
| Intestinal obstruction | 1 (20.0) | 0 | 1 (10.0) |
| Toothache | 0 | 1 (20.0) | 1 (10.0) |
|  | | | |
| Blood and lymphatic system disorders# | 0 | 1 (20.0) | 1 (10.0) |
| Anaemia | 0 | 1 (20.0) | 1 (10.0) |
|  | | | |
| Renal and urinary disorders# | 1 (20.0) | 0 | 1 (10.0) |
| Acute kidney injury | 1 (20.0) | 0 | 1 (10.0) |

TEAE is defined as any AE that newly occurs or worsen after the first investigational drug administration and within end of safety follow up period (i.e., within 30 calendar days after the last administration of investigational drug or the start of new anti-cancer therapy (whichever occurs earlier)). If the timing of the AE cannot be established in relation to the first administration of investigational drug, it will be considered as TEAE to be more conservative.

D-1553 related TEAE is defined as the relationship with D-1553 as 'Definitely Related' or 'Probably Related' or 'Possibly Related' or 'Related/Reasonable Possibility'. To be conservative, if the relationship is missing, TEAE is still considered as D-1553 related TEAE.

Adverse events are coded with MedDRA 25.0.

Subjects with multiple occurrences of adverse events in the same grouped preferred term are counted only once within that grouped preferred term.

Subjects with multiple occurrences of adverse events in the same grouped system organ class are counted only once within that grouped system organ class.

Percentages are based on the number of subjects of each respective group in Safety Analysis Set.

#: Grouped SOC. \*: Grouped PT.  
Source Data: Listing 16.2.7.1

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| Program: t-ae-soc-pt.sas | DCO: 27APR2024 | Executed: 08JUL2024 17:16 |

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| **InxMed (Shanghai) Co., Ltd.  Protocol No. IN10018-602** |  |

**Table 14.3.1.6.2.11 Summary of IN10018 Related TEAEs Leading to IN10018 Drug Interruption by SOC and PT - Phase II part 2 - CRC (Safety Analysis Set)**

| System Organ Class  Preferred Term | Treatment Group (N = 5) n (%) | Control Group (N = 5) n (%) | Total (N = 10) n (%) |
| --- | --- | --- | --- |
| IN10018 Related TEAEs Leading to IN10018 Drug Interruption | 2 (40.0) | 0 | 2 (20.0) |
|  | | | |
| Gastrointestinal disorders | 1 (20.0) | 0 | 1 (10.0) |
| Intestinal obstruction | 1 (20.0) | 0 | 1 (10.0) |
|  | | | |
| Musculoskeletal and connective tissue disorders | 1 (20.0) | 0 | 1 (10.0) |
| Arthritis | 1 (20.0) | 0 | 1 (10.0) |

TEAE is defined as any AE that newly occurs or worsen after the first investigational drug administration and within end of safety follow up period (i.e., within 30 calendar days after the last administration of investigational drug or the start of new anti-cancer therapy (whichever occurs earlier)). If the timing of the AE cannot be established in relation to the first administration of investigational drug, it will be considered as TEAE to be more conservative.

IN10018 related TEAE is defined as the relationship with IN10018 as 'Definitely Related' or 'Probably Related' or 'Possibly Related' or 'Related/Reasonable Possibility'. To be conservative, if the relationship is missing, TEAE is still considered as IN10018 related TEAE.

Adverse events are coded with MedDRA 25.0.

Subjects with multiple occurrences of adverse events in the same preferred term are counted only once within that preferred term.

Subjects with multiple occurrences of adverse events in the same system organ class are counted only once within that system organ class.

Percentages are based on the number of subjects of each respective group in Safety Analysis Set.

Source Data: Listing 16.2.7.1

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| Program: t-ae-soc-pt.sas | DCO: 27APR2024 | Executed: 08JUL2024 17:16 |

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| **InxMed (Shanghai) Co., Ltd.  Protocol No. IN10018-602** |  |

**Table 14.3.1.6.2.12 Summary of IN10018 Related TEAEs Leading to IN10018 Drug Interruption by Grouped SOC and Grouped PT - Phase II part 2 - CRC (Safety Analysis Set)**

| System Organ Class  Preferred Term | Treatment Group (N = 5) n (%) | Control Group (N = 5) n (%) | Total (N = 10) n (%) |
| --- | --- | --- | --- |
| IN10018 Related TEAEs Leading to IN10018 Drug Interruption | 2 (40.0) | 0 | 2 (20.0) |
|  | | | |
| Gastrointestinal disorders | 1 (20.0) | 0 | 1 (10.0) |
| Intestinal obstruction | 1 (20.0) | 0 | 1 (10.0) |
|  | | | |
| Musculoskeletal and connective tissue disorders | 1 (20.0) | 0 | 1 (10.0) |
| Arthritis | 1 (20.0) | 0 | 1 (10.0) |

TEAE is defined as any AE that newly occurs or worsen after the first investigational drug administration and within end of safety follow up period (i.e., within 30 calendar days after the last administration of investigational drug or the start of new anti-cancer therapy (whichever occurs earlier)). If the timing of the AE cannot be established in relation to the first administration of investigational drug, it will be considered as TEAE to be more conservative.

IN10018 related TEAE is defined as the relationship with IN10018 as 'Definitely Related' or 'Probably Related' or 'Possibly Related' or 'Related/Reasonable Possibility'. To be conservative, if the relationship is missing, TEAE is still considered as IN10018 related TEAE.

Adverse events are coded with MedDRA 25.0.

Subjects with multiple occurrences of adverse events in the same grouped preferred term are counted only once within that grouped preferred term.

Subjects with multiple occurrences of adverse events in the same grouped system organ class are counted only once within that grouped system organ class.

Percentages are based on the number of subjects of each respective group in Safety Analysis Set.

Source Data: Listing 16.2.7.1

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| **InxMed (Shanghai) Co., Ltd.  Protocol No. IN10018-602** |  |

**Table 14.3.1.7.1.5 Summary of TEAEs Leading to D-1553 Drug Withdrawn by SOC and PT - Phase II part 2 - CRC (Safety Analysis Set)**

| System Organ Class  Preferred Term | Treatment Group (N = 5) n (%) | Control Group (N = 5) n (%) | Total (N = 10) n (%) |
| --- | --- | --- | --- |
| TEAEs Leading to D-1553 Drug Withdrawn | 0 | 0 | 0 |

TEAE is defined as any AE that newly occurs or worsen after the first investigational drug administration and within end of safety follow up period (i.e., within 30 calendar days after the last administration of investigational drug or the start of new anti-cancer therapy (whichever occurs earlier)). If the timing of the AE cannot be established in relation to the first administration of investigational drug, it will be considered as TEAE to be more conservative.

Adverse events are coded with MedDRA 25.0.

Subjects with multiple occurrences of adverse events in the same preferred term are counted only once within that preferred term.

Subjects with multiple occurrences of adverse events in the same system organ class are counted only once within that system organ class.

Percentages are based on the number of subjects of each respective group in Safety Analysis Set.

Source Data: Listing 16.2.7.1

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| Program: t-ae-soc-pt.sas | DCO: 27APR2024 | Executed: 08JUL2024 17:16 |

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| **InxMed (Shanghai) Co., Ltd.  Protocol No. IN10018-602** |  |

**Table 14.3.1.7.1.6 Summary of TEAEs Leading to D-1553 Drug Withdrawn by Grouped SOC and Grouped PT - Phase II part 2 - CRC (Safety Analysis Set)**

| System Organ Class  Preferred Term | Treatment Group (N = 5) n (%) | Control Group (N = 5) n (%) | Total (N = 10) n (%) |
| --- | --- | --- | --- |
| TEAEs Leading to D-1553 Drug Withdrawn | 0 | 0 | 0 |

TEAE is defined as any AE that newly occurs or worsen after the first investigational drug administration and within end of safety follow up period (i.e., within 30 calendar days after the last administration of investigational drug or the start of new anti-cancer therapy (whichever occurs earlier)). If the timing of the AE cannot be established in relation to the first administration of investigational drug, it will be considered as TEAE to be more conservative.

Adverse events are coded with MedDRA 25.0.

Subjects with multiple occurrences of adverse events in the same grouped preferred term are counted only once within that grouped preferred term.

Subjects with multiple occurrences of adverse events in the same grouped system organ class are counted only once within that grouped system organ class.

Percentages are based on the number of subjects of each respective group in Safety Analysis Set.

Source Data: Listing 16.2.7.1

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| Program: t-ae-soc-pt.sas | DCO: 27APR2024 | Executed: 08JUL2024 17:16 |

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| **InxMed (Shanghai) Co., Ltd.  Protocol No. IN10018-602** |  |

**Table 14.3.1.7.1.11 Summary of TEAEs Leading to IN10018 Drug Withdrawn by SOC and PT - Phase II part 2 - CRC (Safety Analysis Set)**

| System Organ Class  Preferred Term | Treatment Group (N = 5) n (%) | Control Group (N = 5) n (%) | Total (N = 10) n (%) |
| --- | --- | --- | --- |
| TEAEs Leading to IN10018 Drug Withdrawn | 0 | 0 | 0 |

TEAE is defined as any AE that newly occurs or worsen after the first investigational drug administration and within end of safety follow up period (i.e., within 30 calendar days after the last administration of investigational drug or the start of new anti-cancer therapy (whichever occurs earlier)). If the timing of the AE cannot be established in relation to the first administration of investigational drug, it will be considered as TEAE to be more conservative.

Adverse events are coded with MedDRA 25.0.

Subjects with multiple occurrences of adverse events in the same preferred term are counted only once within that preferred term.

Subjects with multiple occurrences of adverse events in the same system organ class are counted only once within that system organ class.

Percentages are based on the number of subjects of each respective group in Safety Analysis Set.

Source Data: Listing 16.2.7.1

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| **InxMed (Shanghai) Co., Ltd.  Protocol No. IN10018-602** |  |

**Table 14.3.1.7.1.12 Summary of TEAEs Leading to IN10018 Drug Withdrawn by Grouped SOC and Grouped PT - Phase II part 2 - CRC (Safety Analysis Set)**

| System Organ Class  Preferred Term | Treatment Group (N = 5) n (%) | Control Group (N = 5) n (%) | Total (N = 10) n (%) |
| --- | --- | --- | --- |
| TEAEs Leading to IN10018 Drug Withdrawn | 0 | 0 | 0 |

TEAE is defined as any AE that newly occurs or worsen after the first investigational drug administration and within end of safety follow up period (i.e., within 30 calendar days after the last administration of investigational drug or the start of new anti-cancer therapy (whichever occurs earlier)). If the timing of the AE cannot be established in relation to the first administration of investigational drug, it will be considered as TEAE to be more conservative.

Adverse events are coded with MedDRA 25.0.

Subjects with multiple occurrences of adverse events in the same grouped preferred term are counted only once within that grouped preferred term.

Subjects with multiple occurrences of adverse events in the same grouped system organ class are counted only once within that grouped system organ class.

Percentages are based on the number of subjects of each respective group in Safety Analysis Set.

Source Data: Listing 16.2.7.1

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| Program: t-ae-soc-pt.sas | DCO: 27APR2024 | Executed: 08JUL2024 17:16 |

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| **InxMed (Shanghai) Co., Ltd.  Protocol No. IN10018-602** |  |

**Table 14.3.1.7.2.5 Summary of D-1553 Related TEAEs Leading to D-1553 Drug Withdrawn by SOC and PT - Phase II part 2 - CRC (Safety Analysis Set)**

| System Organ Class  Preferred Term | Treatment Group (N = 5) n (%) | Control Group (N = 5) n (%) | Total (N = 10) n (%) |
| --- | --- | --- | --- |
| D-1553 Related TEAEs Leading to D-1553 Drug Withdrawn | 0 | 0 | 0 |

TEAE is defined as any AE that newly occurs or worsen after the first investigational drug administration and within end of safety follow up period (i.e., within 30 calendar days after the last administration of investigational drug or the start of new anti-cancer therapy (whichever occurs earlier)). If the timing of the AE cannot be established in relation to the first administration of investigational drug, it will be considered as TEAE to be more conservative.

D-1553 related TEAE is defined as the relationship with D-1553 as 'Definitely Related' or 'Probably Related' or 'Possibly Related' or 'Related/Reasonable Possibility'. To be conservative, if the relationship is missing, TEAE is still considered as D-1553 related TEAE.

Adverse events are coded with MedDRA 25.0.

Subjects with multiple occurrences of adverse events in the same preferred term are counted only once within that preferred term.

Subjects with multiple occurrences of adverse events in the same system organ class are counted only once within that system organ class.

Percentages are based on the number of subjects of each respective group in Safety Analysis Set.

Source Data: Listing 16.2.7.1

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| Program: t-ae-soc-pt.sas | DCO: 27APR2024 | Executed: 08JUL2024 17:16 |

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| **InxMed (Shanghai) Co., Ltd.  Protocol No. IN10018-602** |  |

**Table 14.3.1.7.2.6 Summary of D-1553 Related TEAEs Leading to D-1553 Drug Withdrawn by Grouped SOC and Grouped PT - Phase II part 2 - CRC (Safety Analysis Set)**

| System Organ Class  Preferred Term | Treatment Group (N = 5) n (%) | Control Group (N = 5) n (%) | Total (N = 10) n (%) |
| --- | --- | --- | --- |
| D-1553 Related TEAEs Leading to D-1553 Drug Withdrawn | 0 | 0 | 0 |

TEAE is defined as any AE that newly occurs or worsen after the first investigational drug administration and within end of safety follow up period (i.e., within 30 calendar days after the last administration of investigational drug or the start of new anti-cancer therapy (whichever occurs earlier)). If the timing of the AE cannot be established in relation to the first administration of investigational drug, it will be considered as TEAE to be more conservative.

D-1553 related TEAE is defined as the relationship with D-1553 as 'Definitely Related' or 'Probably Related' or 'Possibly Related' or 'Related/Reasonable Possibility'. To be conservative, if the relationship is missing, TEAE is still considered as D-1553 related TEAE.

Adverse events are coded with MedDRA 25.0.

Subjects with multiple occurrences of adverse events in the same grouped preferred term are counted only once within that grouped preferred term.

Subjects with multiple occurrences of adverse events in the same grouped system organ class are counted only once within that grouped system organ class.

Percentages are based on the number of subjects of each respective group in Safety Analysis Set.

Source Data: Listing 16.2.7.1

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| Program: t-ae-soc-pt.sas | DCO: 27APR2024 | Executed: 08JUL2024 17:16 |

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| **InxMed (Shanghai) Co., Ltd.  Protocol No. IN10018-602** |  |

**Table 14.3.1.7.2.11 Summary of IN10018 Related TEAEs Leading to IN10018 Drug Withdrawn by SOC and PT - Phase II part 2 - CRC (Safety Analysis Set)**

| System Organ Class  Preferred Term | Treatment Group (N = 5) n (%) | Control Group (N = 5) n (%) | Total (N = 10) n (%) |
| --- | --- | --- | --- |
| IN10018 Related TEAEs Leading to IN10018 Drug Withdrawn | 0 | 0 | 0 |

TEAE is defined as any AE that newly occurs or worsen after the first investigational drug administration and within end of safety follow up period (i.e., within 30 calendar days after the last administration of investigational drug or the start of new anti-cancer therapy (whichever occurs earlier)). If the timing of the AE cannot be established in relation to the first administration of investigational drug, it will be considered as TEAE to be more conservative.

IN10018 related TEAE is defined as the relationship with IN10018 as 'Definitely Related' or 'Probably Related' or 'Possibly Related' or 'Related/Reasonable Possibility'. To be conservative, if the relationship is missing, TEAE is still considered as IN10018 related TEAE.

Adverse events are coded with MedDRA 25.0.

Subjects with multiple occurrences of adverse events in the same preferred term are counted only once within that preferred term.

Subjects with multiple occurrences of adverse events in the same system organ class are counted only once within that system organ class.

Percentages are based on the number of subjects of each respective group in Safety Analysis Set.

Source Data: Listing 16.2.7.1

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| **InxMed (Shanghai) Co., Ltd.  Protocol No. IN10018-602** |  |

**Table 14.3.1.7.2.12 Summary of IN10018 Related TEAEs Leading to IN10018 Drug Withdrawn by Grouped SOC and Grouped PT - Phase II part 2 - CRC (Safety Analysis Set)**

| System Organ Class  Preferred Term | Treatment Group (N = 5) n (%) | Control Group (N = 5) n (%) | Total (N = 10) n (%) |
| --- | --- | --- | --- |
| IN10018 Related TEAEs Leading to IN10018 Drug Withdrawn | 0 | 0 | 0 |

TEAE is defined as any AE that newly occurs or worsen after the first investigational drug administration and within end of safety follow up period (i.e., within 30 calendar days after the last administration of investigational drug or the start of new anti-cancer therapy (whichever occurs earlier)). If the timing of the AE cannot be established in relation to the first administration of investigational drug, it will be considered as TEAE to be more conservative.

IN10018 related TEAE is defined as the relationship with IN10018 as 'Definitely Related' or 'Probably Related' or 'Possibly Related' or 'Related/Reasonable Possibility'. To be conservative, if the relationship is missing, TEAE is still considered as IN10018 related TEAE.

Adverse events are coded with MedDRA 25.0.

Subjects with multiple occurrences of adverse events in the same grouped preferred term are counted only once within that grouped preferred term.

Subjects with multiple occurrences of adverse events in the same grouped system organ class are counted only once within that grouped system organ class.

Percentages are based on the number of subjects of each respective group in Safety Analysis Set.

Source Data: Listing 16.2.7.1

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| **InxMed (Shanghai) Co., Ltd.  Protocol No. IN10018-602** |  |

**Table 14.3.1.8.1.5 Summary of AESI by SOC and PT - Phase II part 2 - CRC (Safety Analysis Set)**

| System Organ Class  Preferred Term | Treatment Group (N = 5) n (%) | Control Group (N = 5) n (%) | Total (N = 10) n (%) |
| --- | --- | --- | --- |
| All AESIs | 0 | 0 | 0 |

TEAE is defined as any AE that newly occurs or worsen after the first investigational drug administration and within end of safety follow up period (i.e., within 30 calendar days after the last administration of investigational drug or the start of new anti-cancer therapy (whichever occurs earlier)). If the timing of the AE cannot be established in relation to the first administration of investigational drug, it will be considered as TEAE to be more conservative.

Adverse events are coded with MedDRA 25.0.

Subjects with multiple occurrences of adverse events in the same preferred term are counted only once within that preferred term.

Subjects with multiple occurrences of adverse events in the same system organ class are counted only once within that system organ class.

Percentages are based on the number of subjects of each respective group in Safety Analysis Set.

Source Data: Listing 16.2.7.1

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| Program: t-ae-soc-pt.sas | DCO: 27APR2024 | Executed: 08JUL2024 17:16 |

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| **InxMed (Shanghai) Co., Ltd.  Protocol No. IN10018-602** |  |

**Table 14.3.1.8.1.6 Summary of AESI by Grouped SOC and Grouped PT - Phase II part 2 - CRC (Safety Analysis Set)**

| System Organ Class  Preferred Term | Treatment Group (N = 5) n (%) | Control Group (N = 5) n (%) | Total (N = 10) n (%) |
| --- | --- | --- | --- |
| All AESIs | 0 | 0 | 0 |

TEAE is defined as any AE that newly occurs or worsen after the first investigational drug administration and within end of safety follow up period (i.e., within 30 calendar days after the last administration of investigational drug or the start of new anti-cancer therapy (whichever occurs earlier)). If the timing of the AE cannot be established in relation to the first administration of investigational drug, it will be considered as TEAE to be more conservative.

Adverse events are coded with MedDRA 25.0.

Subjects with multiple occurrences of adverse events in the same grouped preferred term are counted only once within that grouped preferred term.

Subjects with multiple occurrences of adverse events in the same grouped system organ class are counted only once within that grouped system organ class.

Percentages are based on the number of subjects of each respective group in Safety Analysis Set.

Source Data: Listing 16.2.7.1

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| --- | --- | --- |
| Program: t-ae-soc-pt.sas | DCO: 27APR2024 | Executed: 08JUL2024 17:16 |

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| **InxMed (Shanghai) Co., Ltd.  Protocol No. IN10018-602** |  |

**Table 14.3.1.8.2.5 Summary of AESI with CTCAE Grade 3/4 by SOC and PT - Phase II part 2 - CRC (Safety Analysis Set)**

| System Organ Class  Preferred Term | Treatment Group (N = 5) n (%) | Control Group (N = 5) n (%) | Total (N = 10) n (%) |
| --- | --- | --- | --- |
| AESI with CTCAE Grade 3/4 | 0 | 0 | 0 |

TEAE is defined as any AE that newly occurs or worsen after the first investigational drug administration and within end of safety follow up period (i.e., within 30 calendar days after the last administration of investigational drug or the start of new anti-cancer therapy (whichever occurs earlier)). If the timing of the AE cannot be established in relation to the first administration of investigational drug, it will be considered as TEAE to be more conservative.

Adverse events are coded with MedDRA 25.0.

Subjects with multiple occurrences of adverse events in the same preferred term are counted only once within that preferred term.

Subjects with multiple occurrences of adverse events in the same system organ class are counted only once within that system organ class.

Subjects with multiple occurrences of adverse events in the same category are counted only once in that category at the maximum severity.

Percentages are based on the number of subjects of each respective group in Safety Analysis Set.

Source Data: Listing 16.2.7.1

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| Program: t-ae-soc-pt.sas | DCO: 27APR2024 | Executed: 08JUL2024 17:16 |

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| **InxMed (Shanghai) Co., Ltd.  Protocol No. IN10018-602** |  |

**Table 14.3.1.8.2.6 Summary of AESI with CTCAE Grade 3/4 by Grouped SOC and Grouped PT - Phase II part 2 - CRC (Safety Analysis Set)**

| System Organ Class  Preferred Term | Treatment Group (N = 5) n (%) | Control Group (N = 5) n (%) | Total (N = 10) n (%) |
| --- | --- | --- | --- |
| AESI with CTCAE Grade 3/4 | 0 | 0 | 0 |

TEAE is defined as any AE that newly occurs or worsen after the first investigational drug administration and within end of safety follow up period (i.e., within 30 calendar days after the last administration of investigational drug or the start of new anti-cancer therapy (whichever occurs earlier)). If the timing of the AE cannot be established in relation to the first administration of investigational drug, it will be considered as TEAE to be more conservative.

Adverse events are coded with MedDRA 25.0.

Subjects with multiple occurrences of adverse events in the same grouped preferred term are counted only once within that grouped preferred term.

Subjects with multiple occurrences of adverse events in the same grouped system organ class are counted only once within that grouped system organ class.

Subjects with multiple occurrences of adverse events in the same category are counted only once in that category at the maximum severity.

Percentages are based on the number of subjects of each respective group in Safety Analysis Set.

Source Data: Listing 16.2.7.1

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| --- | --- | --- |
| Program: t-ae-soc-pt.sas | DCO: 27APR2024 | Executed: 08JUL2024 17:16 |

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| **InxMed (Shanghai) Co., Ltd.  Protocol No. IN10018-602** |  |

**Table 14.3.1.8.3.5 Summary of D-1553 Related AESI by SOC and PT - Phase II part 2 - CRC (Safety Analysis Set)**

| System Organ Class  Preferred Term | Treatment Group (N = 5) n (%) | Control Group (N = 5) n (%) | Total (N = 10) n (%) |
| --- | --- | --- | --- |
| D-1553 Related AESI | 0 | 0 | 0 |

TEAE is defined as any AE that newly occurs or worsen after the first investigational drug administration and within end of safety follow up period (i.e., within 30 calendar days after the last administration of investigational drug or the start of new anti-cancer therapy (whichever occurs earlier)). If the timing of the AE cannot be established in relation to the first administration of investigational drug, it will be considered as TEAE to be more conservative.

D-1553 related TEAE is defined as the relationship with D-1553 as 'Definitely Related' or 'Probably Related' or 'Possibly Related' or 'Related/Reasonable Possibility'. To be conservative, if the relationship is missing, TEAE is still considered as D-1553 related TEAE.

Adverse events are coded with MedDRA 25.0.

Subjects with multiple occurrences of adverse events in the same preferred term are counted only once within that preferred term.

Subjects with multiple occurrences of adverse events in the same system organ class are counted only once within that system organ class.

Percentages are based on the number of subjects of each respective group in Safety Analysis Set.

Source Data: Listing 16.2.7.1

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| --- | --- | --- |
| Program: t-ae-soc-pt.sas | DCO: 27APR2024 | Executed: 08JUL2024 17:16 |

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| **InxMed (Shanghai) Co., Ltd.  Protocol No. IN10018-602** |  |

**Table 14.3.1.8.3.6 Summary of D-1553 Related AESI by Grouped SOC and Grouped PT - Phase II part 2 - CRC (Safety Analysis Set)**

| System Organ Class  Preferred Term | Treatment Group (N = 5) n (%) | Control Group (N = 5) n (%) | Total (N = 10) n (%) |
| --- | --- | --- | --- |
| D-1553 Related AESI | 0 | 0 | 0 |

TEAE is defined as any AE that newly occurs or worsen after the first investigational drug administration and within end of safety follow up period (i.e., within 30 calendar days after the last administration of investigational drug or the start of new anti-cancer therapy (whichever occurs earlier)). If the timing of the AE cannot be established in relation to the first administration of investigational drug, it will be considered as TEAE to be more conservative.

D-1553 related TEAE is defined as the relationship with D-1553 as 'Definitely Related' or 'Probably Related' or 'Possibly Related' or 'Related/Reasonable Possibility'. To be conservative, if the relationship is missing, TEAE is still considered as D-1553 related TEAE.

Adverse events are coded with MedDRA 25.0.

Subjects with multiple occurrences of adverse events in the same grouped preferred term are counted only once within that grouped preferred term.

Subjects with multiple occurrences of adverse events in the same grouped system organ class are counted only once within that grouped system organ class.

Percentages are based on the number of subjects of each respective group in Safety Analysis Set.

Source Data: Listing 16.2.7.1

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| **InxMed (Shanghai) Co., Ltd.  Protocol No. IN10018-602** |  |

**Table 14.3.1.8.4.5 Summary of IN10018 Related AESI by SOC and PT - Phase II part 2 - CRC (Safety Analysis Set)**

| System Organ Class  Preferred Term | Treatment Group (N = 5) n (%) | Control Group (N = 5) n (%) | Total (N = 10) n (%) |
| --- | --- | --- | --- |
| IN10018 Related AESI | 0 | 0 | 0 |

TEAE is defined as any AE that newly occurs or worsen after the first investigational drug administration and within end of safety follow up period (i.e., within 30 calendar days after the last administration of investigational drug or the start of new anti-cancer therapy (whichever occurs earlier)). If the timing of the AE cannot be established in relation to the first administration of investigational drug, it will be considered as TEAE to be more conservative.

IN10018 related TEAE is defined as the relationship with IN10018 as 'Definitely Related' or 'Probably Related' or 'Possibly Related' or 'Related/Reasonable Possibility'. To be conservative, if the relationship is missing, TEAE is still considered as IN10018 related TEAE.

Adverse events are coded with MedDRA 25.0.

Subjects with multiple occurrences of adverse events in the same preferred term are counted only once within that preferred term.

Subjects with multiple occurrences of adverse events in the same system organ class are counted only once within that system organ class.

Percentages are based on the number of subjects of each respective group in Safety Analysis Set.

Source Data: Listing 16.2.7.1

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| Program: t-ae-soc-pt.sas | DCO: 27APR2024 | Executed: 08JUL2024 17:16 |

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| --- | --- |
| **InxMed (Shanghai) Co., Ltd.  Protocol No. IN10018-602** |  |

**Table 14.3.1.8.4.6 Summary of IN10018 Related AESI by Grouped SOC and Grouped PT - Phase II part 2 - CRC (Safety Analysis Set)**

| System Organ Class  Preferred Term | Treatment Group (N = 5) n (%) | Control Group (N = 5) n (%) | Total (N = 10) n (%) |
| --- | --- | --- | --- |
| IN10018 Related AESI | 0 | 0 | 0 |

TEAE is defined as any AE that newly occurs or worsen after the first investigational drug administration and within end of safety follow up period (i.e., within 30 calendar days after the last administration of investigational drug or the start of new anti-cancer therapy (whichever occurs earlier)). If the timing of the AE cannot be established in relation to the first administration of investigational drug, it will be considered as TEAE to be more conservative.

IN10018 related TEAE is defined as the relationship with IN10018 as 'Definitely Related' or 'Probably Related' or 'Possibly Related' or 'Related/Reasonable Possibility'. To be conservative, if the relationship is missing, TEAE is still considered as IN10018 related TEAE.

Adverse events are coded with MedDRA 25.0.

Subjects with multiple occurrences of adverse events in the same grouped preferred term are counted only once within that grouped preferred term.

Subjects with multiple occurrences of adverse events in the same grouped system organ class are counted only once within that grouped system organ class.

Percentages are based on the number of subjects of each respective group in Safety Analysis Set.

Source Data: Listing 16.2.7.1

|  |  |  |
| --- | --- | --- |
| Program: t-ae-soc-pt.sas | DCO: 27APR2024 | Executed: 08JUL2024 17:16 |

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| **InxMed (Shanghai) Co., Ltd.  Protocol No. IN10018-602** |  |

**Table 14.3.1.9.1.3 Summary of SAEs by SOC and PT - Phase II part 2 - CRC (Safety Analysis Set)**

| System Organ Class  Preferred Term | Treatment Group (N = 5) n (%) | Control Group (N = 5) n (%) | Total (N = 10) n (%) |
| --- | --- | --- | --- |
| All SAEs | 2 (40.0) | 1 (20.0) | 3 (30.0) |
|  | | | |
| Gastrointestinal disorders | 1 (20.0) | 0 | 1 (10.0) |
| Intestinal obstruction | 1 (20.0) | 0 | 1 (10.0) |
|  | | | |
| Infections and infestations | 0 | 1 (20.0) | 1 (10.0) |
| COVID-19 | 0 | 1 (20.0) | 1 (10.0) |
|  | | | |
| Renal and urinary disorders | 1 (20.0) | 0 | 1 (10.0) |
| Acute kidney injury | 1 (20.0) | 0 | 1 (10.0) |

TEAE is defined as any AE that newly occurs or worsen after the first investigational drug administration and within end of safety follow up period (i.e., within 30 calendar days after the last administration of investigational drug or the start of new anti-cancer therapy (whichever occurs earlier)). If the timing of the AE cannot be established in relation to the first administration of investigational drug, it will be considered as TEAE to be more conservative.

Adverse events are coded with MedDRA 25.0.

Subjects with multiple occurrences of adverse events in the same preferred term are counted only once within that preferred term.

Subjects with multiple occurrences of adverse events in the same system organ class are counted only once within that system organ class.

Percentages are based on the number of subjects of each respective group in Safety Analysis Set.

Source Data: Listing 16.2.7.1

|  |  |  |
| --- | --- | --- |
| Program: t-ae-soc-pt.sas | DCO: 27APR2024 | Executed: 08JUL2024 17:16 |

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| --- | --- |
| **InxMed (Shanghai) Co., Ltd.  Protocol No. IN10018-602** |  |

**Table 14.3.1.9.2.3 Summary of D-1553 Related SAEs by SOC and PT - Phase II part 2 - CRC (Safety Analysis Set)**

| System Organ Class  Preferred Term | Treatment Group (N = 5) n (%) | Control Group (N = 5) n (%) | Total (N = 10) n (%) |
| --- | --- | --- | --- |
| D-1553 Related SAEs | 2 (40.0) | 0 | 2 (20.0) |
|  | | | |
| Gastrointestinal disorders | 1 (20.0) | 0 | 1 (10.0) |
| Intestinal obstruction | 1 (20.0) | 0 | 1 (10.0) |
|  | | | |
| Renal and urinary disorders | 1 (20.0) | 0 | 1 (10.0) |
| Acute kidney injury | 1 (20.0) | 0 | 1 (10.0) |

TEAE is defined as any AE that newly occurs or worsen after the first investigational drug administration and within end of safety follow up period (i.e., within 30 calendar days after the last administration of investigational drug or the start of new anti-cancer therapy (whichever occurs earlier)). If the timing of the AE cannot be established in relation to the first administration of investigational drug, it will be considered as TEAE to be more conservative.

D-1553 related TEAE is defined as the relationship with D-1553 as 'Definitely Related' or 'Probably Related' or 'Possibly Related' or 'Related/Reasonable Possibility'. To be conservative, if the relationship is missing, TEAE is still considered as D-1553 related TEAE.

Adverse events are coded with MedDRA 25.0.

Subjects with multiple occurrences of adverse events in the same preferred term are counted only once within that preferred term.

Subjects with multiple occurrences of adverse events in the same system organ class are counted only once within that system organ class.

Percentages are based on the number of subjects of each respective group in Safety Analysis Set.

Source Data: Listing 16.2.7.1

|  |  |  |
| --- | --- | --- |
| Program: t-ae-soc-pt.sas | DCO: 27APR2024 | Executed: 08JUL2024 17:16 |

|  |  |
| --- | --- |
| **InxMed (Shanghai) Co., Ltd.  Protocol No. IN10018-602** |  |

**Table 14.3.1.9.2.6 Summary of IN10018 Related SAEs by SOC and PT - Phase II part 2 - CRC (Safety Analysis Set)**

| System Organ Class  Preferred Term | Treatment Group (N = 5) n (%) | Control Group (N = 5) n (%) | Total (N = 10) n (%) |
| --- | --- | --- | --- |
| IN10018 Related SAEs | 2 (40.0) | 0 | 2 (20.0) |
|  | | | |
| Gastrointestinal disorders | 1 (20.0) | 0 | 1 (10.0) |
| Intestinal obstruction | 1 (20.0) | 0 | 1 (10.0) |
|  | | | |
| Renal and urinary disorders | 1 (20.0) | 0 | 1 (10.0) |
| Acute kidney injury | 1 (20.0) | 0 | 1 (10.0) |

TEAE is defined as any AE that newly occurs or worsen after the first investigational drug administration and within end of safety follow up period (i.e., within 30 calendar days after the last administration of investigational drug or the start of new anti-cancer therapy (whichever occurs earlier)). If the timing of the AE cannot be established in relation to the first administration of investigational drug, it will be considered as TEAE to be more conservative.

IN10018 related TEAE is defined as the relationship with IN10018 as 'Definitely Related' or 'Probably Related' or 'Possibly Related' or 'Related/Reasonable Possibility'. To be conservative, if the relationship is missing, TEAE is still considered as IN10018 related TEAE.

Adverse events are coded with MedDRA 25.0.

Subjects with multiple occurrences of adverse events in the same preferred term are counted only once within that preferred term.

Subjects with multiple occurrences of adverse events in the same system organ class are counted only once within that system organ class.

Percentages are based on the number of subjects of each respective group in Safety Analysis Set.

Source Data: Listing 16.2.7.1

|  |  |  |
| --- | --- | --- |
| Program: t-ae-soc-pt.sas | DCO: 27APR2024 | Executed: 08JUL2024 17:16 |

|  |  |
| --- | --- |
| **InxMed (Shanghai) Co., Ltd.  Protocol No. IN10018-602** |  |

**Table 14.3.1.10.1.3 Summary of TEAEs Leading to Death by SOC and PT - Phase II part 2 - CRC (Safety Analysis Set)**

| System Organ Class  Preferred Term | Treatment Group (N = 5) n (%) | Control Group (N = 5) n (%) | Total (N = 10) n (%) |
| --- | --- | --- | --- |
| TEAEs Leading to Death | 0 | 0 | 0 |

TEAE is defined as any AE that newly occurs or worsen after the first investigational drug administration and within end of safety follow up period (i.e., within 30 calendar days after the last administration of investigational drug or the start of new anti-cancer therapy (whichever occurs earlier)). If the timing of the AE cannot be established in relation to the first administration of investigational drug, it will be considered as TEAE to be more conservative.

Adverse events are coded with MedDRA 25.0.

Subjects with multiple occurrences of adverse events in the same preferred term are counted only once within that preferred term.

Subjects with multiple occurrences of adverse events in the same system organ class are counted only once within that system organ class.

Percentages are based on the number of subjects of each respective group in Safety Analysis Set.

Source Data: Listing 16.2.7.1

|  |  |  |
| --- | --- | --- |
| Program: t-ae-soc-pt.sas | DCO: 27APR2024 | Executed: 08JUL2024 17:16 |

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| --- | --- |
| **InxMed (Shanghai) Co., Ltd.  Protocol No. IN10018-602** |  |

**Table 14.3.1.10.2.3 Summary of D-1553 Related TEAEs Leading to Death by SOC and PT - Phase II part 2 - CRC (Safety Analysis Set)**

| System Organ Class  Preferred Term | Treatment Group (N = 5) n (%) | Control Group (N = 5) n (%) | Total (N = 10) n (%) |
| --- | --- | --- | --- |
| D-1553 Related TEAEs Leading to Death | 0 | 0 | 0 |

TEAE is defined as any AE that newly occurs or worsen after the first investigational drug administration and within end of safety follow up period (i.e., within 30 calendar days after the last administration of investigational drug or the start of new anti-cancer therapy (whichever occurs earlier)). If the timing of the AE cannot be established in relation to the first administration of investigational drug, it will be considered as TEAE to be more conservative.

D-1553 related TEAE is defined as the relationship with D-1553 as 'Definitely Related' or 'Probably Related' or 'Possibly Related' or 'Related/Reasonable Possibility'. To be conservative, if the relationship is missing, TEAE is still considered as D-1553 related TEAE.

Adverse events are coded with MedDRA 25.0.

Subjects with multiple occurrences of adverse events in the same preferred term are counted only once within that preferred term.

Subjects with multiple occurrences of adverse events in the same system organ class are counted only once within that system organ class.

Percentages are based on the number of subjects of each respective group in Safety Analysis Set.

Source Data: Listing 16.2.7.1

|  |  |  |
| --- | --- | --- |
| Program: t-ae-soc-pt.sas | DCO: 27APR2024 | Executed: 08JUL2024 17:16 |

|  |  |
| --- | --- |
| **InxMed (Shanghai) Co., Ltd.  Protocol No. IN10018-602** |  |

**Table 14.3.1.10.2.6 Summary of IN10018 Related TEAEs Leading to Death by SOC and PT - Phase II part 2 - CRC (Safety Analysis Set)**

| System Organ Class  Preferred Term | Treatment Group (N = 5) n (%) | Control Group (N = 5) n (%) | Total (N = 10) n (%) |
| --- | --- | --- | --- |
| IN10018 Related TEAEs Leading to Death | 0 | 0 | 0 |

TEAE is defined as any AE that newly occurs or worsen after the first investigational drug administration and within end of safety follow up period (i.e., within 30 calendar days after the last administration of investigational drug or the start of new anti-cancer therapy (whichever occurs earlier)). If the timing of the AE cannot be established in relation to the first administration of investigational drug, it will be considered as TEAE to be more conservative.

IN10018 related TEAE is defined as the relationship with IN10018 as 'Definitely Related' or 'Probably Related' or 'Possibly Related' or 'Related/Reasonable Possibility'. To be conservative, if the relationship is missing, TEAE is still considered as IN10018 related TEAE.

Adverse events are coded with MedDRA 25.0.

Subjects with multiple occurrences of adverse events in the same preferred term are counted only once within that preferred term.

Subjects with multiple occurrences of adverse events in the same system organ class are counted only once within that system organ class.

Percentages are based on the number of subjects of each respective group in Safety Analysis Set.

Source Data: Listing 16.2.7.1

|  |  |  |
| --- | --- | --- |
| Program: t-ae-soc-pt.sas | DCO: 27APR2024 | Executed: 08JUL2024 17:16 |

|  |  |
| --- | --- |
| **InxMed (Shanghai) Co., Ltd.  Protocol No. IN10018-602** |  |

**Table 14.3.1.11.3 Summary of Deaths - Phase II part 2 - CRC (Safety Analysis Set)**

|  | Treatment Group (N = 5) n (%) | Control Group (N = 5) n (%) | Total (N = 10) n (%) |
| --- | --- | --- | --- |
| All Deaths | 0 | 1 (20.0) | 1 (10.0) |
|  | | | |
| On-treatment Deaths | 0 | 0 | 0 |
| Progressive Disease (PD) | 0 | 0 | 0 |
| Adverse Events | 0 | 0 | 0 |
| Unknown | 0 | 0 | 0 |
| Other | 0 | 0 | 0 |
|  | | | |
| Safety follow-up Deaths | 0 | 0 | 0 |
| Progressive Disease (PD) | 0 | 0 | 0 |
| Adverse Events | 0 | 0 | 0 |
| Unknown | 0 | 0 | 0 |
| Other | 0 | 0 | 0 |
|  | | | |
| Survival follow-up Deaths | 0 | 1 (20.0) | 1 (10.0) |
| Progressive Disease (PD) | 0 | 1 (20.0) | 1 (10.0) |
| Adverse Events | 0 | 0 | 0 |
| Unknown | 0 | 0 | 0 |
| Other | 0 | 0 | 0 |

Percentages are based on the number of subjects of each respective group in the Safety Analysis Set.

Source Data: Listing 16.2.7.16

|  |  |  |
| --- | --- | --- |
| Program: t-dd.sas | DCO: 27APR2024 | Executed: 07JUL2024 20:45 |

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| **InxMed (Shanghai) Co., Ltd.  Protocol No. IN10018-602** |  |

**Table 14.3.1.12.1.3 Summary of Abnormal Liver Function by PT and Severity - Phase II part 2 - CRC (Safety Analysis Set)**

|  | | Total n (%) | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Group | Preferred Term | Grade 1 | Grade 2 | Grade 3 | Grade 4 | Grade 5 | ≥Grade 3 | Total |
| Treatment Group (N = 5) | Subjects with At Least One Abnormal Liver Function | 1 (20.0) | 1 (20.0) | 0 | 0 | 0 | 0 | 2 (40.0) |
|  | | | | | | | | |
|  | Alanine aminotransferase increased | 2 (40.0) | 0 | 0 | 0 | 0 | 0 | 2 (40.0) |
|  | | | | | | | | |
|  | Aspartate aminotransferase increased | 1 (20.0) | 0 | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | | | | | | | | |
|  | Gamma-glutamyltransferase increased | 0 | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | | | | | | | | |
|  | Subjects with At Least One D-1553 Related Abnormal Liver Function | 1 (20.0) | 1 (20.0) | 0 | 0 | 0 | 0 | 2 (40.0) |
|  | | | | | | | | |
|  | Alanine aminotransferase increased | 2 (40.0) | 0 | 0 | 0 | 0 | 0 | 2 (40.0) |
|  | | | | | | | | |
|  | Aspartate aminotransferase increased | 1 (20.0) | 0 | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | | | | | | | | |
|  | Gamma-glutamyltransferase increased | 0 | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | | | | | | | | |
|  | Subjects with At Least One IN10018 Related Abnormal Liver Function | 1 (20.0) | 1 (20.0) | 0 | 0 | 0 | 0 | 2 (40.0) |
|  | | | | | | | | |
|  | Alanine aminotransferase increased | 2 (40.0) | 0 | 0 | 0 | 0 | 0 | 2 (40.0) |
|  | | | | | | | | |
|  | Aspartate aminotransferase increased | 1 (20.0) | 0 | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | | | | | | | | |
|  | Gamma-glutamyltransferase increased | 0 | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | | | | | | | | |
| Control Group (N = 5) | Subjects with At Least One Abnormal Liver Function | 3 (60.0) | 0 | 0 | 0 | 0 | 0 | 3 (60.0) |
|  | | | | | | | | |
|  | Alanine aminotransferase increased | 2 (40.0) | 0 | 0 | 0 | 0 | 0 | 2 (40.0) |
|  | | | | | | | | |
|  | Aspartate aminotransferase increased | 2 (40.0) | 0 | 0 | 0 | 0 | 0 | 2 (40.0) |
|  | | | | | | | | |
|  | Blood bilirubin increased | 1 (20.0) | 0 | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | | | | | | | | |
|  | Gamma-glutamyltransferase increased | 1 (20.0) | 0 | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | | | | | | | | |
|  | Total bile acids increased | 1 (20.0) | 0 | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | | | | | | | | |
|  | Subjects with At Least One D-1553 Related Abnormal Liver Function | 3 (60.0) | 0 | 0 | 0 | 0 | 0 | 3 (60.0) |
|  | | | | | | | | |
|  | Alanine aminotransferase increased | 2 (40.0) | 0 | 0 | 0 | 0 | 0 | 2 (40.0) |
|  | | | | | | | | |
|  | Aspartate aminotransferase increased | 2 (40.0) | 0 | 0 | 0 | 0 | 0 | 2 (40.0) |
|  | | | | | | | | |
|  | Blood bilirubin increased | 1 (20.0) | 0 | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | | | | | | | | |
|  | Gamma-glutamyltransferase increased | 1 (20.0) | 0 | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | | | | | | | | |
|  | Total bile acids increased | 1 (20.0) | 0 | 0 | 0 | 0 | 0 | 1 (20.0) |
|  | | | | | | | | |
| Total (N = 10) | Subjects with At Least One Abnormal Liver Function | 4 (40.0) | 1 (10.0) | 0 | 0 | 0 | 0 | 5 (50.0) |
|  | | | | | | | | |
|  | Alanine aminotransferase increased | 4 (40.0) | 0 | 0 | 0 | 0 | 0 | 4 (40.0) |
|  | | | | | | | | |
|  | Aspartate aminotransferase increased | 3 (30.0) | 0 | 0 | 0 | 0 | 0 | 3 (30.0) |
|  | | | | | | | | |
|  | Gamma-glutamyltransferase increased | 1 (10.0) | 1 (10.0) | 0 | 0 | 0 | 0 | 2 (20.0) |
|  | | | | | | | | |
|  | Blood bilirubin increased | 1 (10.0) | 0 | 0 | 0 | 0 | 0 | 1 (10.0) |
|  | | | | | | | | |
|  | Total bile acids increased | 1 (10.0) | 0 | 0 | 0 | 0 | 0 | 1 (10.0) |
|  | | | | | | | | |
|  | Subjects with At Least One D-1553 Related Abnormal Liver Function | 4 (40.0) | 1 (10.0) | 0 | 0 | 0 | 0 | 5 (50.0) |
|  | | | | | | | | |
|  | Alanine aminotransferase increased | 4 (40.0) | 0 | 0 | 0 | 0 | 0 | 4 (40.0) |
|  | | | | | | | | |
|  | Aspartate aminotransferase increased | 3 (30.0) | 0 | 0 | 0 | 0 | 0 | 3 (30.0) |
|  | | | | | | | | |
|  | Gamma-glutamyltransferase increased | 1 (10.0) | 1 (10.0) | 0 | 0 | 0 | 0 | 2 (20.0) |
|  | | | | | | | | |
|  | Blood bilirubin increased | 1 (10.0) | 0 | 0 | 0 | 0 | 0 | 1 (10.0) |
|  | | | | | | | | |
|  | Total bile acids increased | 1 (10.0) | 0 | 0 | 0 | 0 | 0 | 1 (10.0) |
|  | | | | | | | | |
|  | Subjects with At Least One IN10018 Related Abnormal Liver Function | 1 (10.0) | 1 (10.0) | 0 | 0 | 0 | 0 | 2 (20.0) |
|  | | | | | | | | |
|  | Alanine aminotransferase increased | 2 (20.0) | 0 | 0 | 0 | 0 | 0 | 2 (20.0) |
|  | | | | | | | | |
|  | Aspartate aminotransferase increased | 1 (10.0) | 0 | 0 | 0 | 0 | 0 | 1 (10.0) |
|  | | | | | | | | |
|  | Gamma-glutamyltransferase increased | 0 | 1 (10.0) | 0 | 0 | 0 | 0 | 1 (10.0) |

Grade 1: Mild, Grade 2: Moderate, Grade 3: Severe, Grade 4: Life threatening, Grade 5: Death related to AE.

TEAE is defined as any AE that newly occurs or worsen after the first investigational drug administration and within end of safety follow up period (i.e., within 30 calendar days after the last administration of investigational drug or the start of new anti-cancer therapy (whichever occurs earlier)). If the timing of the AE cannot be established in relation to the first administration of investigational drug, it will be considered as TEAE to be more conservative.

Adverse events are coded with MedDRA 25.0.

Subjects with multiple occurrences of adverse events in the same preferred term are counted only once within that preferred term at the maximum severity.

Percentages are based on the number of subjects of each respective group in the Safety Analysis Set.

Source Data: Listing 16.2.7.13

|  |  |  |
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| Program: t-ae-pt.sas | DCO: 27APR2024 | Executed: 07JUL2024 20:45 |

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| **InxMed (Shanghai) Co., Ltd.  Protocol No. IN10018-602** |  |

**Table 14.3.1.12.2.3 Incidence and Prevalence of Abnormal Liver Function over Time - Phase II part 2 - CRC (Safety Analysis Set)**

|  | Treatment Group (N = 5) [n/# at risk (%)] | Control Group (N = 5) [n/# at risk (%)] | Total (N = 10) [n/# at risk (%)] |
| --- | --- | --- | --- |
| Incidence |  |  |  |
| Abnormal Liver Function |  |  |  |
| 1st 30 days | 2 / 5 (40.0) | 3 / 5 (60.0) | 5 / 10 (50.0) |
| 2nd 30 days | 0 / 4 | 1 / 4 (25.0) | 1 / 8 (12.5) |
| 3rd 30 days | 0 / 2 | 1 / 2 (50.0) | 1 / 4 (25.0) |
| > 3rd 30 days | 0 / 2 | 0 / 1 | 0 / 3 |
|  | | | |
| D-1553 Related Abnormal Liver Function |  |  |  |
| 1st 30 days | 2 / 5 (40.0) | 3 / 5 (60.0) | 5 / 10 (50.0) |
| 2nd 30 days | 0 / 4 | 1 / 4 (25.0) | 1 / 8 (12.5) |
| 3rd 30 days | 0 / 2 | 1 / 2 (50.0) | 1 / 4 (25.0) |
| > 3rd 30 days | 0 / 2 | 0 / 1 | 0 / 3 |
|  | | | |
| CTCAE 3/4 Abnormal Liver Function |  |  |  |
| 1st 30 days | 0 / 5 | 0 / 5 | 0 / 10 |
| 2nd 30 days | 0 / 4 | 0 / 4 | 0 / 8 |
| 3rd 30 days | 0 / 2 | 0 / 2 | 0 / 4 |
| > 3rd 30 days | 0 / 2 | 0 / 1 | 0 / 3 |
|  | | | |
| CTCAE 3/4 D-1553 Related Abnormal Liver Function |  |  |  |
| 1st 30 days | 0 / 5 | 0 / 5 | 0 / 10 |
| 2nd 30 days | 0 / 4 | 0 / 4 | 0 / 8 |
| 3rd 30 days | 0 / 2 | 0 / 2 | 0 / 4 |
| > 3rd 30 days | 0 / 2 | 0 / 1 | 0 / 3 |
|  | | | |
| AESI of Abnormal Liver Function |  |  |  |
| 1st 30 days | 0 / 5 | 0 / 5 | 0 / 10 |
| 2nd 30 days | 0 / 4 | 0 / 4 | 0 / 8 |
| 3rd 30 days | 0 / 2 | 0 / 2 | 0 / 4 |
| > 3rd 30 days | 0 / 2 | 0 / 1 | 0 / 3 |
|  | | | |
| AESI of D-1553 Related Abnormal Liver Function |  |  |  |
| 1st 30 days | 0 / 5 | 0 / 5 | 0 / 10 |
| 2nd 30 days | 0 / 4 | 0 / 4 | 0 / 8 |
| 3rd 30 days | 0 / 2 | 0 / 2 | 0 / 4 |
| > 3rd 30 days | 0 / 2 | 0 / 1 | 0 / 3 |
|  | | | |
| Prevalence |  |  |  |
| Abnormal Liver Function |  |  |  |
| 1st 30 days | 2 / 5 (40.0) | 3 / 5 (60.0) | 5 / 10 (50.0) |
| 2nd 30 days | 1 / 4 (25.0) | 2 / 4 (50.0) | 3 / 8 (37.5) |
| 3rd 30 days | 0 / 2 | 2 / 2 (100) | 2 / 4 (50.0) |
| > 3rd 30 days | 0 / 2 | 1 / 1 (100) | 1 / 3 (33.3) |
|  | | | |
| D-1553 Related Abnormal Liver Function |  |  |  |
| 1st 30 days | 2 / 5 (40.0) | 3 / 5 (60.0) | 5 / 10 (50.0) |
| 2nd 30 days | 1 / 4 (25.0) | 2 / 4 (50.0) | 3 / 8 (37.5) |
| 3rd 30 days | 0 / 2 | 2 / 2 (100) | 2 / 4 (50.0) |
| > 3rd 30 days | 0 / 2 | 1 / 1 (100) | 1 / 3 (33.3) |
|  | | | |
| CTCAE 3/4 Abnormal Liver Function |  |  |  |
| 1st 30 days | 0 / 5 | 0 / 5 | 0 / 10 |
| 2nd 30 days | 0 / 4 | 0 / 4 | 0 / 8 |
| 3rd 30 days | 0 / 2 | 0 / 2 | 0 / 4 |
| > 3rd 30 days | 0 / 2 | 0 / 1 | 0 / 3 |
|  | | | |
| CTCAE 3/4 D-1553 Related Abnormal Liver Function |  |  |  |
| 1st 30 days | 0 / 5 | 0 / 5 | 0 / 10 |
| 2nd 30 days | 0 / 4 | 0 / 4 | 0 / 8 |
| 3rd 30 days | 0 / 2 | 0 / 2 | 0 / 4 |
| > 3rd 30 days | 0 / 2 | 0 / 1 | 0 / 3 |
|  | | | |
| AESI of Abnormal Liver Function |  |  |  |
| 1st 30 days | 0 / 5 | 0 / 5 | 0 / 10 |
| 2nd 30 days | 0 / 4 | 0 / 4 | 0 / 8 |
| 3rd 30 days | 0 / 2 | 0 / 2 | 0 / 4 |
| > 3rd 30 days | 0 / 2 | 0 / 1 | 0 / 3 |
|  | | | |
| AESI of D-1553 Related Abnormal Liver Function |  |  |  |
| 1st 30 days | 0 / 5 | 0 / 5 | 0 / 10 |
| 2nd 30 days | 0 / 4 | 0 / 4 | 0 / 8 |
| 3rd 30 days | 0 / 2 | 0 / 2 | 0 / 4 |
| > 3rd 30 days | 0 / 2 | 0 / 1 | 0 / 3 |

n = number of subjects with onset of Abnormal Liver Function in the time interval.

# at risk = number of subjects on D-1553/IN10018 administration or within 30 days post last dose of D-1553/IN10018 at the beginning of the time interval.

Source Data: Listing 16.2.7.13

|  |  |  |
| --- | --- | --- |
| Program: t-ae-time.sas | DCO: 27APR2024 | Executed: 08JUL2024 17:16 |

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| **InxMed (Shanghai) Co., Ltd.  Protocol No. IN10018-602** |  |

**Table 14.3.1.13.1.3 Summary of Proteinuria by Grouped PT and Severity - Phase II part 2 - CRC (Safety Analysis Set)**

|  | | Total n (%) | | | |
| --- | --- | --- | --- | --- | --- |
| Group | Preferred Term | Grade 1 | Grade 2 | Grade 3 | Total |
| Treatment Group (N = 5) | Subjects with At Least One Proteinuria | 2 (40.0) | 1 (20.0) | 0 | 3 (60.0) |
|  | | | | | |
|  | Proteinuria\* | 2 (40.0) | 1 (20.0) | 0 | 3 (60.0) |
|  | | | | | |
|  | Subjects with At Least One D-1553 Related Proteinuria | 2 (40.0) | 1 (20.0) | 0 | 3 (60.0) |
|  | | | | | |
|  | Proteinuria\* | 2 (40.0) | 1 (20.0) | 0 | 3 (60.0) |
|  | | | | | |
|  | Subjects with At Least One IN10018 Related Proteinuria | 2 (40.0) | 1 (20.0) | 0 | 3 (60.0) |
|  | | | | | |
|  | Proteinuria\* | 2 (40.0) | 1 (20.0) | 0 | 3 (60.0) |
|  | | | | | |
| Control Group (N = 5) | Subjects with At Least One Proteinuria | 0 | 0 | 0 | 0 |
|  | | | | | |
| Total (N = 10) | Subjects with At Least One Proteinuria | 2 (20.0) | 1 (10.0) | 0 | 3 (30.0) |
|  | | | | | |
|  | Proteinuria\* | 2 (20.0) | 1 (10.0) | 0 | 3 (30.0) |
|  | | | | | |
|  | Subjects with At Least One D-1553 Related Proteinuria | 2 (20.0) | 1 (10.0) | 0 | 3 (30.0) |
|  | | | | | |
|  | Proteinuria\* | 2 (20.0) | 1 (10.0) | 0 | 3 (30.0) |
|  | | | | | |
|  | Subjects with At Least One IN10018 Related Proteinuria | 2 (20.0) | 1 (10.0) | 0 | 3 (30.0) |
|  | | | | | |
|  | Proteinuria\* | 2 (20.0) | 1 (10.0) | 0 | 3 (30.0) |

Grade 1: Mild, Grade 2: Moderate, Grade 3: Severe, Grade 4: Life threatening, Grade 5: Death related to AE.

TEAE is defined as any AE that newly occurs or worsen after the first investigational drug administration and within end of safety follow up period (i.e., within 30 calendar days after the last administration of investigational drug or the start of new anti-cancer therapy (whichever occurs earlier)). If the timing of the AE cannot be established in relation to the first administration of investigational drug, it will be considered as TEAE to be more conservative.

Adverse events are coded with MedDRA 25.0.

Subjects with multiple occurrences of adverse events in the same grouped preferred term are counted only once within that grouped preferred term at the maximum severity.

Percentages are based on the number of subjects of each respective group in the Safety Analysis Set.

\*: Grouped PT.  
Source Data: Listing 16.2.7.14

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| Program: t-ae-pt.sas | DCO: 27APR2024 | Executed: 07JUL2024 20:45 |

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| **InxMed (Shanghai) Co., Ltd.  Protocol No. IN10018-602** |  |

**Table 14.3.1.13.2.3 Incidence and Prevalence of Proteinuria over Time - Phase II part 2 - CRC (Safety Analysis Set)**

|  | Treatment Group (N = 5) [n/# at risk (%)] | Control Group (N = 5) [n/# at risk (%)] | Total (N = 10) [n/# at risk (%)] |
| --- | --- | --- | --- |
| Incidence |  |  |  |
| Proteinuria |  |  |  |
| 1st 30 days | 3 / 5 (60.0) | 0 / 5 | 3 / 10 (30.0) |
| 2nd 30 days | 0 / 4 | 0 / 4 | 0 / 8 |
| 3rd 30 days | 1 / 2 (50.0) | 0 / 2 | 1 / 4 (25.0) |
| > 3rd 30 days | 0 / 2 | 0 / 1 | 0 / 3 |
|  | | | |
| IN10018 Related Proteinuria |  |  |  |
| 1st 30 days | 3 / 5 (60.0) | 0 / 5 | 3 / 10 (30.0) |
| 2nd 30 days | 0 / 4 | 0 / 4 | 0 / 8 |
| 3rd 30 days | 1 / 2 (50.0) | 0 / 2 | 1 / 4 (25.0) |
| > 3rd 30 days | 0 / 2 | 0 / 1 | 0 / 3 |
|  | | | |
| CTCAE 3 Proteinuria |  |  |  |
| 1st 30 days | 0 / 5 | 0 / 5 | 0 / 10 |
| 2nd 30 days | 0 / 4 | 0 / 4 | 0 / 8 |
| 3rd 30 days | 0 / 2 | 0 / 2 | 0 / 4 |
| > 3rd 30 days | 0 / 2 | 0 / 1 | 0 / 3 |
|  | | | |
| CTCAE 3 IN10018 Related Proteinuria |  |  |  |
| 1st 30 days | 0 / 5 | 0 / 5 | 0 / 10 |
| 2nd 30 days | 0 / 4 | 0 / 4 | 0 / 8 |
| 3rd 30 days | 0 / 2 | 0 / 2 | 0 / 4 |
| > 3rd 30 days | 0 / 2 | 0 / 1 | 0 / 3 |
|  | | | |
| AESI of Proteinuria |  |  |  |
| 1st 30 days | 0 / 5 | 0 / 5 | 0 / 10 |
| 2nd 30 days | 0 / 4 | 0 / 4 | 0 / 8 |
| 3rd 30 days | 0 / 2 | 0 / 2 | 0 / 4 |
| > 3rd 30 days | 0 / 2 | 0 / 1 | 0 / 3 |
|  | | | |
| AESI of IN10018 Related Proteinuria |  |  |  |
| 1st 30 days | 0 / 5 | 0 / 5 | 0 / 10 |
| 2nd 30 days | 0 / 4 | 0 / 4 | 0 / 8 |
| 3rd 30 days | 0 / 2 | 0 / 2 | 0 / 4 |
| > 3rd 30 days | 0 / 2 | 0 / 1 | 0 / 3 |
|  | | | |
| Prevalence |  |  |  |
| Proteinuria |  |  |  |
| 1st 30 days | 3 / 5 (60.0) | 0 / 5 | 3 / 10 (30.0) |
| 2nd 30 days | 1 / 4 (25.0) | 0 / 4 | 1 / 8 (12.5) |
| 3rd 30 days | 1 / 2 (50.0) | 0 / 2 | 1 / 4 (25.0) |
| > 3rd 30 days | 1 / 2 (50.0) | 0 / 1 | 1 / 3 (33.3) |
|  | | | |
| IN10018 Related Proteinuria |  |  |  |
| 1st 30 days | 3 / 5 (60.0) | 0 / 5 | 3 / 10 (30.0) |
| 2nd 30 days | 1 / 4 (25.0) | 0 / 4 | 1 / 8 (12.5) |
| 3rd 30 days | 1 / 2 (50.0) | 0 / 2 | 1 / 4 (25.0) |
| > 3rd 30 days | 1 / 2 (50.0) | 0 / 1 | 1 / 3 (33.3) |
|  | | | |
| CTCAE 3 Proteinuria |  |  |  |
| 1st 30 days | 0 / 5 | 0 / 5 | 0 / 10 |
| 2nd 30 days | 0 / 4 | 0 / 4 | 0 / 8 |
| 3rd 30 days | 0 / 2 | 0 / 2 | 0 / 4 |
| > 3rd 30 days | 0 / 2 | 0 / 1 | 0 / 3 |
|  | | | |
| CTCAE 3 IN10018 Related Proteinuria |  |  |  |
| 1st 30 days | 0 / 5 | 0 / 5 | 0 / 10 |
| 2nd 30 days | 0 / 4 | 0 / 4 | 0 / 8 |
| 3rd 30 days | 0 / 2 | 0 / 2 | 0 / 4 |
| > 3rd 30 days | 0 / 2 | 0 / 1 | 0 / 3 |
|  | | | |
| AESI of Proteinuria |  |  |  |
| 1st 30 days | 0 / 5 | 0 / 5 | 0 / 10 |
| 2nd 30 days | 0 / 4 | 0 / 4 | 0 / 8 |
| 3rd 30 days | 0 / 2 | 0 / 2 | 0 / 4 |
| > 3rd 30 days | 0 / 2 | 0 / 1 | 0 / 3 |
|  | | | |
| AESI of IN10018 Related Proteinuria |  |  |  |
| 1st 30 days | 0 / 5 | 0 / 5 | 0 / 10 |
| 2nd 30 days | 0 / 4 | 0 / 4 | 0 / 8 |
| 3rd 30 days | 0 / 2 | 0 / 2 | 0 / 4 |
| > 3rd 30 days | 0 / 2 | 0 / 1 | 0 / 3 |

n = number of subjects with onset of Proteinuria in the time interval.

# at risk = number of subjects on D-1553/IN10018 administration or within 30 days post last dose of D-1553/IN10018 at the beginning of the time interval.

Source Data: Listing 16.2.7.14

|  |  |  |
| --- | --- | --- |
| Program: t-ae-time.sas | DCO: 27APR2024 | Executed: 08JUL2024 17:16 |

|  |  |
| --- | --- |
| **InxMed (Shanghai) Co., Ltd.  Protocol No. IN10018-602** |  |

**Table 14.3.5.1.1.3 Summary of Hematology Results - Phase II part 2 - CRC (Safety Analysis Set)**

|  | | | Observed Value | | | | Change from Baseline | | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Parameter | Group | Visit | n | Mean (STD) | Median (Q1, Q3) | Min, Max | n | Mean (STD) | Median (Q1, Q3) | Min, Max |
| Erythrocytes (10^12/L) | Treatment Group (N = 5) | Baseline | 5 | 4.174 (0.3462) | 4.350 (3.850, 4.450) | 3.75, 4.47 |  |  |  |  |
|  |  | C1D8 | 5 | 4.136 (0.2679) | 4.040 (4.030, 4.050) | 3.95, 4.61 | 5 | -0.038 (0.3074) | 0.160 (-0.300, 0.190) | -0.44, 0.20 |
|  |  | C2D1 | 4 | 4.298 (0.2640) | 4.280 (4.085, 4.510) | 4.02, 4.61 | 4 | 0.018 (0.2304) | 0.110 (-0.130, 0.165) | -0.32, 0.17 |
|  |  | C3D1 | 2 | 4.160 (0.1980) | 4.160 (4.020, 4.300) | 4.02, 4.30 | 2 | -0.250 (0.1131) | -0.250 (-0.330, -0.170) | -0.33, -0.17 |
|  |  | C4D1 | 2 | 3.910 (0.2828) | 3.910 (3.710, 4.110) | 3.71, 4.11 | 2 | -0.500 (0.1980) | -0.500 (-0.640, -0.360) | -0.64, -0.36 |
|  |  | C5D1 | 2 | 3.880 (0.0566) | 3.880 (3.840, 3.920) | 3.84, 3.92 | 2 | -0.530 (0.0283) | -0.530 (-0.550, -0.510) | -0.55, -0.51 |
|  | | | | | | | | | | |
|  | Control Group (N = 5) | Baseline | 5 | 3.666 (0.6194) | 3.680 (3.550, 3.920) | 2.74, 4.44 |  |  |  |  |
|  |  | C1D8 | 5 | 3.756 (0.8835) | 3.610 (3.500, 4.150) | 2.56, 4.96 | 5 | 0.090 (0.2840) | -0.050 (-0.070, 0.230) | -0.18, 0.52 |
|  |  | C2D1 | 4 | 3.688 (0.7799) | 3.870 (3.120, 4.255) | 2.62, 4.39 | 4 | 0.025 (0.1406) | 0.010 (-0.085, 0.135) | -0.12, 0.20 |
|  |  | C3D1 | 2 | 3.760 (0.2263) | 3.760 (3.600, 3.920) | 3.60, 3.92 | 2 | 0.025 (0.0354) | 0.025 (0.000, 0.050) | 0.00, 0.05 |
|  |  | C4D1 | 1 | 3.750 (NA) | 3.750 (3.750, 3.750) | 3.75, 3.75 | 1 | 0.200 (NA) | 0.200 (0.200, 0.200) | 0.20, 0.20 |
|  |  | C5D1 | 1 | 3.730 (NA) | 3.730 (3.730, 3.730) | 3.73, 3.73 | 1 | 0.180 (NA) | 0.180 (0.180, 0.180) | 0.18, 0.18 |
|  |  | End of Treatment | 1 | 2.710 (NA) | 2.710 (2.710, 2.710) | 2.71, 2.71 | 1 | -0.030 (NA) | -0.030 (-0.030, -0.030) | -0.03, -0.03 |
|  | | | | | | | | | | |
|  | Total (N = 10) | Baseline | 10 | 3.920 (0.5436) | 3.885 (3.680, 4.440) | 2.74, 4.47 |  |  |  |  |
|  |  | C1D8 | 10 | 3.946 (0.6472) | 4.035 (3.610, 4.150) | 2.56, 4.96 | 10 | 0.026 (0.2871) | 0.055 (-0.180, 0.200) | -0.44, 0.52 |
|  |  | C2D1 | 8 | 3.993 (0.6300) | 4.135 (3.820, 4.400) | 2.62, 4.61 | 8 | 0.021 (0.1768) | 0.065 (-0.085, 0.165) | -0.32, 0.20 |
|  |  | C3D1 | 4 | 3.960 (0.2889) | 3.970 (3.760, 4.160) | 3.60, 4.30 | 4 | -0.113 (0.1729) | -0.085 (-0.250, 0.025) | -0.33, 0.05 |
|  |  | C4D1 | 3 | 3.857 (0.2203) | 3.750 (3.710, 4.110) | 3.71, 4.11 | 3 | -0.267 (0.4277) | -0.360 (-0.640, 0.200) | -0.64, 0.20 |
|  |  | C5D1 | 3 | 3.830 (0.0954) | 3.840 (3.730, 3.920) | 3.73, 3.92 | 3 | -0.293 (0.4104) | -0.510 (-0.550, 0.180) | -0.55, 0.18 |
|  |  | End of Treatment | 1 | 2.710 (NA) | 2.710 (2.710, 2.710) | 2.71, 2.71 | 1 | -0.030 (NA) | -0.030 (-0.030, -0.030) | -0.03, -0.03 |
|  | | | | | | | | | | |
| Hemoglobin (g/L) | Treatment Group (N = 5) | Baseline | 5 | 126.4 (9.10) | 129.0 (127.0, 130.0) | 111, 135 |  |  |  |  |
|  |  | C1D8 | 5 | 125.2 (7.60) | 120.0 (120.0, 133.0) | 119, 134 | 5 | -1.2 (10.52) | 5.0 (-10.0, 6.0) | -15, 8 |
|  |  | C2D1 | 4 | 129.0 (3.16) | 129.5 (126.5, 131.5) | 125, 132 | 4 | -1.3 (6.40) | 0.5 (-6.0, 3.5) | -10, 4 |
|  |  | C3D1 | 2 | 122.0 (5.66) | 122.0 (118.0, 126.0) | 118, 126 | 2 | -10.5 (2.12) | -10.5 (-12.0, -9.0) | -12, -9 |
|  |  | C4D1 | 2 | 116.5 (7.78) | 116.5 (111.0, 122.0) | 111, 122 | 2 | -16.0 (4.24) | -16.0 (-19.0, -13.0) | -19, -13 |
|  |  | C5D1 | 2 | 115.5 (3.54) | 115.5 (113.0, 118.0) | 113, 118 | 2 | -17.0 (0.00) | -17.0 (-17.0, -17.0) | -17, -17 |
|  | | | | | | | | | | |
|  | Control Group (N = 5) | Baseline | 5 | 114.6 (15.47) | 114.0 (111.0, 128.0) | 91, 129 |  |  |  |  |
|  |  | C1D8 | 5 | 116.0 (22.99) | 113.0 (110.0, 130.0) | 83, 144 | 5 | 1.4 (8.44) | -1.0 (-1.0, 2.0) | -8, 15 |
|  |  | C2D1 | 4 | 114.0 (21.56) | 120.0 (98.5, 129.5) | 84, 132 | 4 | -0.8 (4.50) | 0.5 (-4.0, 2.5) | -7, 3 |
|  |  | C3D1 | 2 | 115.0 (2.83) | 115.0 (113.0, 117.0) | 113, 117 | 2 | -4.5 (9.19) | -4.5 (-11.0, 2.0) | -11, 2 |
|  |  | C4D1 | 1 | 119.0 (NA) | 119.0 (119.0, 119.0) | 119, 119 | 1 | 8.0 (NA) | 8.0 (8.0, 8.0) | 8, 8 |
|  |  | C5D1 | 1 | 118.0 (NA) | 118.0 (118.0, 118.0) | 118, 118 | 1 | 7.0 (NA) | 7.0 (7.0, 7.0) | 7, 7 |
|  |  | End of Treatment | 1 | 82.0 (NA) | 82.0 (82.0, 82.0) | 82, 82 | 1 | -9.0 (NA) | -9.0 (-9.0, -9.0) | -9, -9 |
|  | | | | | | | | | | |
|  | Total (N = 10) | Baseline | 10 | 120.5 (13.48) | 127.5 (111.0, 129.0) | 91, 135 |  |  |  |  |
|  |  | C1D8 | 10 | 120.6 (16.85) | 120.0 (113.0, 133.0) | 83, 144 | 10 | 0.1 (9.10) | 0.5 (-8.0, 6.0) | -15, 15 |
|  |  | C2D1 | 8 | 121.5 (16.36) | 127.5 (119.0, 131.5) | 84, 132 | 8 | -1.0 (5.13) | 0.5 (-4.5, 3.0) | -10, 4 |
|  |  | C3D1 | 4 | 118.5 (5.45) | 117.5 (115.0, 122.0) | 113, 126 | 4 | -7.5 (6.45) | -10.0 (-11.5, -3.5) | -12, 2 |
|  |  | C4D1 | 3 | 117.3 (5.69) | 119.0 (111.0, 122.0) | 111, 122 | 3 | -8.0 (14.18) | -13.0 (-19.0, 8.0) | -19, 8 |
|  |  | C5D1 | 3 | 116.3 (2.89) | 118.0 (113.0, 118.0) | 113, 118 | 3 | -9.0 (13.86) | -17.0 (-17.0, 7.0) | -17, 7 |
|  |  | End of Treatment | 1 | 82.0 (NA) | 82.0 (82.0, 82.0) | 82, 82 | 1 | -9.0 (NA) | -9.0 (-9.0, -9.0) | -9, -9 |
|  | | | | | | | | | | |
| Hematocrit (%) | Treatment Group (N = 5) | Baseline | 5 | 38.600 (1.6416) | 39.000 (38.700, 39.500) | 35.80, 40.00 |  |  |  |  |
|  |  | C1D8 | 5 | 37.900 (1.8802) | 37.800 (36.200, 39.700) | 35.90, 39.90 | 5 | -0.700 (2.7920) | 0.700 (-3.300, 1.200) | -4.10, 2.00 |
|  |  | C2D1 | 4 | 38.775 (1.0813) | 38.950 (38.100, 39.450) | 37.30, 39.90 | 4 | -0.525 (1.5756) | -0.150 (-1.650, 0.600) | -2.70, 0.90 |
|  |  | C3D1 | 2 | 36.850 (2.0506) | 36.850 (35.400, 38.300) | 35.40, 38.30 | 2 | -2.900 (1.6971) | -2.900 (-4.100, -1.700) | -4.10, -1.70 |
|  |  | C4D1 | 2 | 34.900 (2.4042) | 34.900 (33.200, 36.600) | 33.20, 36.60 | 2 | -4.850 (2.0506) | -4.850 (-6.300, -3.400) | -6.30, -3.40 |
|  |  | C5D1 | 2 | 34.450 (0.4950) | 34.450 (34.100, 34.800) | 34.10, 34.80 | 2 | -5.300 (0.1414) | -5.300 (-5.400, -5.200) | -5.40, -5.20 |
|  | | | | | | | | | | |
|  | Control Group (N = 5) | Baseline | 5 | 34.400 (4.9960) | 34.700 (32.700, 37.500) | 27.00, 40.10 |  |  |  |  |
|  |  | C1D8 | 5 | 35.500 (6.9127) | 35.200 (32.900, 39.900) | 25.70, 43.80 | 5 | 1.100 (1.9609) | 0.500 (0.200, 2.400) | -1.30, 3.70 |
|  |  | C2D1 | 4 | 34.650 (6.2698) | 36.850 (30.200, 39.100) | 25.80, 39.10 | 4 | 0.325 (1.6520) | 0.300 (-1.100, 1.750) | -1.20, 1.90 |
|  |  | C3D1 | 2 | 35.100 (1.6971) | 35.100 (33.900, 36.300) | 33.90, 36.30 | 2 | -0.000 (1.6971) | -0.000 (-1.200, 1.200) | -1.20, 1.20 |
|  |  | C4D1 | 1 | 35.400 (NA) | 35.400 (35.400, 35.400) | 35.40, 35.40 | 1 | 2.700 (NA) | 2.700 (2.700, 2.700) | 2.70, 2.70 |
|  |  | C5D1 | 1 | 35.200 (NA) | 35.200 (35.200, 35.200) | 35.20, 35.20 | 1 | 2.500 (NA) | 2.500 (2.500, 2.500) | 2.50, 2.50 |
|  |  | End of Treatment | 1 | 26.100 (NA) | 26.100 (26.100, 26.100) | 26.10, 26.10 | 1 | -0.900 (NA) | -0.900 (-0.900, -0.900) | -0.90, -0.90 |
|  | | | | | | | | | | |
|  | Total (N = 10) | Baseline | 10 | 36.500 (4.1462) | 38.100 (34.700, 39.500) | 27.00, 40.10 |  |  |  |  |
|  |  | C1D8 | 10 | 36.700 (4.9405) | 37.000 (35.200, 39.900) | 25.70, 43.80 | 10 | 0.200 (2.4644) | 0.600 (-1.300, 2.000) | -4.10, 3.70 |
|  |  | C2D1 | 8 | 36.713 (4.7127) | 38.950 (35.950, 39.100) | 25.80, 39.90 | 8 | -0.100 (1.5620) | -0.150 (-1.100, 1.250) | -2.70, 1.90 |
|  |  | C3D1 | 4 | 35.975 (1.8392) | 35.850 (34.650, 37.300) | 33.90, 38.30 | 4 | -1.450 (2.1733) | -1.450 (-2.900, -0.000) | -4.10, 1.20 |
|  |  | C4D1 | 3 | 35.067 (1.7243) | 35.400 (33.200, 36.600) | 33.20, 36.60 | 3 | -2.333 (4.5938) | -3.400 (-6.300, 2.700) | -6.30, 2.70 |
|  |  | C5D1 | 3 | 34.700 (0.5568) | 34.800 (34.100, 35.200) | 34.10, 35.20 | 3 | -2.700 (4.5044) | -5.200 (-5.400, 2.500) | -5.40, 2.50 |
|  |  | End of Treatment | 1 | 26.100 (NA) | 26.100 (26.100, 26.100) | 26.10, 26.10 | 1 | -0.900 (NA) | -0.900 (-0.900, -0.900) | -0.90, -0.90 |
|  | | | | | | | | | | |
| Leukocytes (10^9/L) | Treatment Group (N = 5) | Baseline | 5 | 5.670 (1.0667) | 6.200 (5.090, 6.200) | 4.10, 6.76 |  |  |  |  |
|  |  | C1D8 | 5 | 5.590 (2.6063) | 5.810 (4.100, 7.700) | 2.00, 8.34 | 5 | -0.080 (1.8744) | 0.720 (-2.100, 1.500) | -2.10, 1.58 |
|  |  | C2D1 | 4 | 8.575 (2.1608) | 8.750 (6.750, 10.400) | 6.20, 10.60 | 4 | 2.760 (1.9116) | 3.320 (1.600, 3.920) | 0.00, 4.40 |
|  |  | C3D1 | 2 | 4.400 (1.8385) | 4.400 (3.100, 5.700) | 3.10, 5.70 | 2 | -0.750 (0.3536) | -0.750 (-1.000, -0.500) | -1.00, -0.50 |
|  |  | C4D1 | 2 | 3.300 (1.5556) | 3.300 (2.200, 4.400) | 2.20, 4.40 | 2 | -1.850 (0.0707) | -1.850 (-1.900, -1.800) | -1.90, -1.80 |
|  |  | C5D1 | 2 | 3.950 (1.0607) | 3.950 (3.200, 4.700) | 3.20, 4.70 | 2 | -1.200 (0.4243) | -1.200 (-1.500, -0.900) | -1.50, -0.90 |
|  | | | | | | | | | | |
|  | Control Group (N = 5) | Baseline | 5 | 6.176 (2.1437) | 6.400 (5.070, 6.610) | 3.50, 9.30 |  |  |  |  |
|  |  | C1D8 | 5 | 6.812 (3.7922) | 6.400 (4.580, 8.600) | 2.30, 12.18 | 5 | 0.636 (3.6939) | -0.700 (-1.200, 0.000) | -2.03, 7.11 |
|  |  | C2D1 | 4 | 6.348 (1.5607) | 6.895 (5.295, 7.400) | 4.10, 7.50 | 4 | 0.280 (1.5570) | 0.850 (-0.700, 1.260) | -2.00, 1.42 |
|  |  | C3D1 | 2 | 5.700 (0.1414) | 5.700 (5.600, 5.800) | 5.60, 5.80 | 2 | 0.750 (2.1920) | 0.750 (-0.800, 2.300) | -0.80, 2.30 |
|  |  | C4D1 | 1 | 5.600 (NA) | 5.600 (5.600, 5.600) | 5.60, 5.60 | 1 | 2.100 (NA) | 2.100 (2.100, 2.100) | 2.10, 2.10 |
|  |  | C5D1 | 1 | 5.500 (NA) | 5.500 (5.500, 5.500) | 5.50, 5.50 | 1 | 2.000 (NA) | 2.000 (2.000, 2.000) | 2.00, 2.00 |
|  |  | End of Treatment | 1 | 10.000 (NA) | 10.000 (10.000, 10.000) | 10.00, 10.00 | 1 | 0.700 (NA) | 0.700 (0.700, 0.700) | 0.70, 0.70 |
|  | | | | | | | | | | |
|  | Total (N = 10) | Baseline | 10 | 5.923 (1.6184) | 6.200 (5.070, 6.610) | 3.50, 9.30 |  |  |  |  |
|  |  | C1D8 | 10 | 6.201 (3.1345) | 6.105 (4.100, 8.340) | 2.00, 12.18 | 10 | 0.278 (2.7872) | -0.350 (-2.030, 1.500) | -2.10, 7.11 |
|  |  | C2D1 | 8 | 7.461 (2.1125) | 7.300 (6.345, 8.850) | 4.10, 10.60 | 8 | 1.520 (2.0886) | 1.260 (0.300, 3.320) | -2.00, 4.40 |
|  |  | C3D1 | 4 | 5.050 (1.3026) | 5.650 (4.350, 5.750) | 3.10, 5.80 | 4 | -0.000 (1.5470) | -0.650 (-0.900, 0.900) | -1.00, 2.30 |
|  |  | C4D1 | 3 | 4.067 (1.7243) | 4.400 (2.200, 5.600) | 2.20, 5.60 | 3 | -0.533 (2.2811) | -1.800 (-1.900, 2.100) | -1.90, 2.10 |
|  |  | C5D1 | 3 | 4.467 (1.1676) | 4.700 (3.200, 5.500) | 3.20, 5.50 | 3 | -0.133 (1.8717) | -0.900 (-1.500, 2.000) | -1.50, 2.00 |
|  |  | End of Treatment | 1 | 10.000 (NA) | 10.000 (10.000, 10.000) | 10.00, 10.00 | 1 | 0.700 (NA) | 0.700 (0.700, 0.700) | 0.70, 0.70 |
|  | | | | | | | | | | |
| Neutrophils (10^9/L) | Treatment Group (N = 5) | Baseline | 5 | 3.856 (0.7013) | 3.800 (3.200, 4.540) | 3.14, 4.60 |  |  |  |  |
|  |  | C1D8 | 5 | 3.392 (1.6538) | 3.390 (2.300, 4.600) | 1.30, 5.37 | 5 | -0.464 (1.5178) | 0.250 (-1.900, 0.800) | -2.30, 0.83 |
|  |  | C2D1 | 4 | 5.913 (1.4891) | 6.275 (5.025, 6.800) | 3.80, 7.30 | 4 | 1.878 (1.9429) | 2.405 (0.455, 3.300) | -0.80, 3.50 |
|  |  | C3D1 | 2 | 2.750 (1.3435) | 2.750 (1.800, 3.700) | 1.80, 3.70 | 2 | -1.150 (0.3536) | -1.150 (-1.400, -0.900) | -1.40, -0.90 |
|  |  | C4D1 | 2 | 1.950 (0.7778) | 1.950 (1.400, 2.500) | 1.40, 2.50 | 2 | -1.950 (0.2121) | -1.950 (-2.100, -1.800) | -2.10, -1.80 |
|  |  | C5D1 | 2 | 2.600 (0.7071) | 2.600 (2.100, 3.100) | 2.10, 3.10 | 2 | -1.300 (0.2828) | -1.300 (-1.500, -1.100) | -1.50, -1.10 |
|  | | | | | | | | | | |
|  | Control Group (N = 5) | Baseline | 5 | 4.096 (2.0316) | 3.900 (3.020, 4.160) | 2.00, 7.40 |  |  |  |  |
|  |  | C1D8 | 5 | 4.568 (2.9919) | 4.100 (2.230, 6.900) | 1.30, 8.31 | 5 | 0.472 (2.8007) | -0.500 (-0.700, 0.200) | -1.93, 5.29 |
|  |  | C2D1 | 4 | 4.360 (1.1803) | 4.520 (3.520, 5.200) | 2.80, 5.60 | 4 | 0.280 (1.3982) | 0.850 (-0.500, 1.060) | -1.80, 1.22 |
|  |  | C3D1 | 2 | 33.700 (42.2850) | 33.700 (3.800, 63.600) | 3.80, 63.60 | 2 | 30.750 (40.9415) | 30.750 (1.800, 59.700) | 1.80, 59.70 |
|  |  | C4D1 | 1 | 3.800 (NA) | 3.800 (3.800, 3.800) | 3.80, 3.80 | 1 | 1.800 (NA) | 1.800 (1.800, 1.800) | 1.80, 1.80 |
|  |  | C5D1 | 1 | 3.600 (NA) | 3.600 (3.600, 3.600) | 3.60, 3.60 | 1 | 1.600 (NA) | 1.600 (1.600, 1.600) | 1.60, 1.60 |
|  |  | End of Treatment | 1 | 8.200 (NA) | 8.200 (8.200, 8.200) | 8.20, 8.20 | 1 | 0.800 (NA) | 0.800 (0.800, 0.800) | 0.80, 0.80 |
|  | | | | | | | | | | |
|  | Total (N = 10) | Baseline | 10 | 3.976 (1.4384) | 3.850 (3.140, 4.540) | 2.00, 7.40 |  |  |  |  |
|  |  | C1D8 | 10 | 3.980 (2.3618) | 3.745 (2.230, 5.370) | 1.30, 8.31 | 10 | 0.004 (2.1802) | -0.150 (-1.900, 0.800) | -2.30, 5.29 |
|  |  | C2D1 | 8 | 5.136 (1.4953) | 5.200 (4.020, 6.275) | 2.80, 7.30 | 8 | 1.079 (1.7846) | 1.060 (0.000, 2.405) | -1.80, 3.50 |
|  |  | C3D1 | 4 | 18.225 (30.2640) | 3.750 (2.750, 33.700) | 1.80, 63.60 | 4 | 14.800 (29.9663) | 0.450 (-1.150, 30.750) | -1.40, 59.70 |
|  |  | C4D1 | 3 | 2.567 (1.2014) | 2.500 (1.400, 3.800) | 1.40, 3.80 | 3 | -0.700 (2.1703) | -1.800 (-2.100, 1.800) | -2.10, 1.80 |
|  |  | C5D1 | 3 | 2.933 (0.7638) | 3.100 (2.100, 3.600) | 2.10, 3.60 | 3 | -0.333 (1.6862) | -1.100 (-1.500, 1.600) | -1.50, 1.60 |
|  |  | End of Treatment | 1 | 8.200 (NA) | 8.200 (8.200, 8.200) | 8.20, 8.20 | 1 | 0.800 (NA) | 0.800 (0.800, 0.800) | 0.80, 0.80 |
|  | | | | | | | | | | |
| Eosinophils (10^9/L) | Treatment Group (N = 5) | Baseline | 5 | 0.542 (0.9307) | 0.200 (0.070, 0.220) | 0.02, 2.20 |  |  |  |  |
|  |  | C1D8 | 5 | 0.224 (0.2209) | 0.150 (0.090, 0.230) | 0.05, 0.60 | 5 | -0.318 (0.9826) | 0.010 (-0.020, 0.070) | -2.05, 0.40 |
|  |  | C2D1 | 4 | 0.430 (0.4221) | 0.335 (0.090, 0.770) | 0.09, 0.96 | 4 | 0.303 (0.3398) | 0.215 (0.045, 0.560) | 0.02, 0.76 |
|  |  | C3D1 | 2 | 0.115 (0.0071) | 0.115 (0.110, 0.120) | 0.11, 0.12 | 2 | 0.070 (0.0424) | 0.070 (0.040, 0.100) | 0.04, 0.10 |
|  |  | C4D1 | 2 | 0.095 (0.0212) | 0.095 (0.080, 0.110) | 0.08, 0.11 | 2 | 0.050 (0.0566) | 0.050 (0.010, 0.090) | 0.01, 0.09 |
|  |  | C5D1 | 2 | 0.115 (0.0495) | 0.115 (0.080, 0.150) | 0.08, 0.15 | 2 | 0.070 (0.0849) | 0.070 (0.010, 0.130) | 0.01, 0.13 |
|  | | | | | | | | | | |
|  | Control Group (N = 5) | Baseline | 5 | 0.110 (0.1190) | 0.070 (0.040, 0.120) | 0.01, 0.31 |  |  |  |  |
|  |  | C1D8 | 5 | 0.176 (0.1805) | 0.150 (0.050, 0.170) | 0.03, 0.48 | 5 | 0.066 (0.0702) | 0.040 (0.030, 0.100) | -0.01, 0.17 |
|  |  | C2D1 | 4 | 0.168 (0.1365) | 0.155 (0.065, 0.270) | 0.02, 0.34 | 4 | 0.048 (0.0538) | 0.055 (0.005, 0.090) | -0.02, 0.10 |
|  |  | C3D1 | 2 | 0.115 (0.0495) | 0.115 (0.080, 0.150) | 0.08, 0.15 | 2 | 0.035 (0.1061) | 0.035 (-0.040, 0.110) | -0.04, 0.11 |
|  |  | C4D1 | 1 | 0.090 (NA) | 0.090 (0.090, 0.090) | 0.09, 0.09 | 1 | 0.050 (NA) | 0.050 (0.050, 0.050) | 0.05, 0.05 |
|  |  | C5D1 | 1 | 0.150 (NA) | 0.150 (0.150, 0.150) | 0.15, 0.15 | 1 | 0.110 (NA) | 0.110 (0.110, 0.110) | 0.11, 0.11 |
|  |  | End of Treatment | 1 | 0.030 (NA) | 0.030 (0.030, 0.030) | 0.03, 0.03 | 1 | 0.020 (NA) | 0.020 (0.020, 0.020) | 0.02, 0.02 |
|  | | | | | | | | | | |
|  | Total (N = 10) | Baseline | 10 | 0.326 (0.6657) | 0.095 (0.040, 0.220) | 0.01, 2.20 |  |  |  |  |
|  |  | C1D8 | 10 | 0.200 (0.1918) | 0.150 (0.050, 0.230) | 0.03, 0.60 | 10 | -0.126 (0.6872) | 0.035 (-0.010, 0.100) | -2.05, 0.40 |
|  |  | C2D1 | 8 | 0.299 (0.3226) | 0.155 (0.090, 0.460) | 0.02, 0.96 | 8 | 0.175 (0.2633) | 0.075 (0.025, 0.230) | -0.02, 0.76 |
|  |  | C3D1 | 4 | 0.115 (0.0289) | 0.115 (0.095, 0.135) | 0.08, 0.15 | 4 | 0.053 (0.0690) | 0.070 (0.000, 0.105) | -0.04, 0.11 |
|  |  | C4D1 | 3 | 0.093 (0.0153) | 0.090 (0.080, 0.110) | 0.08, 0.11 | 3 | 0.050 (0.0400) | 0.050 (0.010, 0.090) | 0.01, 0.09 |
|  |  | C5D1 | 3 | 0.127 (0.0404) | 0.150 (0.080, 0.150) | 0.08, 0.15 | 3 | 0.083 (0.0643) | 0.110 (0.010, 0.130) | 0.01, 0.13 |
|  |  | End of Treatment | 1 | 0.030 (NA) | 0.030 (0.030, 0.030) | 0.03, 0.03 | 1 | 0.020 (NA) | 0.020 (0.020, 0.020) | 0.02, 0.02 |
|  | | | | | | | | | | |
| Basophils (10^9/L) | Treatment Group (N = 5) | Baseline | 5 | 0.096 (0.1701) | 0.020 (0.020, 0.030) | 0.01, 0.40 |  |  |  |  |
|  |  | C1D8 | 5 | 0.028 (0.0148) | 0.030 (0.020, 0.030) | 0.01, 0.05 | 5 | -0.068 (0.1690) | 0.000 (0.000, 0.010) | -0.37, 0.02 |
|  |  | C2D1 | 4 | 0.035 (0.0173) | 0.030 (0.025, 0.045) | 0.02, 0.06 | 4 | 0.015 (0.0100) | 0.010 (0.010, 0.020) | 0.01, 0.03 |
|  |  | C3D1 | 2 | 0.020 (0.0000) | 0.020 (0.020, 0.020) | 0.02, 0.02 | 2 | 0.005 (0.0071) | 0.005 (0.000, 0.010) | 0.00, 0.01 |
|  |  | C4D1 | 2 | 0.020 (0.0000) | 0.020 (0.020, 0.020) | 0.02, 0.02 | 2 | 0.005 (0.0071) | 0.005 (0.000, 0.010) | 0.00, 0.01 |
|  |  | C5D1 | 2 | 0.015 (0.0071) | 0.015 (0.010, 0.020) | 0.01, 0.02 | 2 | 0.000 (0.0141) | 0.000 (-0.010, 0.010) | -0.01, 0.01 |
|  | | | | | | | | | | |
|  | Control Group (N = 5) | Baseline | 5 | 0.028 (0.0239) | 0.020 (0.020, 0.020) | 0.01, 0.07 |  |  |  |  |
|  |  | C1D8 | 5 | 0.038 (0.0228) | 0.030 (0.030, 0.050) | 0.01, 0.07 | 5 | 0.010 (0.0255) | 0.010 (0.000, 0.010) | -0.02, 0.05 |
|  |  | C2D1 | 4 | 0.033 (0.0096) | 0.035 (0.025, 0.040) | 0.02, 0.04 | 4 | 0.015 (0.0100) | 0.020 (0.010, 0.020) | 0.00, 0.02 |
|  |  | C3D1 | 2 | 0.025 (0.0212) | 0.025 (0.010, 0.040) | 0.01, 0.04 | 2 | 0.010 (0.0283) | 0.010 (-0.010, 0.030) | -0.01, 0.03 |
|  |  | C4D1 | 1 | 0.030 (NA) | 0.030 (0.030, 0.030) | 0.03, 0.03 | 1 | 0.020 (NA) | 0.020 (0.020, 0.020) | 0.02, 0.02 |
|  |  | C5D1 | 1 | 0.060 (NA) | 0.060 (0.060, 0.060) | 0.06, 0.06 | 1 | 0.050 (NA) | 0.050 (0.050, 0.050) | 0.05, 0.05 |
|  |  | End of Treatment | 1 | 0.010 (NA) | 0.010 (0.010, 0.010) | 0.01, 0.01 | 1 | -0.010 (NA) | -0.010 (-0.010, -0.010) | -0.01, -0.01 |
|  | | | | | | | | | | |
|  | Total (N = 10) | Baseline | 10 | 0.062 (0.1200) | 0.020 (0.020, 0.030) | 0.01, 0.40 |  |  |  |  |
|  |  | C1D8 | 10 | 0.033 (0.0189) | 0.030 (0.020, 0.050) | 0.01, 0.07 | 10 | -0.029 (0.1211) | 0.005 (0.000, 0.010) | -0.37, 0.05 |
|  |  | C2D1 | 8 | 0.034 (0.0130) | 0.030 (0.025, 0.040) | 0.02, 0.06 | 8 | 0.015 (0.0093) | 0.015 (0.010, 0.020) | 0.00, 0.03 |
|  |  | C3D1 | 4 | 0.023 (0.0126) | 0.020 (0.015, 0.030) | 0.01, 0.04 | 4 | 0.008 (0.0171) | 0.005 (-0.005, 0.020) | -0.01, 0.03 |
|  |  | C4D1 | 3 | 0.023 (0.0058) | 0.020 (0.020, 0.030) | 0.02, 0.03 | 3 | 0.010 (0.0100) | 0.010 (0.000, 0.020) | 0.00, 0.02 |
|  |  | C5D1 | 3 | 0.030 (0.0265) | 0.020 (0.010, 0.060) | 0.01, 0.06 | 3 | 0.017 (0.0306) | 0.010 (-0.010, 0.050) | -0.01, 0.05 |
|  |  | End of Treatment | 1 | 0.010 (NA) | 0.010 (0.010, 0.010) | 0.01, 0.01 | 1 | -0.010 (NA) | -0.010 (-0.010, -0.010) | -0.01, -0.01 |
|  | | | | | | | | | | |
| Lymphocytes (10^9/L) | Treatment Group (N = 5) | Baseline | 5 | 1.346 (0.3844) | 1.490 (1.300, 1.600) | 0.70, 1.64 |  |  |  |  |
|  |  | C1D8 | 5 | 1.592 (0.6849) | 1.810 (1.400, 2.000) | 0.50, 2.25 | 5 | 0.246 (0.3090) | 0.320 (0.100, 0.400) | -0.20, 0.61 |
|  |  | C2D1 | 4 | 1.673 (0.8538) | 1.700 (1.150, 2.195) | 0.60, 2.69 | 4 | 0.363 (0.5023) | 0.250 (-0.000, 0.725) | -0.10, 1.05 |
|  |  | C3D1 | 2 | 1.250 (0.4950) | 1.250 (0.900, 1.600) | 0.90, 1.60 | 2 | 0.250 (0.0707) | 0.250 (0.200, 0.300) | 0.20, 0.30 |
|  |  | C4D1 | 2 | 1.000 (0.5657) | 1.000 (0.600, 1.400) | 0.60, 1.40 | 2 | -0.000 (0.1414) | -0.000 (-0.100, 0.100) | -0.10, 0.10 |
|  |  | C5D1 | 2 | 1.050 (0.2121) | 1.050 (0.900, 1.200) | 0.90, 1.20 | 2 | 0.050 (0.2121) | 0.050 (-0.100, 0.200) | -0.10, 0.20 |
|  | | | | | | | | | | |
|  | Control Group (N = 5) | Baseline | 5 | 1.324 (0.4380) | 1.320 (1.200, 1.500) | 0.70, 1.90 |  |  |  |  |
|  |  | C1D8 | 5 | 1.380 (0.6387) | 1.400 (0.900, 1.570) | 0.70, 2.33 | 5 | 0.056 (0.6224) | 0.070 (-0.500, 0.200) | -0.50, 1.01 |
|  |  | C2D1 | 4 | 1.393 (0.5564) | 1.285 (0.950, 1.835) | 0.90, 2.10 | 4 | 0.113 (0.2097) | 0.200 (0.000, 0.225) | -0.20, 0.25 |
|  |  | C3D1 | 2 | 1.500 (0.1414) | 1.500 (1.400, 1.600) | 1.40, 1.60 | 2 | -0.050 (0.3536) | -0.050 (-0.300, 0.200) | -0.30, 0.20 |
|  |  | C4D1 | 1 | 1.400 (NA) | 1.400 (1.400, 1.400) | 1.40, 1.40 | 1 | 0.200 (NA) | 0.200 (0.200, 0.200) | 0.20, 0.20 |
|  |  | C5D1 | 1 | 1.400 (NA) | 1.400 (1.400, 1.400) | 1.40, 1.40 | 1 | 0.200 (NA) | 0.200 (0.200, 0.200) | 0.20, 0.20 |
|  |  | End of Treatment | 1 | 0.900 (NA) | 0.900 (0.900, 0.900) | 0.90, 0.90 | 1 | 0.200 (NA) | 0.200 (0.200, 0.200) | 0.20, 0.20 |
|  | | | | | | | | | | |
|  | Total (N = 10) | Baseline | 10 | 1.335 (0.3887) | 1.405 (1.200, 1.600) | 0.70, 1.90 |  |  |  |  |
|  |  | C1D8 | 10 | 1.486 (0.6342) | 1.485 (0.900, 2.000) | 0.50, 2.33 | 10 | 0.151 (0.4739) | 0.150 (-0.200, 0.400) | -0.50, 1.01 |
|  |  | C2D1 | 8 | 1.533 (0.6837) | 1.635 (0.950, 1.900) | 0.60, 2.69 | 8 | 0.238 (0.3806) | 0.200 (-0.000, 0.325) | -0.20, 1.05 |
|  |  | C3D1 | 4 | 1.375 (0.3304) | 1.500 (1.150, 1.600) | 0.90, 1.60 | 4 | 0.100 (0.2708) | 0.200 (-0.050, 0.250) | -0.30, 0.30 |
|  |  | C4D1 | 3 | 1.133 (0.4619) | 1.400 (0.600, 1.400) | 0.60, 1.40 | 3 | 0.067 (0.1528) | 0.100 (-0.100, 0.200) | -0.10, 0.20 |
|  |  | C5D1 | 3 | 1.167 (0.2517) | 1.200 (0.900, 1.400) | 0.90, 1.40 | 3 | 0.100 (0.1732) | 0.200 (-0.100, 0.200) | -0.10, 0.20 |
|  |  | End of Treatment | 1 | 0.900 (NA) | 0.900 (0.900, 0.900) | 0.90, 0.90 | 1 | 0.200 (NA) | 0.200 (0.200, 0.200) | 0.20, 0.20 |
|  | | | | | | | | | | |
| Monocytes (10^9/L) | Treatment Group (N = 5) | Baseline | 5 | 0.312 (0.1236) | 0.330 (0.200, 0.330) | 0.20, 0.50 |  |  |  |  |
|  |  | C1D8 | 5 | 0.312 (0.1525) | 0.400 (0.200, 0.430) | 0.10, 0.43 | 5 | -0.000 (0.1000) | 0.000 (-0.100, 0.100) | -0.10, 0.10 |
|  |  | C2D1 | 4 | 0.503 (0.1438) | 0.550 (0.400, 0.605) | 0.30, 0.61 | 4 | 0.195 (0.1100) | 0.190 (0.100, 0.290) | 0.10, 0.30 |
|  |  | C3D1 | 2 | 0.250 (0.0707) | 0.250 (0.200, 0.300) | 0.20, 0.30 | 2 | 0.050 (0.0707) | 0.050 (0.000, 0.100) | 0.00, 0.10 |
|  |  | C4D1 | 2 | 0.250 (0.0707) | 0.250 (0.200, 0.300) | 0.20, 0.30 | 2 | 0.050 (0.0707) | 0.050 (0.000, 0.100) | 0.00, 0.10 |
|  |  | C5D1 | 2 | 0.250 (0.0707) | 0.250 (0.200, 0.300) | 0.20, 0.30 | 2 | 0.050 (0.0707) | 0.050 (0.000, 0.100) | 0.00, 0.10 |
|  | | | | | | | | | | |
|  | Control Group (N = 5) | Baseline | 5 | 0.602 (0.3550) | 0.500 (0.400, 0.810) | 0.20, 1.10 |  |  |  |  |
|  |  | C1D8 | 5 | 0.612 (0.2876) | 0.600 (0.560, 0.700) | 0.20, 1.00 | 5 | 0.010 (0.3847) | 0.000 (-0.250, 0.100) | -0.40, 0.60 |
|  |  | C2D1 | 4 | 0.428 (0.1871) | 0.355 (0.305, 0.550) | 0.30, 0.70 | 4 | -0.123 (0.2066) | -0.095 (-0.250, 0.005) | -0.40, 0.10 |
|  |  | C3D1 | 2 | 0.350 (0.0707) | 0.350 (0.300, 0.400) | 0.30, 0.40 | 2 | 0.000 (0.2828) | 0.000 (-0.200, 0.200) | -0.20, 0.20 |
|  |  | C4D1 | 1 | 0.300 (NA) | 0.300 (0.300, 0.300) | 0.30, 0.30 | 1 | 0.100 (NA) | 0.100 (0.100, 0.100) | 0.10, 0.10 |
|  |  | C5D1 | 1 | 0.300 (NA) | 0.300 (0.300, 0.300) | 0.30, 0.30 | 1 | 0.100 (NA) | 0.100 (0.100, 0.100) | 0.10, 0.10 |
|  |  | End of Treatment | 1 | 0.900 (NA) | 0.900 (0.900, 0.900) | 0.90, 0.90 | 1 | -0.200 (NA) | -0.200 (-0.200, -0.200) | -0.20, -0.20 |
|  | | | | | | | | | | |
|  | Total (N = 10) | Baseline | 10 | 0.457 (0.2935) | 0.365 (0.200, 0.500) | 0.20, 1.10 |  |  |  |  |
|  |  | C1D8 | 10 | 0.462 (0.2685) | 0.430 (0.200, 0.600) | 0.10, 1.00 | 10 | 0.005 (0.2650) | 0.000 (-0.100, 0.100) | -0.40, 0.60 |
|  |  | C2D1 | 8 | 0.465 (0.1596) | 0.450 (0.305, 0.605) | 0.30, 0.70 | 8 | 0.036 (0.2287) | 0.100 (-0.095, 0.190) | -0.40, 0.30 |
|  |  | C3D1 | 4 | 0.300 (0.0816) | 0.300 (0.250, 0.350) | 0.20, 0.40 | 4 | 0.025 (0.1708) | 0.050 (-0.100, 0.150) | -0.20, 0.20 |
|  |  | C4D1 | 3 | 0.267 (0.0577) | 0.300 (0.200, 0.300) | 0.20, 0.30 | 3 | 0.067 (0.0577) | 0.100 (0.000, 0.100) | 0.00, 0.10 |
|  |  | C5D1 | 3 | 0.267 (0.0577) | 0.300 (0.200, 0.300) | 0.20, 0.30 | 3 | 0.067 (0.0577) | 0.100 (0.000, 0.100) | 0.00, 0.10 |
|  |  | End of Treatment | 1 | 0.900 (NA) | 0.900 (0.900, 0.900) | 0.90, 0.90 | 1 | -0.200 (NA) | -0.200 (-0.200, -0.200) | -0.20, -0.20 |
|  | | | | | | | | | | |
| Platelets (10^9/L) | Treatment Group (N = 5) | Baseline | 5 | 185.6 (126.91) | 138.0 (112.0, 157.0) | 111, 410 |  |  |  |  |
|  |  | C1D8 | 5 | 192.4 (76.31) | 209.0 (129.0, 220.0) | 107, 297 | 5 | 6.8 (84.22) | 17.0 (-31.0, 52.0) | -113, 109 |
|  |  | C2D1 | 4 | 223.0 (79.67) | 211.5 (157.0, 289.0) | 152, 317 | 4 | 18.8 (127.24) | 32.0 (-62.5, 100.0) | -149, 160 |
|  |  | C3D1 | 2 | 166.5 (33.23) | 166.5 (143.0, 190.0) | 143, 190 | 2 | 41.5 (51.62) | 41.5 (5.0, 78.0) | 5, 78 |
|  |  | C4D1 | 2 | 128.5 (24.75) | 128.5 (111.0, 146.0) | 111, 146 | 2 | 3.5 (43.13) | 3.5 (-27.0, 34.0) | -27, 34 |
|  |  | C5D1 | 2 | 178.5 (74.25) | 178.5 (126.0, 231.0) | 126, 231 | 2 | 53.5 (92.63) | 53.5 (-12.0, 119.0) | -12, 119 |
|  | | | | | | | | | | |
|  | Control Group (N = 5) | Baseline | 5 | 219.4 (85.16) | 169.0 (164.0, 248.0) | 159, 357 |  |  |  |  |
|  |  | C1D8 | 5 | 250.8 (124.00) | 184.0 (182.0, 268.0) | 160, 460 | 5 | 31.4 (72.04) | 13.0 (1.0, 103.0) | -64, 104 |
|  |  | C2D1 | 4 | 221.8 (97.02) | 194.5 (161.0, 282.5) | 137, 361 | 4 | -10.3 (68.78) | 15.0 (-53.5, 33.0) | -111, 40 |
|  |  | C3D1 | 2 | 162.0 (77.78) | 162.0 (107.0, 217.0) | 107, 217 | 2 | -41.5 (140.71) | -41.5 (-141.0, 58.0) | -141, 58 |
|  |  | C4D1 | 1 | 226.0 (NA) | 226.0 (226.0, 226.0) | 226, 226 | 1 | 67.0 (NA) | 67.0 (67.0, 67.0) | 67, 67 |
|  |  | C5D1 | 1 | 206.0 (NA) | 206.0 (206.0, 206.0) | 206, 206 | 1 | 47.0 (NA) | 47.0 (47.0, 47.0) | 47, 47 |
|  |  | End of Treatment | 1 | 389.0 (NA) | 389.0 (389.0, 389.0) | 389, 389 | 1 | 32.0 (NA) | 32.0 (32.0, 32.0) | 32, 32 |
|  | | | | | | | | | | |
|  | Total (N = 10) | Baseline | 10 | 202.5 (103.43) | 161.5 (138.0, 248.0) | 111, 410 |  |  |  |  |
|  |  | C1D8 | 10 | 221.6 (101.83) | 196.5 (160.0, 268.0) | 107, 460 | 10 | 19.1 (75.02) | 15.0 (-31.0, 103.0) | -113, 109 |
|  |  | C2D1 | 8 | 222.4 (82.19) | 194.5 (157.0, 289.0) | 137, 361 | 8 | 4.3 (95.95) | 25.0 (-53.5, 40.0) | -149, 160 |
|  |  | C3D1 | 4 | 164.3 (48.90) | 166.5 (125.0, 203.5) | 107, 217 | 4 | 0.0 (98.92) | 31.5 (-68.0, 68.0) | -141, 78 |
|  |  | C4D1 | 3 | 161.0 (58.95) | 146.0 (111.0, 226.0) | 111, 226 | 3 | 24.7 (47.69) | 34.0 (-27.0, 67.0) | -27, 67 |
|  |  | C5D1 | 3 | 187.7 (54.85) | 206.0 (126.0, 231.0) | 126, 231 | 3 | 51.3 (65.61) | 47.0 (-12.0, 119.0) | -12, 119 |
|  |  | End of Treatment | 1 | 389.0 (NA) | 389.0 (389.0, 389.0) | 389, 389 | 1 | 32.0 (NA) | 32.0 (32.0, 32.0) | 32, 32 |

NA = Not applicable.

Baseline is defined as the last available assessment before the first administration of investigational drug (D-1553 or IN10018).

Only subjects with data at both baseline and the relevant post baseline visit are included in the change from baseline summary statistics.

Source Data: Listing 16.2.8.1.1

|  |  |  |
| --- | --- | --- |
| Program: t-lb-chg.sas | DCO: 27APR2024 | Executed: 07JUL2024 20:45 |

|  |  |
| --- | --- |
| **InxMed (Shanghai) Co., Ltd.  Protocol No. IN10018-602** |  |

**Table 14.3.5.1.2.3 Summary of Chemistry Results - Phase II part 2 - CRC (Safety Analysis Set)**

|  | | | Observed Value | | | | Change from Baseline | | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Parameter | Group | Visit | n | Mean (STD) | Median (Q1, Q3) | Min, Max | n | Mean (STD) | Median (Q1, Q3) | Min, Max |
| Creatinine Clearance (mL/min) | Treatment Group (N = 5) | Baseline | 5 | 102.48 (31.068) | 94.40 (81.50, 101.50) | 79.4, 155.6 |  |  |  |  |
|  |  | C2D1 | 4 | 100.50 (40.058) | 96.10 (74.95, 126.05) | 56.3, 153.5 | 4 | -7.75 (11.665) | -2.50 (-14.05, -1.45) | -25.2, -0.8 |
|  |  | C3D1 | 2 | 90.85 (7.990) | 90.85 (85.20, 96.50) | 85.2, 96.5 | 2 | -7.10 (2.970) | -7.10 (-9.20, -5.00) | -9.2, -5.0 |
|  |  | C4D1 | 2 | 96.80 (17.961) | 96.80 (84.10, 109.50) | 84.1, 109.5 | 2 | -1.15 (12.940) | -1.15 (-10.30, 8.00) | -10.3, 8.0 |
|  |  | C5D1 | 2 | 89.80 (13.294) | 89.80 (80.40, 99.20) | 80.4, 99.2 | 2 | -8.15 (8.273) | -8.15 (-14.00, -2.30) | -14.0, -2.3 |
|  | | | | | | | | | | |
|  | Control Group (N = 5) | Baseline | 4 | 86.38 (25.547) | 91.00 (69.65, 103.10) | 51.3, 112.2 |  |  |  |  |
|  |  | C2D1 | 4 | 104.73 (29.536) | 101.55 (82.65, 126.80) | 73.3, 142.5 | 3 | -5.93 (20.136) | -14.70 (-20.20, 17.10) | -20.2, 17.1 |
|  |  | C3D1 | 2 | 135.25 (20.294) | 135.25 (120.90, 149.60) | 120.9, 149.6 | 1 | 26.90 (NA) | 26.90 (26.90, 26.90) | 26.9, 26.9 |
|  |  | C4D1 | 1 | 169.70 (NA) | 169.70 (169.70, 169.70) | 169.7, 169.7 | 0 |  |  |  |
|  |  | C5D1 | 1 | 148.60 (NA) | 148.60 (148.60, 148.60) | 148.6, 148.6 | 0 |  |  |  |
|  |  | End of Treatment | 1 | 88.20 (NA) | 88.20 (88.20, 88.20) | 88.2, 88.2 | 1 | 0.20 (NA) | 0.20 (0.20, 0.20) | 0.2, 0.2 |
|  | | | | | | | | | | |
|  | Total (N = 10) | Baseline | 9 | 95.32 (28.274) | 94.00 (81.50, 101.50) | 51.3, 155.6 |  |  |  |  |
|  |  | C2D1 | 8 | 102.61 (32.660) | 96.10 (82.65, 126.80) | 56.3, 153.5 | 7 | -6.97 (14.288) | -2.90 (-20.20, -0.80) | -25.2, 17.1 |
|  |  | C3D1 | 4 | 113.05 (28.560) | 108.70 (90.85, 135.25) | 85.2, 149.6 | 3 | 4.23 (19.742) | -5.00 (-9.20, 26.90) | -9.2, 26.9 |
|  |  | C4D1 | 3 | 121.10 (43.963) | 109.50 (84.10, 169.70) | 84.1, 169.7 | 2 | -1.15 (12.940) | -1.15 (-10.30, 8.00) | -10.3, 8.0 |
|  |  | C5D1 | 3 | 109.40 (35.226) | 99.20 (80.40, 148.60) | 80.4, 148.6 | 2 | -8.15 (8.273) | -8.15 (-14.00, -2.30) | -14.0, -2.3 |
|  |  | End of Treatment | 1 | 88.20 (NA) | 88.20 (88.20, 88.20) | 88.2, 88.2 | 1 | 0.20 (NA) | 0.20 (0.20, 0.20) | 0.2, 0.2 |
|  | | | | | | | | | | |
| Bilirubin (umol/L) | Treatment Group (N = 5) | Baseline | 5 | 10.420 (5.7347) | 9.600 (8.000, 10.100) | 4.50, 19.90 |  |  |  |  |
|  |  | C1D8 | 5 | 10.260 (3.6170) | 10.300 (7.800, 13.000) | 5.70, 14.50 | 5 | -0.160 (3.9132) | 0.700 (-2.300, 1.200) | -5.40, 5.00 |
|  |  | C2D1 | 4 | 8.025 (3.2847) | 7.850 (5.850, 10.200) | 4.20, 12.20 | 4 | -2.600 (4.4460) | -2.850 (-5.750, 0.550) | -7.70, 3.00 |
|  |  | C3D1 | 2 | 6.500 (4.3841) | 6.500 (3.400, 9.600) | 3.40, 9.60 | 2 | -2.550 (2.8991) | -2.550 (-4.600, -0.500) | -4.60, -0.50 |
|  |  | C4D1 | 2 | 9.850 (3.6062) | 9.850 (7.300, 12.400) | 7.30, 12.40 | 2 | 0.800 (5.0912) | 0.800 (-2.800, 4.400) | -2.80, 4.40 |
|  |  | C5D1 | 2 | 8.550 (1.9092) | 8.550 (7.200, 9.900) | 7.20, 9.90 | 2 | -0.500 (0.4243) | -0.500 (-0.800, -0.200) | -0.80, -0.20 |
|  | | | | | | | | | | |
|  | Control Group (N = 5) | Baseline | 5 | 13.500 (7.9360) | 10.900 (10.000, 15.600) | 5.00, 26.00 |  |  |  |  |
|  |  | C1D8 | 5 | 10.266 (2.5622) | 11.200 (11.200, 11.500) | 5.70, 11.73 | 5 | -3.234 (6.7826) | 0.600 (-3.870, 0.700) | -14.80, 1.20 |
|  |  | C2D1 | 4 | 10.800 (4.2778) | 11.600 (8.050, 13.550) | 4.90, 15.10 | 4 | -2.175 (8.7053) | 0.500 (-7.450, 3.100) | -14.80, 5.10 |
|  |  | C3D1 | 2 | 8.600 (0.1414) | 8.600 (8.500, 8.700) | 8.50, 8.70 | 2 | -1.850 (0.7778) | -1.850 (-2.400, -1.300) | -2.40, -1.30 |
|  |  | C4D1 | 1 | 13.700 (NA) | 13.700 (13.700, 13.700) | 13.70, 13.70 | 1 | 2.800 (NA) | 2.800 (2.800, 2.800) | 2.80, 2.80 |
|  |  | C5D1 | 1 | 9.700 (NA) | 9.700 (9.700, 9.700) | 9.70, 9.70 | 1 | -1.200 (NA) | -1.200 (-1.200, -1.200) | -1.20, -1.20 |
|  |  | End of Treatment | 1 | 27.300 (NA) | 27.300 (27.300, 27.300) | 27.30, 27.30 | 1 | 1.300 (NA) | 1.300 (1.300, 1.300) | 1.30, 1.30 |
|  | | | | | | | | | | |
|  | Total (N = 10) | Baseline | 10 | 11.960 (6.7263) | 10.050 (8.000, 15.600) | 4.50, 26.00 |  |  |  |  |
|  |  | C1D8 | 10 | 10.263 (2.9551) | 11.200 (7.800, 11.730) | 5.70, 14.50 | 10 | -1.697 (5.4659) | 0.650 (-3.870, 1.200) | -14.80, 5.00 |
|  |  | C2D1 | 8 | 9.413 (3.8297) | 9.700 (6.200, 12.100) | 4.20, 15.10 | 8 | -2.388 (6.4032) | -1.000 (-5.750, 2.050) | -14.80, 5.10 |
|  |  | C3D1 | 4 | 7.550 (2.8077) | 8.600 (5.950, 9.150) | 3.40, 9.60 | 4 | -2.200 (1.7795) | -1.850 (-3.500, -0.900) | -4.60, -0.50 |
|  |  | C4D1 | 3 | 11.133 (3.3828) | 12.400 (7.300, 13.700) | 7.30, 13.70 | 3 | 1.467 (3.7807) | 2.800 (-2.800, 4.400) | -2.80, 4.40 |
|  |  | C5D1 | 3 | 8.933 (1.5044) | 9.700 (7.200, 9.900) | 7.20, 9.90 | 3 | -0.733 (0.5033) | -0.800 (-1.200, -0.200) | -1.20, -0.20 |
|  |  | End of Treatment | 1 | 27.300 (NA) | 27.300 (27.300, 27.300) | 27.30, 27.30 | 1 | 1.300 (NA) | 1.300 (1.300, 1.300) | 1.30, 1.30 |
|  | | | | | | | | | | |
| Direct Bilirubin (umol/L) | Treatment Group (N = 5) | Baseline | 5 | 3.780 (2.5753) | 3.600 (1.800, 3.900) | 1.60, 8.00 |  |  |  |  |
|  |  | C1D8 | 5 | 3.820 (2.1159) | 2.800 (2.300, 5.900) | 1.80, 6.30 | 5 | 0.040 (1.5550) | 0.200 (-1.100, 0.500) | -1.70, 2.30 |
|  |  | C2D1 | 4 | 3.925 (2.0759) | 3.100 (2.700, 5.150) | 2.50, 7.00 | 4 | -0.400 (1.0231) | -0.800 (-1.050, 0.250) | -1.10, 1.10 |
|  |  | C3D1 | 2 | 3.050 (0.6364) | 3.050 (2.600, 3.500) | 2.60, 3.50 | 2 | -0.700 (0.4243) | -0.700 (-1.000, -0.400) | -1.00, -0.40 |
|  |  | C4D1 | 2 | 4.200 (1.8385) | 4.200 (2.900, 5.500) | 2.90, 5.50 | 2 | 0.450 (2.0506) | 0.450 (-1.000, 1.900) | -1.00, 1.90 |
|  |  | C5D1 | 2 | 3.450 (0.0707) | 3.450 (3.400, 3.500) | 3.40, 3.50 | 2 | -0.300 (0.2828) | -0.300 (-0.500, -0.100) | -0.50, -0.10 |
|  | | | | | | | | | | |
|  | Control Group (N = 5) | Baseline | 5 | 6.160 (5.7064) | 3.600 (2.900, 5.800) | 2.40, 16.10 |  |  |  |  |
|  |  | C1D8 | 5 | 4.530 (2.5420) | 5.200 (2.550, 5.500) | 1.50, 7.90 | 5 | -1.630 (3.7927) | -0.350 (-0.900, -0.300) | -8.20, 1.60 |
|  |  | C2D1 | 4 | 5.450 (3.0315) | 5.500 (3.450, 7.450) | 1.70, 9.10 | 4 | -1.525 (3.8896) | -0.650 (-3.850, 0.800) | -7.00, 2.20 |
|  |  | C3D1 | 2 | 4.550 (0.7778) | 4.550 (4.000, 5.100) | 4.00, 5.10 | 2 | -0.150 (0.7778) | -0.150 (-0.700, 0.400) | -0.70, 0.40 |
|  |  | C4D1 | 1 | 7.200 (NA) | 7.200 (7.200, 7.200) | 7.20, 7.20 | 1 | 1.400 (NA) | 1.400 (1.400, 1.400) | 1.40, 1.40 |
|  |  | C5D1 | 1 | 7.500 (NA) | 7.500 (7.500, 7.500) | 7.50, 7.50 | 1 | 1.700 (NA) | 1.700 (1.700, 1.700) | 1.70, 1.70 |
|  |  | End of Treatment | 1 | 23.000 (NA) | 23.000 (23.000, 23.000) | 23.00, 23.00 | 1 | 6.900 (NA) | 6.900 (6.900, 6.900) | 6.90, 6.90 |
|  | | | | | | | | | | |
|  | Total (N = 10) | Baseline | 10 | 4.970 (4.3581) | 3.600 (2.400, 5.800) | 1.60, 16.10 |  |  |  |  |
|  |  | C1D8 | 10 | 4.175 (2.2365) | 4.000 (2.300, 5.900) | 1.50, 7.90 | 10 | -0.795 (2.8710) | -0.325 (-1.100, 0.500) | -8.20, 2.30 |
|  |  | C2D1 | 8 | 4.688 (2.5396) | 4.250 (2.700, 6.400) | 1.70, 9.10 | 8 | -0.963 (2.7008) | -0.650 (-1.050, 0.250) | -7.00, 2.20 |
|  |  | C3D1 | 4 | 3.800 (1.0424) | 3.750 (3.050, 4.550) | 2.60, 5.10 | 4 | -0.425 (0.6021) | -0.550 (-0.850, 0.000) | -1.00, 0.40 |
|  |  | C4D1 | 3 | 5.200 (2.1656) | 5.500 (2.900, 7.200) | 2.90, 7.20 | 3 | 0.767 (1.5503) | 1.400 (-1.000, 1.900) | -1.00, 1.90 |
|  |  | C5D1 | 3 | 4.800 (2.3388) | 3.500 (3.400, 7.500) | 3.40, 7.50 | 3 | 0.367 (1.1719) | -0.100 (-0.500, 1.700) | -0.50, 1.70 |
|  |  | End of Treatment | 1 | 23.000 (NA) | 23.000 (23.000, 23.000) | 23.00, 23.00 | 1 | 6.900 (NA) | 6.900 (6.900, 6.900) | 6.90, 6.90 |
|  | | | | | | | | | | |
| Indirect Bilirubin (umol/L) | Treatment Group (N = 5) | Baseline | 5 | 6.640 (3.5444) | 6.200 (4.400, 8.000) | 2.70, 11.90 |  |  |  |  |
|  |  | C1D8 | 5 | 6.440 (2.1847) | 7.100 (5.000, 8.200) | 3.40, 8.50 | 5 | -0.200 (2.3958) | 0.500 (-1.200, 0.700) | -3.70, 2.70 |
|  |  | C2D1 | 4 | 4.100 (1.6186) | 4.750 (3.150, 5.050) | 1.70, 5.20 | 4 | -2.200 (3.5646) | -2.000 (-4.700, 0.300) | -6.70, 1.90 |
|  |  | C3D1 | 2 | 3.450 (3.7477) | 3.450 (0.800, 6.100) | 0.80, 6.10 | 2 | -1.850 (2.4749) | -1.850 (-3.600, -0.100) | -3.60, -0.10 |
|  |  | C4D1 | 2 | 5.650 (1.7678) | 5.650 (4.400, 6.900) | 4.40, 6.90 | 2 | 0.350 (3.0406) | 0.350 (-1.800, 2.500) | -1.80, 2.50 |
|  |  | C5D1 | 2 | 5.100 (1.9799) | 5.100 (3.700, 6.500) | 3.70, 6.50 | 2 | -0.200 (0.7071) | -0.200 (-0.700, 0.300) | -0.70, 0.30 |
|  | | | | | | | | | | |
|  | Control Group (N = 5) | Baseline | 5 | 7.340 (3.9891) | 6.400 (5.100, 9.900) | 2.60, 12.70 |  |  |  |  |
|  |  | C1D8 | 5 | 5.736 (2.2524) | 6.000 (4.200, 6.000) | 3.30, 9.18 | 5 | -1.604 (3.4138) | -0.400 (-3.520, 0.900) | -6.60, 1.60 |
|  |  | C2D1 | 4 | 5.350 (3.3111) | 5.000 (2.650, 8.050) | 2.10, 9.30 | 4 | -0.650 (4.8583) | 1.150 (-3.600, 2.300) | -7.80, 2.90 |
|  |  | C3D1 | 2 | 4.050 (0.9192) | 4.050 (3.400, 4.700) | 3.40, 4.70 | 2 | -1.700 (0.0000) | -1.700 (-1.700, -1.700) | -1.70, -1.70 |
|  |  | C4D1 | 1 | 6.500 (NA) | 6.500 (6.500, 6.500) | 6.50, 6.50 | 1 | 1.400 (NA) | 1.400 (1.400, 1.400) | 1.40, 1.40 |
|  |  | C5D1 | 1 | 4.000 (NA) | 4.000 (4.000, 4.000) | 4.00, 4.00 | 1 | -1.100 (NA) | -1.100 (-1.100, -1.100) | -1.10, -1.10 |
|  |  | End of Treatment | 1 | 4.300 (NA) | 4.300 (4.300, 4.300) | 4.30, 4.30 | 1 | -5.600 (NA) | -5.600 (-5.600, -5.600) | -5.60, -5.60 |
|  | | | | | | | | | | |
|  | Total (N = 10) | Baseline | 10 | 6.990 (3.5766) | 6.300 (4.400, 9.900) | 2.60, 12.70 |  |  |  |  |
|  |  | C1D8 | 10 | 6.088 (2.1246) | 6.000 (4.200, 8.200) | 3.30, 9.18 | 10 | -0.902 (2.8772) | 0.050 (-3.520, 0.900) | -6.60, 2.70 |
|  |  | C2D1 | 8 | 4.725 (2.5036) | 4.750 (2.650, 6.000) | 1.70, 9.30 | 8 | -1.425 (4.0309) | -0.350 (-4.700, 1.800) | -7.80, 2.90 |
|  |  | C3D1 | 4 | 3.750 (2.2546) | 4.050 (2.100, 5.400) | 0.80, 6.10 | 4 | -1.775 (1.4315) | -1.700 (-2.650, -0.900) | -3.60, -0.10 |
|  |  | C4D1 | 3 | 5.933 (1.3429) | 6.500 (4.400, 6.900) | 4.40, 6.90 | 3 | 0.700 (2.2338) | 1.400 (-1.800, 2.500) | -1.80, 2.50 |
|  |  | C5D1 | 3 | 4.733 (1.5373) | 4.000 (3.700, 6.500) | 3.70, 6.50 | 3 | -0.500 (0.7211) | -0.700 (-1.100, 0.300) | -1.10, 0.30 |
|  |  | End of Treatment | 1 | 4.300 (NA) | 4.300 (4.300, 4.300) | 4.30, 4.30 | 1 | -5.600 (NA) | -5.600 (-5.600, -5.600) | -5.60, -5.60 |
|  | | | | | | | | | | |
| Alanine Aminotransferase (IU/L) | Treatment Group (N = 5) | Baseline | 5 | 23.00 (5.701) | 26.00 (19.00, 27.00) | 15.0, 28.0 |  |  |  |  |
|  |  | C1D8 | 5 | 28.20 (16.254) | 21.00 (18.00, 34.00) | 14.0, 54.0 | 5 | 5.20 (13.217) | 2.00 (-1.00, 6.00) | -8.0, 27.0 |
|  |  | C2D1 | 4 | 29.25 (31.405) | 15.50 (11.00, 47.50) | 10.0, 76.0 | 4 | 7.25 (28.040) | -1.50 (-9.50, 24.00) | -16.0, 48.0 |
|  |  | C3D1 | 2 | 15.50 (2.121) | 15.50 (14.00, 17.00) | 14.0, 17.0 | 2 | -1.50 (0.707) | -1.50 (-2.00, -1.00) | -2.0, -1.0 |
|  |  | C4D1 | 2 | 14.50 (2.121) | 14.50 (13.00, 16.00) | 13.0, 16.0 | 2 | -2.50 (0.707) | -2.50 (-3.00, -2.00) | -3.0, -2.0 |
|  |  | C5D1 | 2 | 11.50 (2.121) | 11.50 (10.00, 13.00) | 10.0, 13.0 | 2 | -5.50 (0.707) | -5.50 (-6.00, -5.00) | -6.0, -5.0 |
|  | | | | | | | | | | |
|  | Control Group (N = 5) | Baseline | 5 | 31.52 (23.019) | 20.00 (19.00, 28.60) | 18.0, 72.0 |  |  |  |  |
|  |  | C1D8 | 5 | 31.76 (22.913) | 24.00 (24.00, 28.80) | 11.0, 71.0 | 5 | 0.24 (35.280) | 0.20 (-7.00, 5.00) | -48.0, 51.0 |
|  |  | C2D1 | 4 | 25.75 (12.842) | 22.50 (16.00, 35.50) | 15.0, 43.0 | 4 | -6.50 (15.801) | -2.50 (-16.00, 3.00) | -29.0, 8.0 |
|  |  | C3D1 | 2 | 17.50 (6.364) | 17.50 (13.00, 22.00) | 13.0, 22.0 | 2 | -1.50 (4.950) | -1.50 (-5.00, 2.00) | -5.0, 2.0 |
|  |  | C4D1 | 1 | 12.00 (NA) | 12.00 (12.00, 12.00) | 12.0, 12.0 | 1 | -6.00 (NA) | -6.00 (-6.00, -6.00) | -6.0, -6.0 |
|  |  | C5D1 | 1 | 11.00 (NA) | 11.00 (11.00, 11.00) | 11.0, 11.0 | 1 | -7.00 (NA) | -7.00 (-7.00, -7.00) | -7.0, -7.0 |
|  |  | End of Treatment | 1 | 37.00 (NA) | 37.00 (37.00, 37.00) | 37.0, 37.0 | 1 | -35.00 (NA) | -35.00 (-35.00, -35.00) | -35.0, -35.0 |
|  | | | | | | | | | | |
|  | Total (N = 10) | Baseline | 10 | 27.26 (16.435) | 23.00 (19.00, 28.00) | 15.0, 72.0 |  |  |  |  |
|  |  | C1D8 | 10 | 29.98 (18.822) | 24.00 (18.00, 34.00) | 11.0, 71.0 | 10 | 2.72 (25.252) | 1.10 (-7.00, 6.00) | -48.0, 51.0 |
|  |  | C2D1 | 8 | 27.50 (22.290) | 18.00 (13.50, 35.50) | 10.0, 76.0 | 8 | 0.38 (22.316) | -2.50 (-9.50, 4.00) | -29.0, 48.0 |
|  |  | C3D1 | 4 | 16.50 (4.041) | 15.50 (13.50, 19.50) | 13.0, 22.0 | 4 | -1.50 (2.887) | -1.50 (-3.50, 0.50) | -5.0, 2.0 |
|  |  | C4D1 | 3 | 13.67 (2.082) | 13.00 (12.00, 16.00) | 12.0, 16.0 | 3 | -3.67 (2.082) | -3.00 (-6.00, -2.00) | -6.0, -2.0 |
|  |  | C5D1 | 3 | 11.33 (1.528) | 11.00 (10.00, 13.00) | 10.0, 13.0 | 3 | -6.00 (1.000) | -6.00 (-7.00, -5.00) | -7.0, -5.0 |
|  |  | End of Treatment | 1 | 37.00 (NA) | 37.00 (37.00, 37.00) | 37.0, 37.0 | 1 | -35.00 (NA) | -35.00 (-35.00, -35.00) | -35.0, -35.0 |
|  | | | | | | | | | | |
| Aspartate Aminotransferase (IU/L) | Treatment Group (N = 5) | Baseline | 5 | 31.00 (11.113) | 31.00 (21.00, 40.00) | 19.0, 44.0 |  |  |  |  |
|  |  | C1D8 | 5 | 33.60 (18.284) | 22.00 (20.00, 51.00) | 19.0, 56.0 | 5 | 2.60 (9.397) | 1.00 (0.00, 11.00) | -11.0, 12.0 |
|  |  | C2D1 | 4 | 32.00 (24.967) | 21.50 (17.00, 47.00) | 16.0, 69.0 | 4 | 4.25 (17.914) | 0.50 (-8.00, 16.50) | -13.0, 29.0 |
|  |  | C3D1 | 2 | 18.50 (0.707) | 18.50 (18.00, 19.00) | 18.0, 19.0 | 2 | -1.50 (2.121) | -1.50 (-3.00, 0.00) | -3.0, 0.0 |
|  |  | C4D1 | 2 | 20.00 (1.414) | 20.00 (19.00, 21.00) | 19.0, 21.0 | 2 | 0.00 (0.000) | 0.00 (0.00, 0.00) | 0.0, 0.0 |
|  |  | C5D1 | 2 | 19.50 (4.950) | 19.50 (16.00, 23.00) | 16.0, 23.0 | 2 | -0.50 (3.536) | -0.50 (-3.00, 2.00) | -3.0, 2.0 |
|  | | | | | | | | | | |
|  | Control Group (N = 5) | Baseline | 5 | 41.24 (29.764) | 25.00 (20.00, 62.00) | 16.0, 83.2 |  |  |  |  |
|  |  | C1D8 | 5 | 41.30 (28.350) | 26.00 (21.00, 54.00) | 20.0, 85.5 | 5 | 0.06 (25.036) | 2.30 (-5.00, 5.00) | -36.0, 34.0 |
|  |  | C2D1 | 4 | 29.25 (17.115) | 24.00 (18.50, 40.00) | 15.0, 54.0 | 4 | -1.50 (5.802) | -2.00 (-5.50, 2.50) | -8.0, 6.0 |
|  |  | C3D1 | 2 | 22.00 (2.828) | 22.00 (20.00, 24.00) | 20.0, 24.0 | 2 | -0.50 (0.707) | -0.50 (-1.00, 0.00) | -1.0, 0.0 |
|  |  | C4D1 | 1 | 20.00 (NA) | 20.00 (20.00, 20.00) | 20.0, 20.0 | 1 | -5.00 (NA) | -5.00 (-5.00, -5.00) | -5.0, -5.0 |
|  |  | C5D1 | 1 | 22.00 (NA) | 22.00 (22.00, 22.00) | 22.0, 22.0 | 1 | -3.00 (NA) | -3.00 (-3.00, -3.00) | -3.0, -3.0 |
|  |  | End of Treatment | 1 | 94.00 (NA) | 94.00 (94.00, 94.00) | 94.0, 94.0 | 1 | 32.00 (NA) | 32.00 (32.00, 32.00) | 32.0, 32.0 |
|  | | | | | | | | | | |
|  | Total (N = 10) | Baseline | 10 | 36.12 (21.857) | 28.00 (20.00, 44.00) | 16.0, 83.2 |  |  |  |  |
|  |  | C1D8 | 10 | 37.45 (22.853) | 24.00 (20.00, 54.00) | 19.0, 85.5 | 10 | 1.33 (17.878) | 1.65 (-5.00, 11.00) | -36.0, 34.0 |
|  |  | C2D1 | 8 | 30.63 (19.871) | 23.50 (17.00, 40.00) | 15.0, 69.0 | 8 | 1.38 (12.705) | -2.00 (-5.50, 5.00) | -13.0, 29.0 |
|  |  | C3D1 | 4 | 20.25 (2.630) | 19.50 (18.50, 22.00) | 18.0, 24.0 | 4 | -1.00 (1.414) | -0.50 (-2.00, 0.00) | -3.0, 0.0 |
|  |  | C4D1 | 3 | 20.00 (1.000) | 20.00 (19.00, 21.00) | 19.0, 21.0 | 3 | -1.67 (2.887) | 0.00 (-5.00, 0.00) | -5.0, 0.0 |
|  |  | C5D1 | 3 | 20.33 (3.786) | 22.00 (16.00, 23.00) | 16.0, 23.0 | 3 | -1.33 (2.887) | -3.00 (-3.00, 2.00) | -3.0, 2.0 |
|  |  | End of Treatment | 1 | 94.00 (NA) | 94.00 (94.00, 94.00) | 94.0, 94.0 | 1 | 32.00 (NA) | 32.00 (32.00, 32.00) | 32.0, 32.0 |
|  | | | | | | | | | | |
| Gamma Glutamyl Transferase (IU/L) | Treatment Group (N = 5) | Baseline | 5 | 82.80 (69.237) | 52.00 (31.00, 141.00) | 18.0, 172.0 |  |  |  |  |
|  |  | C1D8 | 5 | 90.00 (73.171) | 69.00 (35.00, 165.00) | 12.0, 169.0 | 5 | 7.20 (12.911) | 4.00 (-3.00, 17.00) | -6.0, 24.0 |
|  |  | C2D1 | 4 | 124.50 (179.749) | 48.50 (21.00, 228.00) | 9.0, 392.0 | 4 | 64.00 (124.961) | 7.00 (-3.50, 131.50) | -9.0, 251.0 |
|  |  | C3D1 | 2 | 43.50 (21.920) | 43.50 (28.00, 59.00) | 28.0, 59.0 | 2 | 2.00 (7.071) | 2.00 (-3.00, 7.00) | -3.0, 7.0 |
|  |  | C4D1 | 2 | 37.00 (21.213) | 37.00 (22.00, 52.00) | 22.0, 52.0 | 2 | -4.50 (6.364) | -4.50 (-9.00, 0.00) | -9.0, 0.0 |
|  |  | C5D1 | 2 | 33.50 (16.263) | 33.50 (22.00, 45.00) | 22.0, 45.0 | 2 | -8.00 (1.414) | -8.00 (-9.00, -7.00) | -9.0, -7.0 |
|  | | | | | | | | | | |
|  | Control Group (N = 5) | Baseline | 5 | 171.20 (184.910) | 48.00 (39.00, 373.00) | 22.0, 374.0 |  |  |  |  |
|  |  | C1D8 | 5 | 136.14 (133.493) | 43.00 (39.00, 245.00) | 39.0, 314.7 | 5 | -35.06 (60.033) | -9.00 (-58.30, 0.00) | -129.0, 21.0 |
|  |  | C2D1 | 4 | 108.50 (146.812) | 42.50 (28.00, 189.00) | 21.0, 328.0 | 4 | -12.25 (25.902) | -8.00 (-32.00, 7.50) | -46.0, 13.0 |
|  |  | C3D1 | 2 | 38.00 (21.213) | 38.00 (23.00, 53.00) | 23.0, 53.0 | 2 | 3.00 (2.828) | 3.00 (1.00, 5.00) | 1.0, 5.0 |
|  |  | C4D1 | 1 | 50.00 (NA) | 50.00 (50.00, 50.00) | 50.0, 50.0 | 1 | 2.00 (NA) | 2.00 (2.00, 2.00) | 2.0, 2.0 |
|  |  | C5D1 | 1 | 54.00 (NA) | 54.00 (54.00, 54.00) | 54.0, 54.0 | 1 | 6.00 (NA) | 6.00 (6.00, 6.00) | 6.0, 6.0 |
|  |  | End of Treatment | 1 | 415.00 (NA) | 415.00 (415.00, 415.00) | 415.0, 415.0 | 1 | 41.00 (NA) | 41.00 (41.00, 41.00) | 41.0, 41.0 |
|  | | | | | | | | | | |
|  | Total (N = 10) | Baseline | 10 | 127.00 (139.634) | 50.00 (31.00, 172.00) | 18.0, 374.0 |  |  |  |  |
|  |  | C1D8 | 10 | 113.07 (104.360) | 56.00 (39.00, 169.00) | 12.0, 314.7 | 10 | -13.93 (46.604) | -1.50 (-9.00, 17.00) | -129.0, 24.0 |
|  |  | C2D1 | 8 | 116.50 (152.176) | 42.50 (27.00, 196.00) | 9.0, 392.0 | 8 | 25.88 (92.957) | 2.00 (-13.50, 12.50) | -46.0, 251.0 |
|  |  | C3D1 | 4 | 40.75 (17.896) | 40.50 (25.50, 56.00) | 23.0, 59.0 | 4 | 2.50 (4.435) | 3.00 (-1.00, 6.00) | -3.0, 7.0 |
|  |  | C4D1 | 3 | 41.33 (16.773) | 50.00 (22.00, 52.00) | 22.0, 52.0 | 3 | -2.33 (5.859) | 0.00 (-9.00, 2.00) | -9.0, 2.0 |
|  |  | C5D1 | 3 | 40.33 (16.503) | 45.00 (22.00, 54.00) | 22.0, 54.0 | 3 | -3.33 (8.145) | -7.00 (-9.00, 6.00) | -9.0, 6.0 |
|  |  | End of Treatment | 1 | 415.00 (NA) | 415.00 (415.00, 415.00) | 415.0, 415.0 | 1 | 41.00 (NA) | 41.00 (41.00, 41.00) | 41.0, 41.0 |
|  | | | | | | | | | | |
| Alkaline Phosphatase (IU/L) | Treatment Group (N = 5) | Baseline | 5 | 119.000 (45.7220) | 147.000 (86.000, 151.000) | 55.00, 156.00 |  |  |  |  |
|  |  | C1D8 | 5 | 121.800 (51.6885) | 129.000 (76.000, 150.000) | 65.00, 189.00 | 5 | 2.800 (20.8734) | 3.000 (-10.000, 10.000) | -22.00, 33.00 |
|  |  | C2D1 | 4 | 173.500 (168.7572) | 103.500 (68.000, 279.000) | 65.00, 422.00 | 4 | 61.500 (137.2941) | 0.500 (-18.000, 141.000) | -21.00, 266.00 |
|  |  | C3D1 | 2 | 94.000 (38.1838) | 94.000 (67.000, 121.000) | 67.00, 121.00 | 2 | -9.000 (29.6985) | -9.000 (-30.000, 12.000) | -30.00, 12.00 |
|  |  | C4D1 | 2 | 94.500 (34.6482) | 94.500 (70.000, 119.000) | 70.00, 119.00 | 2 | -8.500 (33.2340) | -8.500 (-32.000, 15.000) | -32.00, 15.00 |
|  |  | C5D1 | 2 | 91.000 (26.8701) | 91.000 (72.000, 110.000) | 72.00, 110.00 | 2 | -12.000 (41.0122) | -12.000 (-41.000, 17.000) | -41.00, 17.00 |
|  | | | | | | | | | | |
|  | Control Group (N = 5) | Baseline | 5 | 248.800 (250.4969) | 113.000 (89.000, 316.000) | 66.00, 660.00 |  |  |  |  |
|  |  | C1D8 | 5 | 181.800 (131.0065) | 96.000 (91.000, 255.000) | 88.00, 379.00 | 5 | -67.000 (123.5051) | -17.000 (-61.000, 2.000) | -281.00, 22.00 |
|  |  | C2D1 | 4 | 152.500 (144.7584) | 84.500 (72.500, 232.500) | 72.00, 369.00 | 4 | 6.500 (32.7669) | -5.000 (-16.500, 29.500) | -17.00, 53.00 |
|  |  | C3D1 | 2 | 78.000 (18.3848) | 78.000 (65.000, 91.000) | 65.00, 91.00 | 2 | -23.000 (1.4142) | -23.000 (-24.000, -22.000) | -24.00, -22.00 |
|  |  | C4D1 | 1 | 96.000 (NA) | 96.000 (96.000, 96.000) | 96.00, 96.00 | 1 | -17.000 (NA) | -17.000 (-17.000, -17.000) | -17.00, -17.00 |
|  |  | C5D1 | 1 | 109.000 (NA) | 109.000 (109.000, 109.000) | 109.00, 109.00 | 1 | -4.000 (NA) | -4.000 (-4.000, -4.000) | -4.00, -4.00 |
|  |  | End of Treatment | 1 | 441.000 (NA) | 441.000 (441.000, 441.000) | 441.00, 441.00 | 1 | 125.000 (NA) | 125.000 (125.000, 125.000) | 125.00, 125.00 |
|  | | | | | | | | | | |
|  | Total (N = 10) | Baseline | 10 | 183.900 (183.0230) | 130.000 (86.000, 156.000) | 55.00, 660.00 |  |  |  |  |
|  |  | C1D8 | 10 | 151.800 (99.0721) | 112.500 (88.000, 189.000) | 65.00, 379.00 | 10 | -32.100 (91.2487) | -4.000 (-22.000, 10.000) | -281.00, 33.00 |
|  |  | C2D1 | 8 | 163.000 (145.9863) | 84.500 (71.500, 252.500) | 65.00, 422.00 | 8 | 34.000 (96.9683) | -4.500 (-16.500, 34.500) | -21.00, 266.00 |
|  |  | C3D1 | 4 | 86.000 (26.1534) | 79.000 (66.000, 106.000) | 65.00, 121.00 | 4 | -16.000 (18.9737) | -23.000 (-27.000, -5.000) | -30.00, 12.00 |
|  |  | C4D1 | 3 | 95.000 (24.5153) | 96.000 (70.000, 119.000) | 70.00, 119.00 | 3 | -11.333 (24.0069) | -17.000 (-32.000, 15.000) | -32.00, 15.00 |
|  |  | C5D1 | 3 | 97.000 (21.6564) | 109.000 (72.000, 110.000) | 72.00, 110.00 | 3 | -9.333 (29.3655) | -4.000 (-41.000, 17.000) | -41.00, 17.00 |
|  |  | End of Treatment | 1 | 441.000 (NA) | 441.000 (441.000, 441.000) | 441.00, 441.00 | 1 | 125.000 (NA) | 125.000 (125.000, 125.000) | 125.00, 125.00 |
|  | | | | | | | | | | |
| Lactate Dehydrogenase (IU/L) | Treatment Group (N = 5) | Baseline | 5 | 285.80 (160.638) | 241.00 (228.00, 244.00) | 151.0, 565.0 |  |  |  |  |
|  |  | C1D8 | 5 | 219.80 (75.820) | 201.00 (172.00, 255.00) | 139.0, 332.0 | 5 | -66.00 (103.189) | -40.00 (-89.00, 11.00) | -233.0, 21.0 |
|  |  | C2D1 | 4 | 213.75 (42.484) | 205.00 (180.00, 247.50) | 177.0, 268.0 | 4 | -83.25 (145.461) | -31.00 (-171.00, 4.50) | -297.0, 26.0 |
|  |  | C3D1 | 2 | 186.50 (33.234) | 186.50 (163.00, 210.00) | 163.0, 210.0 | 2 | -3.00 (87.681) | -3.00 (-65.00, 59.00) | -65.0, 59.0 |
|  |  | C4D1 | 2 | 197.00 (22.627) | 197.00 (181.00, 213.00) | 181.0, 213.0 | 2 | 7.50 (77.075) | 7.50 (-47.00, 62.00) | -47.0, 62.0 |
|  |  | C5D1 | 2 | 215.00 (5.657) | 215.00 (211.00, 219.00) | 211.0, 219.0 | 2 | 25.50 (48.790) | 25.50 (-9.00, 60.00) | -9.0, 60.0 |
|  | | | | | | | | | | |
|  | Control Group (N = 5) | Baseline | 5 | 308.46 (121.501) | 251.00 (241.00, 366.30) | 191.0, 493.0 |  |  |  |  |
|  |  | C1D8 | 5 | 258.28 (51.205) | 254.00 (225.00, 280.00) | 200.0, 332.4 | 5 | -50.18 (97.281) | -33.90 (-51.00, 13.00) | -213.0, 34.0 |
|  |  | C2D1 | 4 | 285.00 (148.508) | 224.00 (193.00, 377.00) | 188.0, 504.0 | 4 | -9.00 (29.755) | 3.00 (-27.00, 9.00) | -53.0, 11.0 |
|  |  | C3D1 | 2 | 221.00 (18.385) | 221.00 (208.00, 234.00) | 208.0, 234.0 | 2 | 0.00 (24.042) | 0.00 (-17.00, 17.00) | -17.0, 17.0 |
|  |  | C4D1 | 1 | 249.00 (NA) | 249.00 (249.00, 249.00) | 249.0, 249.0 | 1 | -2.00 (NA) | -2.00 (-2.00, -2.00) | -2.0, -2.0 |
|  |  | C5D1 | 1 | 306.00 (NA) | 306.00 (306.00, 306.00) | 306.0, 306.0 | 1 | 55.00 (NA) | 55.00 (55.00, 55.00) | 55.0, 55.0 |
|  |  | End of Treatment | 1 | 1570.00 (NA) | 1570.00 (1570.00, 1570.00) | 1570.0, 1570.0 | 1 | 1077.00 (NA) | 1077.00 (1077.00, 1077.00) | 1077.0, 1077.0 |
|  | | | | | | | | | | |
|  | Total (N = 10) | Baseline | 10 | 297.13 (134.805) | 242.50 (228.00, 366.30) | 151.0, 565.0 |  |  |  |  |
|  |  | C1D8 | 10 | 239.04 (64.278) | 239.50 (200.00, 280.00) | 139.0, 332.4 | 10 | -58.09 (94.910) | -36.95 (-89.00, 13.00) | -233.0, 34.0 |
|  |  | C2D1 | 8 | 249.38 (108.055) | 212.50 (185.50, 259.00) | 177.0, 504.0 | 8 | -46.13 (104.989) | -9.00 (-49.00, 9.00) | -297.0, 26.0 |
|  |  | C3D1 | 4 | 203.75 (29.624) | 209.00 (185.50, 222.00) | 163.0, 234.0 | 4 | -1.50 (52.520) | 0.00 (-41.00, 38.00) | -65.0, 59.0 |
|  |  | C4D1 | 3 | 214.33 (34.020) | 213.00 (181.00, 249.00) | 181.0, 249.0 | 3 | 4.33 (54.775) | -2.00 (-47.00, 62.00) | -47.0, 62.0 |
|  |  | C5D1 | 3 | 245.33 (52.691) | 219.00 (211.00, 306.00) | 211.0, 306.0 | 3 | 35.33 (38.475) | 55.00 (-9.00, 60.00) | -9.0, 60.0 |
|  |  | End of Treatment | 1 | 1570.00 (NA) | 1570.00 (1570.00, 1570.00) | 1570.0, 1570.0 | 1 | 1077.00 (NA) | 1077.00 (1077.00, 1077.00) | 1077.0, 1077.0 |
|  | | | | | | | | | | |
| Protein (g/L) | Treatment Group (N = 5) | Baseline | 5 | 73.200 (7.6446) | 74.300 (68.100, 77.000) | 63.50, 83.10 |  |  |  |  |
|  |  | C1D8 | 5 | 72.040 (7.4248) | 69.700 (66.300, 76.300) | 65.10, 82.80 | 5 | -1.160 (3.9677) | -0.300 (-0.700, 1.600) | -8.00, 1.60 |
|  |  | C2D1 | 4 | 70.675 (3.3837) | 71.050 (67.800, 73.550) | 67.00, 73.60 | 4 | -0.050 (7.4182) | -1.450 (-5.350, 5.250) | -7.30, 10.00 |
|  |  | C3D1 | 2 | 74.450 (0.4950) | 74.450 (74.100, 74.800) | 74.10, 74.80 | 2 | 5.550 (8.1317) | 5.550 (-0.200, 11.300) | -0.20, 11.30 |
|  |  | C4D1 | 2 | 68.450 (2.8991) | 68.450 (66.400, 70.500) | 66.40, 70.50 | 2 | -0.450 (4.7376) | -0.450 (-3.800, 2.900) | -3.80, 2.90 |
|  |  | C5D1 | 2 | 71.550 (5.1619) | 71.550 (67.900, 75.200) | 67.90, 75.20 | 2 | 2.650 (2.4749) | 2.650 (0.900, 4.400) | 0.90, 4.40 |
|  | | | | | | | | | | |
|  | Control Group (N = 5) | Baseline | 5 | 72.600 (2.7166) | 72.300 (70.300, 74.800) | 69.70, 75.90 |  |  |  |  |
|  |  | C1D8 | 5 | 73.320 (6.1856) | 71.800 (71.700, 73.900) | 66.10, 83.10 | 5 | 0.720 (5.4127) | 1.500 (-3.100, 4.200) | -6.20, 7.20 |
|  |  | C2D1 | 4 | 76.100 (5.8986) | 76.250 (71.000, 81.200) | 70.60, 81.30 | 4 | 2.925 (3.6900) | 3.450 (0.000, 5.850) | -1.70, 6.50 |
|  |  | C3D1 | 2 | 69.100 (2.4042) | 69.100 (67.400, 70.800) | 67.40, 70.80 | 2 | -1.900 (0.5657) | -1.900 (-2.300, -1.500) | -2.30, -1.50 |
|  |  | C4D1 | 1 | 71.800 (NA) | 71.800 (71.800, 71.800) | 71.80, 71.80 | 1 | -0.500 (NA) | -0.500 (-0.500, -0.500) | -0.50, -0.50 |
|  |  | C5D1 | 1 | 72.000 (NA) | 72.000 (72.000, 72.000) | 72.00, 72.00 | 1 | -0.300 (NA) | -0.300 (-0.300, -0.300) | -0.30, -0.30 |
|  |  | End of Treatment | 1 | 80.300 (NA) | 80.300 (80.300, 80.300) | 80.30, 80.30 | 1 | 5.500 (NA) | 5.500 (5.500, 5.500) | 5.50, 5.50 |
|  | | | | | | | | | | |
|  | Total (N = 10) | Baseline | 10 | 72.900 (5.4179) | 73.300 (69.700, 75.900) | 63.50, 83.10 |  |  |  |  |
|  |  | C1D8 | 10 | 72.680 (6.4778) | 71.750 (66.300, 76.300) | 65.10, 83.10 | 10 | -0.220 (4.5825) | 0.600 (-3.100, 1.600) | -8.00, 7.20 |
|  |  | C2D1 | 8 | 73.388 (5.3129) | 72.450 (69.600, 77.350) | 67.00, 81.30 | 8 | 1.438 (5.6523) | 1.100 (-2.550, 5.850) | -7.30, 10.00 |
|  |  | C3D1 | 4 | 71.775 (3.3984) | 72.450 (69.100, 74.450) | 67.40, 74.80 | 4 | 1.825 (6.3757) | -0.850 (-1.900, 5.550) | -2.30, 11.30 |
|  |  | C4D1 | 3 | 69.567 (2.8184) | 70.500 (66.400, 71.800) | 66.40, 71.80 | 3 | -0.467 (3.3501) | -0.500 (-3.800, 2.900) | -3.80, 2.90 |
|  |  | C5D1 | 3 | 71.700 (3.6592) | 72.000 (67.900, 75.200) | 67.90, 75.20 | 3 | 1.667 (2.4420) | 0.900 (-0.300, 4.400) | -0.30, 4.40 |
|  |  | End of Treatment | 1 | 80.300 (NA) | 80.300 (80.300, 80.300) | 80.30, 80.30 | 1 | 5.500 (NA) | 5.500 (5.500, 5.500) | 5.50, 5.50 |
|  | | | | | | | | | | |
| Albumin (g/L) | Treatment Group (N = 5) | Baseline | 5 | 41.800 (4.8944) | 39.800 (38.000, 43.900) | 37.90, 49.40 |  |  |  |  |
|  |  | C1D8 | 5 | 40.880 (2.0632) | 41.000 (39.300, 42.300) | 38.40, 43.40 | 5 | -0.920 (3.7393) | -0.500 (-0.500, 0.500) | -7.10, 3.00 |
|  |  | C2D1 | 4 | 42.850 (2.6789) | 41.850 (41.250, 44.450) | 40.90, 46.80 | 4 | 0.550 (3.2016) | 0.600 (-2.200, 3.300) | -2.60, 3.60 |
|  |  | C3D1 | 2 | 44.200 (4.3841) | 44.200 (41.100, 47.300) | 41.10, 47.30 | 2 | 0.550 (3.7477) | 0.550 (-2.100, 3.200) | -2.10, 3.20 |
|  |  | C4D1 | 2 | 42.950 (4.5962) | 42.950 (39.700, 46.200) | 39.70, 46.20 | 2 | -0.700 (3.5355) | -0.700 (-3.200, 1.800) | -3.20, 1.80 |
|  |  | C5D1 | 2 | 45.300 (6.2225) | 45.300 (40.900, 49.700) | 40.90, 49.70 | 2 | 1.650 (1.9092) | 1.650 (0.300, 3.000) | 0.30, 3.00 |
|  | | | | | | | | | | |
|  | Control Group (N = 5) | Baseline | 5 | 40.920 (3.6031) | 41.800 (39.100, 43.100) | 35.70, 44.90 |  |  |  |  |
|  |  | C1D8 | 5 | 40.660 (3.3171) | 40.900 (37.700, 43.000) | 37.00, 44.70 | 5 | -0.260 (1.4943) | -0.200 (-0.900, -0.100) | -2.10, 2.00 |
|  |  | C2D1 | 4 | 41.900 (2.7129) | 42.100 (39.700, 44.100) | 38.70, 44.70 | 4 | -0.325 (0.6185) | -0.300 (-0.750, 0.100) | -1.10, 0.40 |
|  |  | C3D1 | 2 | 42.000 (1.2728) | 42.000 (41.100, 42.900) | 41.10, 42.90 | 2 | -1.350 (0.9192) | -1.350 (-2.000, -0.700) | -2.00, -0.70 |
|  |  | C4D1 | 1 | 46.100 (NA) | 46.100 (46.100, 46.100) | 46.10, 46.10 | 1 | 4.300 (NA) | 4.300 (4.300, 4.300) | 4.30, 4.30 |
|  |  | C5D1 | 1 | 43.600 (NA) | 43.600 (43.600, 43.600) | 43.60, 43.60 | 1 | 1.800 (NA) | 1.800 (1.800, 1.800) | 1.80, 1.80 |
|  |  | End of Treatment | 1 | 37.400 (NA) | 37.400 (37.400, 37.400) | 37.40, 37.40 | 1 | -1.700 (NA) | -1.700 (-1.700, -1.700) | -1.70, -1.70 |
|  | | | | | | | | | | |
|  | Total (N = 10) | Baseline | 10 | 41.360 (4.0782) | 40.800 (38.000, 43.900) | 35.70, 49.40 |  |  |  |  |
|  |  | C1D8 | 10 | 40.770 (2.6068) | 40.950 (38.400, 43.000) | 37.00, 44.70 | 10 | -0.590 (2.7070) | -0.350 (-0.900, 0.500) | -7.10, 3.00 |
|  |  | C2D1 | 8 | 42.375 (2.5471) | 41.850 (40.800, 44.100) | 38.70, 46.80 | 8 | 0.113 (2.1853) | -0.300 (-1.450, 1.700) | -2.60, 3.60 |
|  |  | C3D1 | 4 | 43.100 (2.9257) | 42.000 (41.100, 45.100) | 41.10, 47.30 | 4 | -0.400 (2.4833) | -1.350 (-2.050, 1.250) | -2.10, 3.20 |
|  |  | C4D1 | 3 | 44.000 (3.7242) | 46.100 (39.700, 46.200) | 39.70, 46.20 | 3 | 0.967 (3.8188) | 1.800 (-3.200, 4.300) | -3.20, 4.30 |
|  |  | C5D1 | 3 | 44.733 (4.5081) | 43.600 (40.900, 49.700) | 40.90, 49.70 | 3 | 1.700 (1.3528) | 1.800 (0.300, 3.000) | 0.30, 3.00 |
|  |  | End of Treatment | 1 | 37.400 (NA) | 37.400 (37.400, 37.400) | 37.40, 37.40 | 1 | -1.700 (NA) | -1.700 (-1.700, -1.700) | -1.70, -1.70 |
|  | | | | | | | | | | |
| Triglycerides (mmol/L) | Treatment Group (N = 5) | Baseline | 5 | 1.190 (0.5943) | 1.090 (0.710, 1.460) | 0.62, 2.07 |  |  |  |  |
|  |  | C1D8 | 5 | 1.322 (0.6262) | 1.320 (0.890, 1.400) | 0.69, 2.31 | 5 | 0.132 (0.3127) | 0.070 (-0.060, 0.240) | -0.20, 0.61 |
|  |  | C2D1 | 4 | 1.955 (1.7011) | 1.265 (0.965, 2.945) | 0.81, 4.48 | 4 | 0.833 (1.0555) | 0.365 (0.255, 1.410) | 0.19, 2.41 |
|  |  | C3D1 | 2 | 1.710 (1.4849) | 1.710 (0.660, 2.760) | 0.66, 2.76 | 2 | 0.365 (0.4596) | 0.365 (0.040, 0.690) | 0.04, 0.69 |
|  |  | C4D1 | 2 | 1.660 (1.1455) | 1.660 (0.850, 2.470) | 0.85, 2.47 | 2 | 0.315 (0.1202) | 0.315 (0.230, 0.400) | 0.23, 0.40 |
|  |  | C5D1 | 2 | 2.145 (1.7890) | 2.145 (0.880, 3.410) | 0.88, 3.41 | 2 | 0.800 (0.7637) | 0.800 (0.260, 1.340) | 0.26, 1.34 |
|  | | | | | | | | | | |
|  | Control Group (N = 5) | Baseline | 5 | 2.104 (1.1949) | 1.470 (1.340, 3.250) | 0.93, 3.53 |  |  |  |  |
|  |  | C1D8 | 5 | 1.668 (0.6961) | 1.390 (1.220, 1.850) | 1.08, 2.80 | 5 | -0.436 (0.7830) | -0.390 (-0.450, -0.120) | -1.68, 0.46 |
|  |  | C2D1 | 4 | 2.135 (1.3738) | 1.680 (1.195, 3.075) | 1.08, 4.10 | 4 | -0.128 (0.9783) | 0.060 (-0.755, 0.500) | -1.48, 0.85 |
|  |  | C3D1 | 2 | 2.075 (0.5728) | 2.075 (1.670, 2.480) | 1.67, 2.48 | 2 | -0.360 (0.9758) | -0.360 (-1.050, 0.330) | -1.05, 0.33 |
|  |  | C4D1 | 1 | 0.930 (NA) | 0.930 (0.930, 0.930) | 0.93, 0.93 | 1 | -0.410 (NA) | -0.410 (-0.410, -0.410) | -0.41, -0.41 |
|  |  | C5D1 | 1 | 1.100 (NA) | 1.100 (1.100, 1.100) | 1.10, 1.10 | 1 | -0.240 (NA) | -0.240 (-0.240, -0.240) | -0.24, -0.24 |
|  |  | End of Treatment | 1 | 1.490 (NA) | 1.490 (1.490, 1.490) | 1.49, 1.49 | 1 | 0.560 (NA) | 0.560 (0.560, 0.560) | 0.56, 0.56 |
|  | | | | | | | | | | |
|  | Total (N = 10) | Baseline | 10 | 1.647 (1.0117) | 1.400 (0.930, 2.070) | 0.62, 3.53 |  |  |  |  |
|  |  | C1D8 | 10 | 1.495 (0.6503) | 1.355 (1.080, 1.850) | 0.69, 2.80 | 10 | -0.152 (0.6368) | -0.090 (-0.390, 0.240) | -1.68, 0.61 |
|  |  | C2D1 | 8 | 2.045 (1.4347) | 1.360 (1.100, 3.075) | 0.81, 4.48 | 8 | 0.353 (1.0728) | 0.255 (0.060, 0.630) | -1.48, 2.41 |
|  |  | C3D1 | 4 | 1.893 (0.9427) | 2.075 (1.165, 2.620) | 0.66, 2.76 | 4 | 0.003 (0.7503) | 0.185 (-0.505, 0.510) | -1.05, 0.69 |
|  |  | C4D1 | 3 | 1.417 (0.9131) | 0.930 (0.850, 2.470) | 0.85, 2.47 | 3 | 0.073 (0.4271) | 0.230 (-0.410, 0.400) | -0.41, 0.40 |
|  |  | C5D1 | 3 | 1.797 (1.4015) | 1.100 (0.880, 3.410) | 0.88, 3.41 | 3 | 0.453 (0.8075) | 0.260 (-0.240, 1.340) | -0.24, 1.34 |
|  |  | End of Treatment | 1 | 1.490 (NA) | 1.490 (1.490, 1.490) | 1.49, 1.49 | 1 | 0.560 (NA) | 0.560 (0.560, 0.560) | 0.56, 0.56 |
|  | | | | | | | | | | |
| Cholesterol (mmol/L) | Treatment Group (N = 5) | Baseline | 5 | 4.962 (0.9747) | 5.030 (4.000, 5.630) | 3.98, 6.17 |  |  |  |  |
|  |  | C1D8 | 5 | 5.212 (1.2124) | 4.950 (4.730, 5.360) | 3.87, 7.15 | 5 | 0.250 (1.2089) | -0.110 (-0.680, 0.730) | -0.81, 2.12 |
|  |  | C2D1 | 4 | 5.060 (1.2205) | 4.885 (4.115, 6.005) | 3.85, 6.62 | 4 | 0.400 (1.5437) | 0.895 (-0.690, 1.490) | -1.78, 1.59 |
|  |  | C3D1 | 2 | 5.955 (1.5344) | 5.955 (4.870, 7.040) | 4.87, 7.04 | 2 | 1.450 (0.7920) | 1.450 (0.890, 2.010) | 0.89, 2.01 |
|  |  | C4D1 | 2 | 5.140 (0.7354) | 5.140 (4.620, 5.660) | 4.62, 5.66 | 2 | 0.635 (0.0071) | 0.635 (0.630, 0.640) | 0.63, 0.64 |
|  |  | C5D1 | 2 | 5.510 (0.7212) | 5.510 (5.000, 6.020) | 5.00, 6.02 | 2 | 1.005 (0.0212) | 1.005 (0.990, 1.020) | 0.99, 1.02 |
|  | | | | | | | | | | |
|  | Control Group (N = 5) | Baseline | 5 | 5.120 (1.1931) | 5.130 (4.930, 5.140) | 3.52, 6.88 |  |  |  |  |
|  |  | C1D8 | 5 | 4.864 (1.1533) | 4.680 (4.380, 4.760) | 3.71, 6.79 | 5 | -0.256 (0.3025) | -0.380 (-0.450, -0.090) | -0.55, 0.19 |
|  |  | C2D1 | 4 | 6.995 (3.8186) | 6.215 (4.045, 9.945) | 3.55, 12.00 | 4 | 1.878 (3.5245) | 0.520 (-0.285, 4.040) | -0.60, 7.07 |
|  |  | C3D1 | 2 | 3.955 (1.1526) | 3.955 (3.140, 4.770) | 3.14, 4.77 | 2 | -0.270 (0.1556) | -0.270 (-0.380, -0.160) | -0.38, -0.16 |
|  |  | C4D1 | 1 | 4.520 (NA) | 4.520 (4.520, 4.520) | 4.52, 4.52 | 1 | -0.410 (NA) | -0.410 (-0.410, -0.410) | -0.41, -0.41 |
|  |  | C5D1 | 1 | 4.750 (NA) | 4.750 (4.750, 4.750) | 4.75, 4.75 | 1 | -0.180 (NA) | -0.180 (-0.180, -0.180) | -0.18, -0.18 |
|  |  | End of Treatment | 1 | 8.900 (NA) | 8.900 (8.900, 8.900) | 8.90, 8.90 | 1 | 2.020 (NA) | 2.020 (2.020, 2.020) | 2.02, 2.02 |
|  | | | | | | | | | | |
|  | Total (N = 10) | Baseline | 10 | 5.041 (1.0305) | 5.080 (4.000, 5.630) | 3.52, 6.88 |  |  |  |  |
|  |  | C1D8 | 10 | 5.038 (1.1305) | 4.745 (4.380, 5.360) | 3.71, 7.15 | 10 | -0.003 (0.8725) | -0.245 (-0.550, 0.190) | -0.81, 2.12 |
|  |  | C2D1 | 8 | 6.028 (2.8209) | 4.965 (4.115, 7.255) | 3.55, 12.00 | 8 | 1.139 (2.6398) | 0.705 (-0.285, 1.490) | -1.78, 7.07 |
|  |  | C3D1 | 4 | 4.955 (1.6003) | 4.820 (3.955, 5.955) | 3.14, 7.04 | 4 | 0.590 (1.0969) | 0.365 (-0.270, 1.450) | -0.38, 2.01 |
|  |  | C4D1 | 3 | 4.933 (0.6313) | 4.620 (4.520, 5.660) | 4.52, 5.66 | 3 | 0.287 (0.6034) | 0.630 (-0.410, 0.640) | -0.41, 0.64 |
|  |  | C5D1 | 3 | 5.257 (0.6728) | 5.000 (4.750, 6.020) | 4.75, 6.02 | 3 | 0.610 (0.6843) | 0.990 (-0.180, 1.020) | -0.18, 1.02 |
|  |  | End of Treatment | 1 | 8.900 (NA) | 8.900 (8.900, 8.900) | 8.90, 8.90 | 1 | 2.020 (NA) | 2.020 (2.020, 2.020) | 2.02, 2.02 |
|  | | | | | | | | | | |
| Sodium (mmol/L) | Treatment Group (N = 5) | Baseline | 5 | 139.500 (3.3541) | 141.000 (137.000, 141.500) | 135.00, 143.00 |  |  |  |  |
|  |  | C1D8 | 5 | 140.600 (0.8944) | 140.000 (140.000, 141.000) | 140.00, 142.00 | 5 | 1.100 (2.7928) | 0.000 (-1.000, 3.000) | -1.50, 5.00 |
|  |  | C2D1 | 4 | 140.000 (3.7417) | 139.500 (137.500, 142.500) | 136.00, 145.00 | 4 | -0.125 (3.4248) | -0.250 (-2.750, 2.500) | -4.00, 4.00 |
|  |  | C3D1 | 2 | 140.000 (2.8284) | 140.000 (138.000, 142.000) | 138.00, 142.00 | 2 | -2.000 (4.2426) | -2.000 (-5.000, 1.000) | -5.00, 1.00 |
|  |  | C4D1 | 2 | 139.500 (0.7071) | 139.500 (139.000, 140.000) | 139.00, 140.00 | 2 | -2.500 (0.7071) | -2.500 (-3.000, -2.000) | -3.00, -2.00 |
|  |  | C5D1 | 2 | 140.000 (1.4142) | 140.000 (139.000, 141.000) | 139.00, 141.00 | 2 | -2.000 (0.0000) | -2.000 (-2.000, -2.000) | -2.00, -2.00 |
|  | | | | | | | | | | |
|  | Control Group (N = 5) | Baseline | 5 | 139.540 (3.7760) | 141.000 (139.700, 142.000) | 133.00, 142.00 |  |  |  |  |
|  |  | C1D8 | 5 | 139.240 (2.9813) | 141.000 (136.000, 141.200) | 136.00, 142.00 | 5 | -0.300 (3.4205) | 0.000 (0.000, 1.500) | -6.00, 3.00 |
|  |  | C2D1 | 4 | 138.775 (1.8980) | 139.550 (137.550, 140.000) | 136.00, 140.00 | 4 | -0.725 (2.6018) | -1.500 (-2.450, 1.000) | -2.90, 3.00 |
|  |  | C3D1 | 2 | 140.000 (0.0000) | 140.000 (140.000, 140.000) | 140.00, 140.00 | 2 | -1.500 (0.7071) | -1.500 (-2.000, -1.000) | -2.00, -1.00 |
|  |  | C4D1 | 1 | 140.000 (NA) | 140.000 (140.000, 140.000) | 140.00, 140.00 | 1 | -1.000 (NA) | -1.000 (-1.000, -1.000) | -1.00, -1.00 |
|  |  | C5D1 | 1 | 137.000 (NA) | 137.000 (137.000, 137.000) | 137.00, 137.00 | 1 | -4.000 (NA) | -4.000 (-4.000, -4.000) | -4.00, -4.00 |
|  |  | End of Treatment | 1 | 137.000 (NA) | 137.000 (137.000, 137.000) | 137.00, 137.00 | 1 | 4.000 (NA) | 4.000 (4.000, 4.000) | 4.00, 4.00 |
|  | | | | | | | | | | |
|  | Total (N = 10) | Baseline | 10 | 139.520 (3.3671) | 141.000 (137.000, 142.000) | 133.00, 143.00 |  |  |  |  |
|  |  | C1D8 | 10 | 139.920 (2.1953) | 140.500 (140.000, 141.200) | 136.00, 142.00 | 10 | 0.400 (3.0350) | 0.000 (-1.000, 3.000) | -6.00, 5.00 |
|  |  | C2D1 | 8 | 139.388 (2.8236) | 139.550 (137.500, 140.000) | 136.00, 145.00 | 8 | -0.425 (2.8339) | -1.250 (-2.450, 2.000) | -4.00, 4.00 |
|  |  | C3D1 | 4 | 140.000 (1.6330) | 140.000 (139.000, 141.000) | 138.00, 142.00 | 4 | -1.750 (2.5000) | -1.500 (-3.500, 0.000) | -5.00, 1.00 |
|  |  | C4D1 | 3 | 139.667 (0.5774) | 140.000 (139.000, 140.000) | 139.00, 140.00 | 3 | -2.000 (1.0000) | -2.000 (-3.000, -1.000) | -3.00, -1.00 |
|  |  | C5D1 | 3 | 139.000 (2.0000) | 139.000 (137.000, 141.000) | 137.00, 141.00 | 3 | -2.667 (1.1547) | -2.000 (-4.000, -2.000) | -4.00, -2.00 |
|  |  | End of Treatment | 1 | 137.000 (NA) | 137.000 (137.000, 137.000) | 137.00, 137.00 | 1 | 4.000 (NA) | 4.000 (4.000, 4.000) | 4.00, 4.00 |
|  | | | | | | | | | | |
| Potassium (mmol/L) | Treatment Group (N = 5) | Baseline | 5 | 4.1080 (0.1851) | 4.0800 (3.9500, 4.2400) | 3.920, 4.350 |  |  |  |  |
|  |  | C1D8 | 5 | 4.0140 (0.3446) | 4.0400 (3.8300, 4.3300) | 3.530, 4.340 | 5 | -0.0940 (0.2717) | -0.0100 (-0.1200, 0.0900) | -0.550, 0.120 |
|  |  | C2D1 | 4 | 4.0175 (0.3724) | 4.0000 (3.7800, 4.2550) | 3.580, 4.490 | 4 | -0.0575 (0.2985) | 0.0650 (-0.2350, 0.1200) | -0.500, 0.140 |
|  |  | C3D1 | 2 | 3.8950 (0.1909) | 3.8950 (3.7600, 4.0300) | 3.760, 4.030 | 2 | -0.1200 (0.2828) | -0.1200 (-0.3200, 0.0800) | -0.320, 0.080 |
|  |  | C4D1 | 2 | 3.8000 (0.0424) | 3.8000 (3.7700, 3.8300) | 3.770, 3.830 | 2 | -0.2150 (0.0495) | -0.2150 (-0.2500, -0.1800) | -0.250, -0.180 |
|  |  | C5D1 | 2 | 3.7650 (0.1061) | 3.7650 (3.6900, 3.8400) | 3.690, 3.840 | 2 | -0.2500 (0.1980) | -0.2500 (-0.3900, -0.1100) | -0.390, -0.110 |
|  | | | | | | | | | | |
|  | Control Group (N = 5) | Baseline | 5 | 4.2460 (0.3666) | 4.3800 (4.0400, 4.5000) | 3.710, 4.600 |  |  |  |  |
|  |  | C1D8 | 5 | 4.3740 (0.7271) | 4.0500 (3.8400, 4.9200) | 3.700, 5.360 | 5 | 0.1280 (0.9101) | 0.3400 (-0.6600, 0.5400) | -0.900, 1.320 |
|  |  | C2D1 | 4 | 4.3750 (0.2641) | 4.4300 (4.1950, 4.5550) | 4.010, 4.630 | 4 | 0.1625 (0.6319) | 0.2350 (-0.3550, 0.6800) | -0.590, 0.770 |
|  |  | C3D1 | 2 | 3.7450 (0.4313) | 3.7450 (3.4400, 4.0500) | 3.440, 4.050 | 2 | -0.8050 (0.5020) | -0.8050 (-1.1600, -0.4500) | -1.160, -0.450 |
|  |  | C4D1 | 1 | 4.0400 (NA) | 4.0400 (4.0400, 4.0400) | 4.040, 4.040 | 1 | -0.5600 (NA) | -0.5600 (-0.5600, -0.5600) | -0.560, -0.560 |
|  |  | C5D1 | 1 | 3.8200 (NA) | 3.8200 (3.8200, 3.8200) | 3.820, 3.820 | 1 | -0.7800 (NA) | -0.7800 (-0.7800, -0.7800) | -0.780, -0.780 |
|  |  | End of Treatment | 1 | 4.5700 (NA) | 4.5700 (4.5700, 4.5700) | 4.570, 4.570 | 1 | 0.8600 (NA) | 0.8600 (0.8600, 0.8600) | 0.860, 0.860 |
|  | | | | | | | | | | |
|  | Total (N = 10) | Baseline | 10 | 4.1770 (0.2833) | 4.1600 (3.9500, 4.3800) | 3.710, 4.600 |  |  |  |  |
|  |  | C1D8 | 10 | 4.1940 (0.5690) | 4.0450 (3.8300, 4.3400) | 3.530, 5.360 | 10 | 0.0170 (0.6439) | 0.0400 (-0.5500, 0.3400) | -0.900, 1.320 |
|  |  | C2D1 | 8 | 4.1963 (0.3548) | 4.2000 (3.9950, 4.4850) | 3.580, 4.630 | 8 | 0.0525 (0.4724) | 0.0650 (-0.3100, 0.3650) | -0.590, 0.770 |
|  |  | C3D1 | 4 | 3.8200 (0.2858) | 3.8950 (3.6000, 4.0400) | 3.440, 4.050 | 4 | -0.4625 (0.5168) | -0.3850 (-0.8050, -0.1200) | -1.160, 0.080 |
|  |  | C4D1 | 3 | 3.8800 (0.1418) | 3.8300 (3.7700, 4.0400) | 3.770, 4.040 | 3 | -0.3300 (0.2022) | -0.2500 (-0.5600, -0.1800) | -0.560, -0.180 |
|  |  | C5D1 | 3 | 3.7833 (0.0814) | 3.8200 (3.6900, 3.8400) | 3.690, 3.840 | 3 | -0.4267 (0.3365) | -0.3900 (-0.7800, -0.1100) | -0.780, -0.110 |
|  |  | End of Treatment | 1 | 4.5700 (NA) | 4.5700 (4.5700, 4.5700) | 4.570, 4.570 | 1 | 0.8600 (NA) | 0.8600 (0.8600, 0.8600) | 0.860, 0.860 |
|  | | | | | | | | | | |
| Magnesium (mmol/L) | Treatment Group (N = 5) | Baseline | 5 | 0.892 (0.0769) | 0.850 (0.840, 0.930) | 0.83, 1.01 |  |  |  |  |
|  |  | C1D8 | 5 | 0.838 (0.0705) | 0.830 (0.810, 0.890) | 0.74, 0.92 | 5 | -0.054 (0.0770) | -0.090 (-0.100, -0.030) | -0.12, 0.07 |
|  |  | C2D1 | 4 | 0.873 (0.0954) | 0.870 (0.790, 0.955) | 0.79, 0.96 | 4 | -0.033 (0.1044) | -0.050 (-0.100, 0.035) | -0.14, 0.11 |
|  |  | C3D1 | 2 | 0.870 (0.1131) | 0.870 (0.790, 0.950) | 0.79, 0.95 | 2 | -0.050 (0.0141) | -0.050 (-0.060, -0.040) | -0.06, -0.04 |
|  |  | C4D1 | 2 | 0.840 (0.0566) | 0.840 (0.800, 0.880) | 0.80, 0.88 | 2 | -0.080 (0.0707) | -0.080 (-0.130, -0.030) | -0.13, -0.03 |
|  |  | C5D1 | 2 | 0.905 (0.1626) | 0.905 (0.790, 1.020) | 0.79, 1.02 | 2 | -0.015 (0.0354) | -0.015 (-0.040, 0.010) | -0.04, 0.01 |
|  | | | | | | | | | | |
|  | Control Group (N = 5) | Baseline | 5 | 0.918 (0.0606) | 0.910 (0.900, 0.970) | 0.83, 0.98 |  |  |  |  |
|  |  | C1D8 | 5 | 0.952 (0.1057) | 0.920 (0.880, 0.960) | 0.87, 1.13 | 5 | 0.034 (0.0730) | 0.020 (-0.010, 0.050) | -0.04, 0.15 |
|  |  | C2D1 | 4 | 0.925 (0.0968) | 0.905 (0.865, 0.985) | 0.83, 1.06 | 4 | -0.015 (0.0719) | -0.030 (-0.070, 0.040) | -0.08, 0.08 |
|  |  | C3D1 | 2 | 0.845 (0.0212) | 0.845 (0.830, 0.860) | 0.83, 0.86 | 2 | -0.060 (0.0141) | -0.060 (-0.070, -0.050) | -0.07, -0.05 |
|  |  | C4D1 | 1 | 0.880 (NA) | 0.880 (0.880, 0.880) | 0.88, 0.88 | 1 | -0.030 (NA) | -0.030 (-0.030, -0.030) | -0.03, -0.03 |
|  |  | C5D1 | 1 | 0.910 (NA) | 0.910 (0.910, 0.910) | 0.91, 0.91 | 1 | 0.000 (NA) | 0.000 (0.000, 0.000) | 0.00, 0.00 |
|  |  | End of Treatment | 1 | 0.940 (NA) | 0.940 (0.940, 0.940) | 0.94, 0.94 | 1 | -0.030 (NA) | -0.030 (-0.030, -0.030) | -0.03, -0.03 |
|  | | | | | | | | | | |
|  | Total (N = 10) | Baseline | 10 | 0.905 (0.0667) | 0.905 (0.840, 0.970) | 0.83, 1.01 |  |  |  |  |
|  |  | C1D8 | 10 | 0.895 (0.1038) | 0.885 (0.830, 0.920) | 0.74, 1.13 | 10 | -0.010 (0.0846) | -0.020 (-0.090, 0.050) | -0.12, 0.15 |
|  |  | C2D1 | 8 | 0.899 (0.0933) | 0.905 (0.810, 0.955) | 0.79, 1.06 | 8 | -0.024 (0.0835) | -0.050 (-0.070, 0.040) | -0.14, 0.11 |
|  |  | C3D1 | 4 | 0.858 (0.0680) | 0.845 (0.810, 0.905) | 0.79, 0.95 | 4 | -0.055 (0.0129) | -0.055 (-0.065, -0.045) | -0.07, -0.04 |
|  |  | C4D1 | 3 | 0.853 (0.0462) | 0.880 (0.800, 0.880) | 0.80, 0.88 | 3 | -0.063 (0.0577) | -0.030 (-0.130, -0.030) | -0.13, -0.03 |
|  |  | C5D1 | 3 | 0.907 (0.1150) | 0.910 (0.790, 1.020) | 0.79, 1.02 | 3 | -0.010 (0.0265) | 0.000 (-0.040, 0.010) | -0.04, 0.01 |
|  |  | End of Treatment | 1 | 0.940 (NA) | 0.940 (0.940, 0.940) | 0.94, 0.94 | 1 | -0.030 (NA) | -0.030 (-0.030, -0.030) | -0.03, -0.03 |
|  | | | | | | | | | | |
| Chloride (mmol/L) | Treatment Group (N = 5) | Baseline | 5 | 102.360 (1.7459) | 102.000 (102.000, 104.000) | 99.80, 104.00 |  |  |  |  |
|  |  | C1D8 | 5 | 102.740 (2.7364) | 104.000 (100.700, 105.000) | 99.00, 105.00 | 5 | 0.380 (1.7035) | 0.000 (-0.800, 1.000) | -1.30, 3.00 |
|  |  | C2D1 | 4 | 102.000 (3.5590) | 101.000 (99.500, 104.500) | 99.00, 107.00 | 4 | -0.450 (3.3282) | 0.100 (-2.500, 1.600) | -5.00, 3.00 |
|  |  | C3D1 | 2 | 101.500 (0.7071) | 101.500 (101.000, 102.000) | 101.00, 102.00 | 2 | -2.500 (0.7071) | -2.500 (-3.000, -2.000) | -3.00, -2.00 |
|  |  | C4D1 | 2 | 103.000 (2.8284) | 103.000 (101.000, 105.000) | 101.00, 105.00 | 2 | -1.000 (2.8284) | -1.000 (-3.000, 1.000) | -3.00, 1.00 |
|  |  | C5D1 | 2 | 102.000 (1.4142) | 102.000 (101.000, 103.000) | 101.00, 103.00 | 2 | -2.000 (1.4142) | -2.000 (-3.000, -1.000) | -3.00, -1.00 |
|  | | | | | | | | | | |
|  | Control Group (N = 5) | Baseline | 5 | 101.980 (5.0845) | 104.000 (103.000, 104.900) | 93.00, 105.00 |  |  |  |  |
|  |  | C1D8 | 5 | 102.680 (3.9385) | 104.000 (99.000, 106.000) | 98.00, 106.40 | 5 | 0.700 (4.5222) | 1.500 (-1.000, 3.000) | -6.00, 6.00 |
|  |  | C2D1 | 4 | 101.000 (2.4495) | 100.500 (99.000, 103.000) | 99.00, 104.00 | 4 | -0.250 (4.8563) | -1.000 (-4.000, 3.500) | -5.00, 6.00 |
|  |  | C3D1 | 2 | 106.000 (0.0000) | 106.000 (106.000, 106.000) | 106.00, 106.00 | 2 | 2.000 (1.4142) | 2.000 (1.000, 3.000) | 1.00, 3.00 |
|  |  | C4D1 | 1 | 103.000 (NA) | 103.000 (103.000, 103.000) | 103.00, 103.00 | 1 | 0.000 (NA) | 0.000 (0.000, 0.000) | 0.00, 0.00 |
|  |  | C5D1 | 1 | 101.000 (NA) | 101.000 (101.000, 101.000) | 101.00, 101.00 | 1 | -2.000 (NA) | -2.000 (-2.000, -2.000) | -2.00, -2.00 |
|  |  | End of Treatment | 1 | 102.000 (NA) | 102.000 (102.000, 102.000) | 102.00, 102.00 | 1 | 9.000 (NA) | 9.000 (9.000, 9.000) | 9.00, 9.00 |
|  | | | | | | | | | | |
|  | Total (N = 10) | Baseline | 10 | 102.170 (3.5895) | 103.500 (102.000, 104.000) | 93.00, 105.00 |  |  |  |  |
|  |  | C1D8 | 10 | 102.710 (3.1974) | 104.000 (99.000, 105.000) | 98.00, 106.40 | 10 | 0.540 (3.2260) | 0.500 (-1.000, 3.000) | -6.00, 6.00 |
|  |  | C2D1 | 8 | 101.500 (2.8785) | 101.000 (99.000, 103.000) | 99.00, 107.00 | 8 | -0.350 (3.8556) | 0.100 (-4.000, 2.000) | -5.00, 6.00 |
|  |  | C3D1 | 4 | 103.750 (2.6300) | 104.000 (101.500, 106.000) | 101.00, 106.00 | 4 | -0.250 (2.7538) | -0.500 (-2.500, 2.000) | -3.00, 3.00 |
|  |  | C4D1 | 3 | 103.000 (2.0000) | 103.000 (101.000, 105.000) | 101.00, 105.00 | 3 | -0.667 (2.0817) | 0.000 (-3.000, 1.000) | -3.00, 1.00 |
|  |  | C5D1 | 3 | 101.667 (1.1547) | 101.000 (101.000, 103.000) | 101.00, 103.00 | 3 | -2.000 (1.0000) | -2.000 (-3.000, -1.000) | -3.00, -1.00 |
|  |  | End of Treatment | 1 | 102.000 (NA) | 102.000 (102.000, 102.000) | 102.00, 102.00 | 1 | 9.000 (NA) | 9.000 (9.000, 9.000) | 9.00, 9.00 |
|  | | | | | | | | | | |
| Calcium (mmol/L) | Treatment Group (N = 5) | Baseline | 5 | 2.226 (0.1324) | 2.230 (2.130, 2.350) | 2.06, 2.36 |  |  |  |  |
|  |  | C1D8 | 5 | 2.268 (0.1587) | 2.180 (2.160, 2.330) | 2.15, 2.52 | 5 | 0.042 (0.0847) | 0.030 (-0.020, 0.090) | -0.05, 0.16 |
|  |  | C2D1 | 4 | 2.235 (0.0810) | 2.215 (2.185, 2.285) | 2.16, 2.35 | 4 | 0.043 (0.0971) | 0.045 (-0.035, 0.120) | -0.07, 0.15 |
|  |  | C3D1 | 2 | 2.320 (0.0283) | 2.320 (2.300, 2.340) | 2.30, 2.34 | 2 | 0.175 (0.0919) | 0.175 (0.110, 0.240) | 0.11, 0.24 |
|  |  | C4D1 | 2 | 2.255 (0.1061) | 2.255 (2.180, 2.330) | 2.18, 2.33 | 2 | 0.110 (0.0141) | 0.110 (0.100, 0.120) | 0.10, 0.12 |
|  |  | C5D1 | 2 | 2.370 (0.0849) | 2.370 (2.310, 2.430) | 2.31, 2.43 | 2 | 0.225 (0.0354) | 0.225 (0.200, 0.250) | 0.20, 0.25 |
|  | | | | | | | | | | |
|  | Control Group (N = 5) | Baseline | 5 | 2.238 (0.0482) | 2.250 (2.210, 2.270) | 2.17, 2.29 |  |  |  |  |
|  |  | C1D8 | 5 | 2.310 (0.1903) | 2.250 (2.200, 2.420) | 2.10, 2.58 | 5 | 0.072 (0.2112) | 0.080 (-0.050, 0.150) | -0.19, 0.37 |
|  |  | C2D1 | 4 | 2.295 (0.1025) | 2.280 (2.220, 2.370) | 2.19, 2.43 | 4 | 0.065 (0.1310) | 0.070 (-0.020, 0.150) | -0.10, 0.22 |
|  |  | C3D1 | 2 | 2.170 (0.0283) | 2.170 (2.150, 2.190) | 2.15, 2.19 | 2 | -0.060 (0.1131) | -0.060 (-0.140, 0.020) | -0.14, 0.02 |
|  |  | C4D1 | 1 | 2.200 (NA) | 2.200 (2.200, 2.200) | 2.20, 2.20 | 1 | -0.090 (NA) | -0.090 (-0.090, -0.090) | -0.09, -0.09 |
|  |  | C5D1 | 1 | 2.320 (NA) | 2.320 (2.320, 2.320) | 2.32, 2.32 | 1 | 0.030 (NA) | 0.030 (0.030, 0.030) | 0.03, 0.03 |
|  |  | End of Treatment | 1 | 2.230 (NA) | 2.230 (2.230, 2.230) | 2.23, 2.23 | 1 | -0.020 (NA) | -0.020 (-0.020, -0.020) | -0.02, -0.02 |
|  | | | | | | | | | | |
|  | Total (N = 10) | Baseline | 10 | 2.232 (0.0941) | 2.240 (2.170, 2.290) | 2.06, 2.36 |  |  |  |  |
|  |  | C1D8 | 10 | 2.289 (0.1666) | 2.225 (2.160, 2.420) | 2.10, 2.58 | 10 | 0.057 (0.1525) | 0.055 (-0.050, 0.150) | -0.19, 0.37 |
|  |  | C2D1 | 8 | 2.265 (0.0913) | 2.235 (2.200, 2.330) | 2.16, 2.43 | 8 | 0.054 (0.1074) | 0.070 (-0.035, 0.120) | -0.10, 0.22 |
|  |  | C3D1 | 4 | 2.245 (0.0896) | 2.245 (2.170, 2.320) | 2.15, 2.34 | 4 | 0.058 (0.1597) | 0.065 (-0.060, 0.175) | -0.14, 0.24 |
|  |  | C4D1 | 3 | 2.237 (0.0814) | 2.200 (2.180, 2.330) | 2.18, 2.33 | 3 | 0.043 (0.1159) | 0.100 (-0.090, 0.120) | -0.09, 0.12 |
|  |  | C5D1 | 3 | 2.353 (0.0666) | 2.320 (2.310, 2.430) | 2.31, 2.43 | 3 | 0.160 (0.1153) | 0.200 (0.030, 0.250) | 0.03, 0.25 |
|  |  | End of Treatment | 1 | 2.230 (NA) | 2.230 (2.230, 2.230) | 2.23, 2.23 | 1 | -0.020 (NA) | -0.020 (-0.020, -0.020) | -0.02, -0.02 |
|  | | | | | | | | | | |
| Phosphorus (mmol/L) | Treatment Group (N = 5) | Baseline | 5 | 1.146 (0.2324) | 1.170 (1.150, 1.290) | 0.76, 1.36 |  |  |  |  |
|  |  | C1D8 | 5 | 1.154 (0.2245) | 1.240 (1.040, 1.290) | 0.82, 1.38 | 5 | 0.008 (0.1143) | 0.060 (-0.110, 0.090) | -0.12, 0.12 |
|  |  | C2D1 | 4 | 1.218 (0.2250) | 1.255 (1.075, 1.360) | 0.91, 1.45 | 4 | 0.108 (0.1537) | 0.120 (0.000, 0.215) | -0.09, 0.28 |
|  |  | C3D1 | 2 | 1.715 (0.1485) | 1.715 (1.610, 1.820) | 1.61, 1.82 | 2 | 0.450 (0.2828) | 0.450 (0.250, 0.650) | 0.25, 0.65 |
|  |  | C4D1 | 2 | 1.525 (0.1061) | 1.525 (1.450, 1.600) | 1.45, 1.60 | 2 | 0.260 (0.2404) | 0.260 (0.090, 0.430) | 0.09, 0.43 |
|  |  | C5D1 | 2 | 1.315 (0.2333) | 1.315 (1.150, 1.480) | 1.15, 1.48 | 2 | 0.050 (0.0990) | 0.050 (-0.020, 0.120) | -0.02, 0.12 |
|  | | | | | | | | | | |
|  | Control Group (N = 5) | Baseline | 5 | 1.210 (0.2619) | 1.180 (1.030, 1.400) | 0.90, 1.54 |  |  |  |  |
|  |  | C1D8 | 5 | 1.350 (0.1279) | 1.380 (1.270, 1.410) | 1.18, 1.51 | 5 | 0.140 (0.2954) | 0.000 (-0.020, 0.240) | -0.13, 0.61 |
|  |  | C2D1 | 4 | 1.468 (0.2069) | 1.425 (1.320, 1.615) | 1.27, 1.75 | 4 | 0.250 (0.1623) | 0.225 (0.145, 0.355) | 0.08, 0.47 |
|  |  | C3D1 | 2 | 1.430 (0.0566) | 1.430 (1.390, 1.470) | 1.39, 1.47 | 2 | -0.040 (0.0424) | -0.040 (-0.070, -0.010) | -0.07, -0.01 |
|  |  | C4D1 | 1 | 1.670 (NA) | 1.670 (1.670, 1.670) | 1.67, 1.67 | 1 | 0.130 (NA) | 0.130 (0.130, 0.130) | 0.13, 0.13 |
|  |  | C5D1 | 1 | 1.720 (NA) | 1.720 (1.720, 1.720) | 1.72, 1.72 | 1 | 0.180 (NA) | 0.180 (0.180, 0.180) | 0.18, 0.18 |
|  |  | End of Treatment | 1 | 1.200 (NA) | 1.200 (1.200, 1.200) | 1.20, 1.20 | 1 | 0.170 (NA) | 0.170 (0.170, 0.170) | 0.17, 0.17 |
|  | | | | | | | | | | |
|  | Total (N = 10) | Baseline | 10 | 1.178 (0.2359) | 1.175 (1.030, 1.360) | 0.76, 1.54 |  |  |  |  |
|  |  | C1D8 | 10 | 1.252 (0.2008) | 1.280 (1.180, 1.380) | 0.82, 1.51 | 10 | 0.074 (0.2223) | 0.030 (-0.110, 0.120) | -0.13, 0.61 |
|  |  | C2D1 | 8 | 1.343 (0.2406) | 1.320 (1.255, 1.465) | 0.91, 1.75 | 8 | 0.179 (0.1650) | 0.180 (0.085, 0.260) | -0.09, 0.47 |
|  |  | C3D1 | 4 | 1.573 (0.1884) | 1.540 (1.430, 1.715) | 1.39, 1.82 | 4 | 0.205 (0.3276) | 0.120 (-0.040, 0.450) | -0.07, 0.65 |
|  |  | C4D1 | 3 | 1.573 (0.1124) | 1.600 (1.450, 1.670) | 1.45, 1.67 | 3 | 0.217 (0.1858) | 0.130 (0.090, 0.430) | 0.09, 0.43 |
|  |  | C5D1 | 3 | 1.450 (0.2862) | 1.480 (1.150, 1.720) | 1.15, 1.72 | 3 | 0.093 (0.1026) | 0.120 (-0.020, 0.180) | -0.02, 0.18 |
|  |  | End of Treatment | 1 | 1.200 (NA) | 1.200 (1.200, 1.200) | 1.20, 1.20 | 1 | 0.170 (NA) | 0.170 (0.170, 0.170) | 0.17, 0.17 |
|  | | | | | | | | | | |
| Urea (mmol/L) | Treatment Group (N = 5) | Baseline | 5 | 4.234 (1.4100) | 4.780 (4.280, 5.030) | 1.80, 5.28 |  |  |  |  |
|  |  | C1D8 | 5 | 47.620 (95.8070) | 4.570 (4.550, 5.960) | 4.02, 219.00 | 5 | 43.386 (97.1660) | -0.230 (-0.260, 0.680) | -0.46, 217.20 |
|  |  | C2D1 | 4 | 4.785 (1.1158) | 5.140 (4.010, 5.560) | 3.20, 5.66 | 4 | 0.813 (0.3959) | 0.655 (0.585, 1.040) | 0.54, 1.40 |
|  |  | C3D1 | 2 | 5.360 (1.2869) | 5.360 (4.450, 6.270) | 4.45, 6.27 | 2 | 0.455 (1.4637) | 0.455 (-0.580, 1.490) | -0.58, 1.49 |
|  |  | C4D1 | 2 | 4.790 (1.4142) | 4.790 (3.790, 5.790) | 3.79, 5.79 | 2 | -0.115 (1.5910) | -0.115 (-1.240, 1.010) | -1.24, 1.01 |
|  |  | C5D1 | 2 | 5.160 (1.1314) | 5.160 (4.360, 5.960) | 4.36, 5.96 | 2 | 0.255 (1.3081) | 0.255 (-0.670, 1.180) | -0.67, 1.18 |
|  | | | | | | | | | | |
|  | Control Group (N = 5) | Baseline | 5 | 6.114 (1.7776) | 5.820 (4.760, 6.700) | 4.43, 8.86 |  |  |  |  |
|  |  | C1D8 | 5 | 5.730 (2.2965) | 5.360 (4.460, 7.300) | 2.86, 8.67 | 5 | -0.384 (0.7787) | -0.300 (-0.460, -0.190) | -1.57, 0.60 |
|  |  | C2D1 | 4 | 5.803 (1.8922) | 6.010 (4.375, 7.230) | 3.39, 7.80 | 4 | 0.375 (0.9652) | 0.720 (-0.220, 0.970) | -1.04, 1.10 |
|  |  | C3D1 | 2 | 4.300 (0.9899) | 4.300 (3.600, 5.000) | 3.60, 5.00 | 2 | -0.295 (0.7566) | -0.295 (-0.830, 0.240) | -0.83, 0.24 |
|  |  | C4D1 | 1 | 3.350 (NA) | 3.350 (3.350, 3.350) | 3.35, 3.35 | 1 | -1.080 (NA) | -1.080 (-1.080, -1.080) | -1.08, -1.08 |
|  |  | C5D1 | 1 | 3.880 (NA) | 3.880 (3.880, 3.880) | 3.88, 3.88 | 1 | -0.550 (NA) | -0.550 (-0.550, -0.550) | -0.55, -0.55 |
|  |  | End of Treatment | 1 | 4.920 (NA) | 4.920 (4.920, 4.920) | 4.92, 4.92 | 1 | -0.900 (NA) | -0.900 (-0.900, -0.900) | -0.90, -0.90 |
|  | | | | | | | | | | |
|  | Total (N = 10) | Baseline | 10 | 5.174 (1.8082) | 4.905 (4.430, 5.820) | 1.80, 8.86 |  |  |  |  |
|  |  | C1D8 | 10 | 26.675 (67.5968) | 4.965 (4.460, 7.300) | 2.86, 219.00 | 10 | 21.501 (68.7644) | -0.245 (-0.460, 0.600) | -1.57, 217.20 |
|  |  | C2D1 | 8 | 5.294 (1.5375) | 5.410 (4.105, 6.160) | 3.20, 7.80 | 8 | 0.594 (0.7219) | 0.655 (0.570, 0.970) | -1.04, 1.40 |
|  |  | C3D1 | 4 | 4.830 (1.1195) | 4.725 (4.025, 5.635) | 3.60, 6.27 | 4 | 0.080 (1.0452) | -0.170 (-0.705, 0.865) | -0.83, 1.49 |
|  |  | C4D1 | 3 | 4.310 (1.3005) | 3.790 (3.350, 5.790) | 3.35, 5.79 | 3 | -0.437 (1.2554) | -1.080 (-1.240, 1.010) | -1.24, 1.01 |
|  |  | C5D1 | 3 | 4.733 (1.0891) | 4.360 (3.880, 5.960) | 3.88, 5.96 | 3 | -0.013 (1.0352) | -0.550 (-0.670, 1.180) | -0.67, 1.18 |
|  |  | End of Treatment | 1 | 4.920 (NA) | 4.920 (4.920, 4.920) | 4.92, 4.92 | 1 | -0.900 (NA) | -0.900 (-0.900, -0.900) | -0.90, -0.90 |
|  | | | | | | | | | | |
| Creatinine (umol/L) | Treatment Group (N = 5) | Baseline | 5 | 57.62 (10.678) | 56.40 (55.00, 63.00) | 42.4, 71.3 |  |  |  |  |
|  |  | C1D8 | 5 | 62.42 (13.222) | 61.10 (50.00, 73.00) | 49.4, 78.6 | 5 | 4.80 (5.792) | 7.00 (4.70, 7.30) | -5.0, 10.0 |
|  |  | C2D1 | 4 | 63.03 (24.002) | 56.60 (48.75, 77.30) | 41.5, 97.4 | 4 | 6.75 (12.928) | 0.90 (-0.05, 13.55) | -0.9, 26.1 |
|  |  | C3D1 | 2 | 52.35 (12.657) | 52.35 (43.40, 61.30) | 43.4, 61.3 | 2 | 2.95 (2.758) | 2.95 (1.00, 4.90) | 1.0, 4.9 |
|  |  | C4D1 | 2 | 50.90 (17.678) | 50.90 (38.40, 63.40) | 38.4, 63.4 | 2 | 1.50 (7.778) | 1.50 (-4.00, 7.00) | -4.0, 7.0 |
|  |  | C5D1 | 2 | 51.70 (13.152) | 51.70 (42.40, 61.00) | 42.4, 61.0 | 2 | 2.30 (3.253) | 2.30 (0.00, 4.60) | 0.0, 4.6 |
|  | | | | | | | | | | |
|  | Control Group (N = 5) | Baseline | 5 | 57.16 (5.448) | 59.10 (51.90, 62.00) | 50.8, 62.0 |  |  |  |  |
|  |  | C1D8 | 5 | 58.08 (15.465) | 57.80 (52.40, 69.60) | 35.6, 75.0 | 5 | 0.92 (11.096) | 1.60 (-1.30, 7.60) | -16.3, 13.0 |
|  |  | C2D1 | 4 | 56.90 (19.359) | 57.25 (40.40, 73.40) | 37.1, 76.0 | 4 | 0.95 (14.127) | 2.30 (-10.95, 12.85) | -14.8, 14.0 |
|  |  | C3D1 | 2 | 37.95 (3.606) | 37.95 (35.40, 40.50) | 35.4, 40.5 | 2 | -13.40 (4.384) | -13.40 (-16.50, -10.30) | -16.5, -10.3 |
|  |  | C4D1 | 1 | 31.20 (NA) | 31.20 (31.20, 31.20) | 31.2, 31.2 | 1 | -20.70 (NA) | -20.70 (-20.70, -20.70) | -20.7, -20.7 |
|  |  | C5D1 | 1 | 35.40 (NA) | 35.40 (35.40, 35.40) | 35.4, 35.4 | 1 | -16.50 (NA) | -16.50 (-16.50, -16.50) | -16.5, -16.5 |
|  |  | End of Treatment | 1 | 57.90 (NA) | 57.90 (57.90, 57.90) | 57.9, 57.9 | 1 | -1.20 (NA) | -1.20 (-1.20, -1.20) | -1.2, -1.2 |
|  | | | | | | | | | | |
|  | Total (N = 10) | Baseline | 10 | 57.39 (7.995) | 57.75 (51.90, 62.00) | 42.4, 71.3 |  |  |  |  |
|  |  | C1D8 | 10 | 60.25 (13.756) | 59.45 (50.00, 73.00) | 35.6, 78.6 | 10 | 2.86 (8.591) | 5.85 (-1.30, 7.60) | -16.3, 13.0 |
|  |  | C2D1 | 8 | 59.96 (20.451) | 56.60 (42.60, 73.40) | 37.1, 97.4 | 8 | 3.85 (12.914) | 0.90 (-4.00, 12.85) | -14.8, 26.1 |
|  |  | C3D1 | 4 | 45.15 (11.263) | 41.95 (37.95, 52.35) | 35.4, 61.3 | 4 | -5.23 (9.902) | -4.65 (-13.40, 2.95) | -16.5, 4.9 |
|  |  | C4D1 | 3 | 44.33 (16.900) | 38.40 (31.20, 63.40) | 31.2, 63.4 | 3 | -5.90 (13.947) | -4.00 (-20.70, 7.00) | -20.7, 7.0 |
|  |  | C5D1 | 3 | 46.27 (13.231) | 42.40 (35.40, 61.00) | 35.4, 61.0 | 3 | -3.97 (11.095) | 0.00 (-16.50, 4.60) | -16.5, 4.6 |
|  |  | End of Treatment | 1 | 57.90 (NA) | 57.90 (57.90, 57.90) | 57.9, 57.9 | 1 | -1.20 (NA) | -1.20 (-1.20, -1.20) | -1.2, -1.2 |
|  | | | | | | | | | | |
| Urate (umol/L) | Treatment Group (N = 5) | Baseline | 5 | 274.80 (50.776) | 283.00 (255.00, 298.00) | 201.0, 337.0 |  |  |  |  |
|  |  | C1D8 | 5 | 281.40 (89.207) | 270.00 (219.00, 306.00) | 192.0, 420.0 | 5 | 6.60 (45.501) | -9.00 (-13.00, 8.00) | -36.0, 83.0 |
|  |  | C2D1 | 4 | 284.25 (58.745) | 263.50 (247.00, 321.50) | 240.0, 370.0 | 4 | 15.25 (30.794) | 25.50 (-5.50, 36.00) | -29.0, 39.0 |
|  |  | C3D1 | 2 | 233.00 (52.326) | 233.00 (196.00, 270.00) | 196.0, 270.0 | 2 | -9.00 (5.657) | -9.00 (-13.00, -5.00) | -13.0, -5.0 |
|  |  | C4D1 | 2 | 224.50 (19.092) | 224.50 (211.00, 238.00) | 211.0, 238.0 | 2 | -17.50 (77.075) | -17.50 (-72.00, 37.00) | -72.0, 37.0 |
|  |  | C5D1 | 2 | 241.50 (43.134) | 241.50 (211.00, 272.00) | 211.0, 272.0 | 2 | -0.50 (14.849) | -0.50 (-11.00, 10.00) | -11.0, 10.0 |
|  | | | | | | | | | | |
|  | Control Group (N = 5) | Baseline | 5 | 239.20 (51.611) | 262.00 (258.00, 264.00) | 147.0, 265.0 |  |  |  |  |
|  |  | C1D8 | 5 | 258.62 (51.214) | 265.00 (240.00, 291.10) | 182.0, 315.0 | 5 | 19.42 (29.388) | 26.10 (7.00, 35.00) | -24.0, 53.0 |
|  |  | C2D1 | 4 | 244.75 (47.577) | 227.00 (217.00, 272.50) | 210.0, 315.0 | 4 | 12.00 (53.273) | 9.50 (-34.00, 58.00) | -34.0, 63.0 |
|  |  | C3D1 | 2 | 200.00 (12.728) | 200.00 (191.00, 209.00) | 191.0, 209.0 | 2 | -61.00 (8.485) | -61.00 (-67.00, -55.00) | -67.0, -55.0 |
|  |  | C4D1 | 1 | 189.00 (NA) | 189.00 (189.00, 189.00) | 189.0, 189.0 | 1 | -69.00 (NA) | -69.00 (-69.00, -69.00) | -69.0, -69.0 |
|  |  | C5D1 | 1 | 188.00 (NA) | 188.00 (188.00, 188.00) | 188.0, 188.0 | 1 | -70.00 (NA) | -70.00 (-70.00, -70.00) | -70.0, -70.0 |
|  |  | End of Treatment | 1 | 277.00 (NA) | 277.00 (277.00, 277.00) | 277.0, 277.0 | 1 | 15.00 (NA) | 15.00 (15.00, 15.00) | 15.0, 15.0 |
|  | | | | | | | | | | |
|  | Total (N = 10) | Baseline | 10 | 257.00 (51.786) | 263.00 (255.00, 283.00) | 147.0, 337.0 |  |  |  |  |
|  |  | C1D8 | 10 | 270.01 (69.618) | 267.50 (219.00, 306.00) | 182.0, 420.0 | 10 | 13.01 (36.737) | 7.50 (-13.00, 35.00) | -36.0, 83.0 |
|  |  | C2D1 | 8 | 264.50 (53.804) | 247.00 (227.00, 294.00) | 210.0, 370.0 | 8 | 13.63 (40.320) | 25.50 (-31.50, 46.00) | -34.0, 63.0 |
|  |  | C3D1 | 4 | 216.50 (36.465) | 202.50 (193.50, 239.50) | 191.0, 270.0 | 4 | -35.00 (30.594) | -34.00 (-61.00, -9.00) | -67.0, -5.0 |
|  |  | C4D1 | 3 | 212.67 (24.542) | 211.00 (189.00, 238.00) | 189.0, 238.0 | 3 | -34.67 (62.083) | -69.00 (-72.00, 37.00) | -72.0, 37.0 |
|  |  | C5D1 | 3 | 223.67 (43.409) | 211.00 (188.00, 272.00) | 188.0, 272.0 | 3 | -23.67 (41.477) | -11.00 (-70.00, 10.00) | -70.0, 10.0 |
|  |  | End of Treatment | 1 | 277.00 (NA) | 277.00 (277.00, 277.00) | 277.0, 277.0 | 1 | 15.00 (NA) | 15.00 (15.00, 15.00) | 15.0, 15.0 |
|  | | | | | | | | | | |
| Glucose (mmol/L) | Treatment Group (N = 5) | Baseline | 5 | 4.986 (0.0879) | 5.020 (4.910, 5.030) | 4.88, 5.09 |  |  |  |  |
|  |  | C1D8 | 5 | 4.738 (0.3285) | 4.750 (4.470, 4.790) | 4.43, 5.25 | 5 | -0.248 (0.2891) | -0.240 (-0.440, -0.130) | -0.59, 0.16 |
|  |  | C2D1 | 4 | 5.388 (1.1662) | 5.125 (4.540, 6.235) | 4.32, 6.98 | 4 | 0.413 (1.1154) | 0.230 (-0.410, 1.235) | -0.70, 1.89 |
|  |  | C3D1 | 2 | 4.805 (0.4738) | 4.805 (4.470, 5.140) | 4.47, 5.14 | 2 | -0.180 (0.3253) | -0.180 (-0.410, 0.050) | -0.41, 0.05 |
|  |  | C4D1 | 2 | 5.120 (0.2121) | 5.120 (4.970, 5.270) | 4.97, 5.27 | 2 | 0.135 (0.0636) | 0.135 (0.090, 0.180) | 0.09, 0.18 |
|  |  | C5D1 | 2 | 4.985 (0.2616) | 4.985 (4.800, 5.170) | 4.80, 5.17 | 2 | 0.000 (0.1131) | 0.000 (-0.080, 0.080) | -0.08, 0.08 |
|  | | | | | | | | | | |
|  | Control Group (N = 5) | Baseline | 5 | 5.540 (1.0226) | 5.740 (4.570, 5.840) | 4.55, 7.00 |  |  |  |  |
|  |  | C1D8 | 5 | 5.150 (0.8479) | 4.860 (4.630, 5.570) | 4.28, 6.41 | 5 | -0.390 (1.0324) | -0.170 (-0.290, 0.080) | -2.14, 0.57 |
|  |  | C2D1 | 4 | 5.098 (0.3879) | 5.015 (4.800, 5.395) | 4.75, 5.61 | 4 | -0.685 (0.9235) | -0.610 (-1.405, 0.035) | -1.82, 0.30 |
|  |  | C3D1 | 2 | 5.610 (1.5415) | 5.610 (4.520, 6.700) | 4.52, 6.70 | 2 | 0.465 (0.7000) | 0.465 (-0.030, 0.960) | -0.03, 0.96 |
|  |  | C4D1 | 1 | 4.450 (NA) | 4.450 (4.450, 4.450) | 4.45, 4.45 | 1 | -1.290 (NA) | -1.290 (-1.290, -1.290) | -1.29, -1.29 |
|  |  | C5D1 | 1 | 4.370 (NA) | 4.370 (4.370, 4.370) | 4.37, 4.37 | 1 | -1.370 (NA) | -1.370 (-1.370, -1.370) | -1.37, -1.37 |
|  |  | End of Treatment | 1 | 5.000 (NA) | 5.000 (5.000, 5.000) | 5.00, 5.00 | 1 | -2.000 (NA) | -2.000 (-2.000, -2.000) | -2.00, -2.00 |
|  | | | | | | | | | | |
|  | Total (N = 10) | Baseline | 10 | 5.263 (0.7439) | 5.025 (4.880, 5.740) | 4.55, 7.00 |  |  |  |  |
|  |  | C1D8 | 10 | 4.944 (0.6439) | 4.770 (4.470, 5.250) | 4.28, 6.41 | 10 | -0.319 (0.7186) | -0.205 (-0.440, 0.080) | -2.14, 0.57 |
|  |  | C2D1 | 8 | 5.243 (0.8194) | 5.015 (4.755, 5.550) | 4.32, 6.98 | 8 | -0.136 (1.1148) | -0.175 (-0.845, 0.440) | -1.82, 1.89 |
|  |  | C3D1 | 4 | 5.208 (1.0406) | 4.830 (4.495, 5.920) | 4.47, 6.70 | 4 | 0.143 (0.5808) | 0.010 (-0.220, 0.505) | -0.41, 0.96 |
|  |  | C4D1 | 3 | 4.897 (0.4149) | 4.970 (4.450, 5.270) | 4.45, 5.27 | 3 | -0.340 (0.8240) | 0.090 (-1.290, 0.180) | -1.29, 0.18 |
|  |  | C5D1 | 3 | 4.780 (0.4004) | 4.800 (4.370, 5.170) | 4.37, 5.17 | 3 | -0.457 (0.7950) | -0.080 (-1.370, 0.080) | -1.37, 0.08 |
|  |  | End of Treatment | 1 | 5.000 (NA) | 5.000 (5.000, 5.000) | 5.00, 5.00 | 1 | -2.000 (NA) | -2.000 (-2.000, -2.000) | -2.00, -2.00 |
|  | | | | | | | | | | |
| Amylase (IU/L) | Treatment Group (N = 5) | Baseline | 4 | 57.750 (14.6828) | 55.000 (46.500, 69.000) | 44.00, 77.00 |  |  |  |  |
|  |  | C1D8 | 4 | 48.250 (10.8743) | 48.500 (39.000, 57.500) | 37.00, 59.00 | 4 | -9.500 (5.8023) | -7.500 (-13.000, -6.000) | -18.00, -5.00 |
|  |  | C2D1 | 3 | 49.667 (13.5031) | 50.000 (36.000, 63.000) | 36.00, 63.00 | 3 | -1.667 (5.5076) | 1.000 (-8.000, 2.000) | -8.00, 2.00 |
|  |  | C3D1 | 2 | 49.000 (5.6569) | 49.000 (45.000, 53.000) | 45.00, 53.00 | 2 | 2.500 (2.1213) | 2.500 (1.000, 4.000) | 1.00, 4.00 |
|  |  | C4D1 | 2 | 41.000 (7.0711) | 41.000 (36.000, 46.000) | 36.00, 46.00 | 2 | -5.500 (3.5355) | -5.500 (-8.000, -3.000) | -8.00, -3.00 |
|  |  | C5D1 | 2 | 45.000 (1.4142) | 45.000 (44.000, 46.000) | 44.00, 46.00 | 2 | -1.500 (2.1213) | -1.500 (-3.000, 0.000) | -3.00, 0.00 |
|  | | | | | | | | | | |
|  | Control Group (N = 5) | Baseline | 4 | 66.748 (34.2147) | 66.500 (40.500, 92.995) | 27.00, 106.99 |  |  |  |  |
|  |  | C1D8 | 3 | 56.000 (20.8806) | 46.000 (42.000, 80.000) | 42.00, 80.00 | 3 | 2.667 (11.5902) | 1.000 (-8.000, 15.000) | -8.00, 15.00 |
|  |  | C2D1 | 3 | 49.667 (22.0303) | 39.000 (35.000, 75.000) | 35.00, 75.00 | 3 | -3.667 (15.5027) | -4.000 (-19.000, 12.000) | -19.00, 12.00 |
|  |  | C3D1 | 2 | 55.000 (28.2843) | 55.000 (35.000, 75.000) | 35.00, 75.00 | 2 | -11.500 (10.6066) | -11.500 (-19.000, -4.000) | -19.00, -4.00 |
|  |  | C4D1 | 1 | 31.000 (NA) | 31.000 (31.000, 31.000) | 31.00, 31.00 | 1 | -23.000 (NA) | -23.000 (-23.000, -23.000) | -23.00, -23.00 |
|  |  | C5D1 | 1 | 35.000 (NA) | 35.000 (35.000, 35.000) | 35.00, 35.00 | 1 | -19.000 (NA) | -19.000 (-19.000, -19.000) | -19.00, -19.00 |
|  |  | End of Treatment | 1 | 37.000 (NA) | 37.000 (37.000, 37.000) | 37.00, 37.00 | 1 | 10.000 (NA) | 10.000 (10.000, 10.000) | 10.00, 10.00 |
|  | | | | | | | | | | |
|  | Total (N = 10) | Baseline | 8 | 62.249 (24.8441) | 57.500 (46.500, 78.000) | 27.00, 106.99 |  |  |  |  |
|  |  | C1D8 | 7 | 51.571 (14.8869) | 46.000 (41.000, 59.000) | 37.00, 80.00 | 7 | -4.286 (10.1934) | -7.000 (-8.000, 1.000) | -18.00, 15.00 |
|  |  | C2D1 | 6 | 49.667 (16.3422) | 44.500 (36.000, 63.000) | 35.00, 75.00 | 6 | -2.667 (10.4626) | -1.500 (-8.000, 2.000) | -19.00, 12.00 |
|  |  | C3D1 | 4 | 52.000 (17.0098) | 49.000 (40.000, 64.000) | 35.00, 75.00 | 4 | -4.500 (10.2144) | -1.500 (-11.500, 2.500) | -19.00, 4.00 |
|  |  | C4D1 | 3 | 37.667 (7.6376) | 36.000 (31.000, 46.000) | 31.00, 46.00 | 3 | -11.333 (10.4083) | -8.000 (-23.000, -3.000) | -23.00, -3.00 |
|  |  | C5D1 | 3 | 41.667 (5.8595) | 44.000 (35.000, 46.000) | 35.00, 46.00 | 3 | -7.333 (10.2144) | -3.000 (-19.000, 0.000) | -19.00, 0.00 |
|  |  | End of Treatment | 1 | 37.000 (NA) | 37.000 (37.000, 37.000) | 37.00, 37.00 | 1 | 10.000 (NA) | 10.000 (10.000, 10.000) | 10.00, 10.00 |
|  | | | | | | | | | | |
| Lipase (IU/L) | Treatment Group (N = 5) | Baseline | 4 | 32.925 (22.1703) | 24.500 (18.100, 47.750) | 17.70, 65.00 |  |  |  |  |
|  |  | C1D8 | 4 | 27.975 (11.8317) | 24.050 (20.050, 35.900) | 18.80, 45.00 | 4 | -4.950 (10.4040) | -1.300 (-11.850, 1.950) | -20.00, 2.80 |
|  |  | C2D1 | 3 | 20.767 (8.9673) | 23.700 (10.700, 27.900) | 10.70, 27.90 | 3 | -1.467 (6.9695) | -2.600 (-7.800, 6.000) | -7.80, 6.00 |
|  |  | C3D1 | 2 | 30.050 (9.2631) | 30.050 (23.500, 36.600) | 23.50, 36.60 | 2 | 5.550 (0.7778) | 5.550 (5.000, 6.100) | 5.00, 6.10 |
|  |  | C4D1 | 2 | 30.350 (8.1317) | 30.350 (24.600, 36.100) | 24.60, 36.10 | 2 | 5.850 (0.3536) | 5.850 (5.600, 6.100) | 5.60, 6.10 |
|  |  | C5D1 | 2 | 33.300 (14.9907) | 33.300 (22.700, 43.900) | 22.70, 43.90 | 2 | 8.800 (6.5054) | 8.800 (4.200, 13.400) | 4.20, 13.40 |
|  | | | | | | | | | | |
|  | Control Group (N = 5) | Baseline | 4 | 23.810 (9.5057) | 21.500 (17.700, 29.920) | 15.00, 37.24 |  |  |  |  |
|  |  | C1D8 | 4 | 30.228 (15.2861) | 24.750 (21.150, 39.305) | 18.70, 52.71 | 4 | 6.418 (7.3558) | 5.950 (0.800, 12.035) | -1.70, 15.47 |
|  |  | C2D1 | 3 | 28.833 (9.8678) | 32.300 (17.700, 36.500) | 17.70, 36.50 | 3 | 9.500 (12.1012) | 9.700 (-2.700, 21.500) | -2.70, 21.50 |
|  |  | C3D1 | 2 | 26.050 (14.9200) | 26.050 (15.500, 36.600) | 15.50, 36.60 | 2 | 8.350 (18.7383) | 8.350 (-4.900, 21.600) | -4.90, 21.60 |
|  |  | C4D1 | 1 | 22.500 (NA) | 22.500 (22.500, 22.500) | 22.50, 22.50 | 1 | 2.100 (NA) | 2.100 (2.100, 2.100) | 2.10, 2.10 |
|  |  | C5D1 | 1 | 21.300 (NA) | 21.300 (21.300, 21.300) | 21.30, 21.30 | 1 | 0.900 (NA) | 0.900 (0.900, 0.900) | 0.90, 0.90 |
|  |  | End of Treatment | 1 | 32.500 (NA) | 32.500 (32.500, 32.500) | 32.50, 32.50 | 1 | 9.900 (NA) | 9.900 (9.900, 9.900) | 9.90, 9.90 |
|  | | | | | | | | | | |
|  | Total (N = 10) | Baseline | 8 | 28.368 (16.5262) | 21.500 (18.100, 33.870) | 15.00, 65.00 |  |  |  |  |
|  |  | C1D8 | 8 | 29.101 (12.7117) | 24.750 (20.050, 35.900) | 18.70, 52.71 | 8 | 0.734 (10.3198) | 1.950 (-2.700, 5.950) | -20.00, 15.47 |
|  |  | C2D1 | 6 | 24.800 (9.5203) | 25.800 (17.700, 32.300) | 10.70, 36.50 | 6 | 4.017 (10.6811) | 1.700 (-2.700, 9.700) | -7.80, 21.50 |
|  |  | C3D1 | 4 | 28.050 (10.3989) | 30.050 (19.500, 36.600) | 15.50, 36.60 | 4 | 6.950 (10.9479) | 5.550 (0.050, 13.850) | -4.90, 21.60 |
|  |  | C4D1 | 3 | 27.733 (7.3214) | 24.600 (22.500, 36.100) | 22.50, 36.10 | 3 | 4.600 (2.1794) | 5.600 (2.100, 6.100) | 2.10, 6.10 |
|  |  | C5D1 | 3 | 29.300 (12.6633) | 22.700 (21.300, 43.900) | 21.30, 43.90 | 3 | 6.167 (6.4779) | 4.200 (0.900, 13.400) | 0.90, 13.40 |
|  |  | End of Treatment | 1 | 32.500 (NA) | 32.500 (32.500, 32.500) | 32.50, 32.50 | 1 | 9.900 (NA) | 9.900 (9.900, 9.900) | 9.90, 9.90 |
|  | | | | | | | | | | |
| Creatine Kinase (IU/L) | Treatment Group (N = 5) | Baseline | 4 | 60.00 (24.819) | 58.00 (43.00, 77.00) | 32.0, 92.0 |  |  |  |  |
|  |  | C1D8 | 4 | 62.75 (16.840) | 67.50 (50.00, 75.50) | 40.0, 76.0 | 4 | 2.75 (12.842) | 7.00 (-5.00, 10.50) | -16.0, 13.0 |
|  |  | C2D1 | 3 | 42.00 (11.533) | 41.00 (31.00, 54.00) | 31.0, 54.0 | 3 | -17.33 (29.160) | -1.00 (-51.00, 0.00) | -51.0, 0.0 |
|  |  | C3D1 | 2 | 58.00 (11.314) | 58.00 (50.00, 66.00) | 50.0, 66.0 | 2 | 15.00 (4.243) | 15.00 (12.00, 18.00) | 12.0, 18.0 |
|  |  | C4D1 | 2 | 79.50 (9.192) | 79.50 (73.00, 86.00) | 73.0, 86.0 | 2 | 36.50 (6.364) | 36.50 (32.00, 41.00) | 32.0, 41.0 |
|  |  | C5D1 | 2 | 85.00 (24.042) | 85.00 (68.00, 102.00) | 68.0, 102.0 | 2 | 42.00 (8.485) | 42.00 (36.00, 48.00) | 36.0, 48.0 |
|  | | | | | | | | | | |
|  | Control Group (N = 5) | Baseline | 4 | 54.33 (18.960) | 48.65 (40.00, 68.65) | 40.0, 80.0 |  |  |  |  |
|  |  | C1D8 | 4 | 52.98 (20.010) | 50.00 (36.50, 69.45) | 35.0, 76.9 | 4 | -1.35 (15.598) | -3.50 (-11.50, 8.80) | -18.0, 19.6 |
|  |  | C2D1 | 3 | 66.00 (39.051) | 46.00 (41.00, 111.00) | 41.0, 111.0 | 3 | 12.67 (16.073) | 6.00 (1.00, 31.00) | 1.0, 31.0 |
|  |  | C3D1 | 2 | 49.50 (2.121) | 49.50 (48.00, 51.00) | 48.0, 51.0 | 2 | 9.50 (2.121) | 9.50 (8.00, 11.00) | 8.0, 11.0 |
|  |  | C4D1 | 1 | 49.00 (NA) | 49.00 (49.00, 49.00) | 49.0, 49.0 | 1 | 9.00 (NA) | 9.00 (9.00, 9.00) | 9.0, 9.0 |
|  |  | C5D1 | 1 | 54.00 (NA) | 54.00 (54.00, 54.00) | 54.0, 54.0 | 1 | 14.00 (NA) | 14.00 (14.00, 14.00) | 14.0, 14.0 |
|  |  | End of Treatment | 1 | 353.00 (NA) | 353.00 (353.00, 353.00) | 353.0, 353.0 | 1 | 273.00 (NA) | 273.00 (273.00, 273.00) | 273.0, 273.0 |
|  | | | | | | | | | | |
|  | Total (N = 10) | Baseline | 8 | 57.16 (20.670) | 55.65 (40.00, 71.00) | 32.0, 92.0 |  |  |  |  |
|  |  | C1D8 | 8 | 57.86 (17.901) | 61.00 (39.00, 75.50) | 35.0, 76.9 | 8 | 0.70 (13.407) | 2.00 (-10.50, 10.50) | -18.0, 19.6 |
|  |  | C2D1 | 6 | 54.00 (28.914) | 43.50 (41.00, 54.00) | 31.0, 111.0 | 6 | -2.33 (26.711) | 0.50 (-1.00, 6.00) | -51.0, 31.0 |
|  |  | C3D1 | 4 | 53.75 (8.261) | 50.50 (49.00, 58.50) | 48.0, 66.0 | 4 | 12.25 (4.193) | 11.50 (9.50, 15.00) | 8.0, 18.0 |
|  |  | C4D1 | 3 | 69.33 (18.771) | 73.00 (49.00, 86.00) | 49.0, 86.0 | 3 | 27.33 (16.503) | 32.00 (9.00, 41.00) | 9.0, 41.0 |
|  |  | C5D1 | 3 | 74.67 (24.685) | 68.00 (54.00, 102.00) | 54.0, 102.0 | 3 | 32.67 (17.243) | 36.00 (14.00, 48.00) | 14.0, 48.0 |
|  |  | End of Treatment | 1 | 353.00 (NA) | 353.00 (353.00, 353.00) | 353.0, 353.0 | 1 | 273.00 (NA) | 273.00 (273.00, 273.00) | 273.0, 273.0 |

NA = Not applicable.

Baseline is defined as the last available assessment before the first administration of investigational drug (D-1553 or IN10018).

Only subjects with data at both baseline and the relevant post baseline visit are included in the change from baseline summary statistics.

Source Data: Listing 16.2.8.2.1

|  |  |  |
| --- | --- | --- |
| Program: t-lb-chg.sas | DCO: 27APR2024 | Executed: 07JUL2024 20:45 |

|  |  |
| --- | --- |
| **InxMed (Shanghai) Co., Ltd.  Protocol No. IN10018-602** |  |

**Table 14.3.5.1.3.3 Summary of Urinalysis Results - Phase II part 2 - CRC (Safety Analysis Set)**

|  | | | Observed Value | | | | Change from Baseline | | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Parameter | Group | Visit | n | Mean (STD) | Median (Q1, Q3) | Min, Max | n | Mean (STD) | Median (Q1, Q3) | Min, Max |
| pH, Quantitative | Treatment Group (N = 5) | Baseline | 5 | 6.20 (0.570) | 6.00 (6.00, 6.50) | 5.5, 7.0 |  |  |  |  |
|  |  | C1D8 | 5 | 5.70 (0.447) | 5.50 (5.50, 5.50) | 5.5, 6.5 | 5 | -0.50 (0.612) | -0.50 (-0.50, 0.00) | -1.5, 0.0 |
|  |  | C2D1 | 4 | 5.75 (0.289) | 5.75 (5.50, 6.00) | 5.5, 6.0 | 4 | -0.63 (0.629) | -0.50 (-1.00, -0.25) | -1.5, 0.0 |
|  |  | C3D1 | 2 | 5.75 (0.354) | 5.75 (5.50, 6.00) | 5.5, 6.0 | 2 | -0.50 (0.000) | -0.50 (-0.50, -0.50) | -0.5, -0.5 |
|  |  | C4D1 | 2 | 5.75 (0.354) | 5.75 (5.50, 6.00) | 5.5, 6.0 | 2 | -0.50 (0.000) | -0.50 (-0.50, -0.50) | -0.5, -0.5 |
|  |  | C5D1 | 2 | 6.50 (1.414) | 6.50 (5.50, 7.50) | 5.5, 7.5 | 2 | 0.25 (1.061) | 0.25 (-0.50, 1.00) | -0.5, 1.0 |
|  | | | | | | | | | | |
|  | Control Group (N = 5) | Baseline | 5 | 5.70 (0.447) | 6.00 (5.50, 6.00) | 5.0, 6.0 |  |  |  |  |
|  |  | C1D8 | 5 | 5.60 (0.652) | 5.50 (5.00, 6.00) | 5.0, 6.5 | 5 | -0.10 (0.418) | 0.00 (-0.50, 0.00) | -0.5, 0.5 |
|  |  | C2D1 | 4 | 5.38 (0.479) | 5.25 (5.00, 5.75) | 5.0, 6.0 | 4 | -0.25 (0.289) | -0.25 (-0.50, 0.00) | -0.5, 0.0 |
|  |  | C3D1 | 2 | 5.75 (0.354) | 5.75 (5.50, 6.00) | 5.5, 6.0 | 2 | 0.00 (0.000) | 0.00 (0.00, 0.00) | 0.0, 0.0 |
|  |  | C4D1 | 1 | 5.00 (NA) | 5.00 (5.00, 5.00) | 5.0, 5.0 | 1 | -0.50 (NA) | -0.50 (-0.50, -0.50) | -0.5, -0.5 |
|  |  | C5D1 | 1 | 6.00 (NA) | 6.00 (6.00, 6.00) | 6.0, 6.0 | 1 | 0.50 (NA) | 0.50 (0.50, 0.50) | 0.5, 0.5 |
|  |  | End of Treatment | 1 | 6.00 (NA) | 6.00 (6.00, 6.00) | 6.0, 6.0 | 1 | 0.00 (NA) | 0.00 (0.00, 0.00) | 0.0, 0.0 |
|  | | | | | | | | | | |
|  | Total (N = 10) | Baseline | 10 | 5.95 (0.550) | 6.00 (5.50, 6.00) | 5.0, 7.0 |  |  |  |  |
|  |  | C1D8 | 10 | 5.65 (0.530) | 5.50 (5.50, 6.00) | 5.0, 6.5 | 10 | -0.30 (0.537) | -0.25 (-0.50, 0.00) | -1.5, 0.5 |
|  |  | C2D1 | 8 | 5.56 (0.417) | 5.50 (5.25, 6.00) | 5.0, 6.0 | 8 | -0.44 (0.496) | -0.50 (-0.50, 0.00) | -1.5, 0.0 |
|  |  | C3D1 | 4 | 5.75 (0.289) | 5.75 (5.50, 6.00) | 5.5, 6.0 | 4 | -0.25 (0.289) | -0.25 (-0.50, 0.00) | -0.5, 0.0 |
|  |  | C4D1 | 3 | 5.50 (0.500) | 5.50 (5.00, 6.00) | 5.0, 6.0 | 3 | -0.50 (0.000) | -0.50 (-0.50, -0.50) | -0.5, -0.5 |
|  |  | C5D1 | 3 | 6.33 (1.041) | 6.00 (5.50, 7.50) | 5.5, 7.5 | 3 | 0.33 (0.764) | 0.50 (-0.50, 1.00) | -0.5, 1.0 |
|  |  | End of Treatment | 1 | 6.00 (NA) | 6.00 (6.00, 6.00) | 6.0, 6.0 | 1 | 0.00 (NA) | 0.00 (0.00, 0.00) | 0.0, 0.0 |
|  | | | | | | | | | | |
| Specific Gravity, Quantitative | Treatment Group (N = 5) | Baseline | 5 | 1.0244 (0.0099) | 1.0210 (1.0200, 1.0210) | 1.018, 1.042 |  |  |  |  |
|  |  | C1D8 | 5 | 1.0234 (0.0056) | 1.0210 (1.0200, 1.0260) | 1.018, 1.032 | 5 | -0.0010 (0.0123) | 0.0000 (-0.0010, 0.0050) | -0.021, 0.012 |
|  |  | C2D1 | 4 | 1.0128 (0.0049) | 1.0125 (1.0095, 1.0160) | 1.007, 1.019 | 4 | -0.0125 (0.0119) | -0.0095 (-0.0210, -0.0040) | -0.029, -0.002 |
|  |  | C3D1 | 2 | 1.0135 (0.0021) | 1.0135 (1.0120, 1.0150) | 1.012, 1.015 | 2 | -0.0060 (0.0000) | -0.0060 (-0.0060, -0.0060) | -0.006, -0.006 |
|  |  | C4D1 | 2 | 1.0065 (0.0049) | 1.0065 (1.0030, 1.0100) | 1.003, 1.010 | 2 | -0.0130 (0.0028) | -0.0130 (-0.0150, -0.0110) | -0.015, -0.011 |
|  |  | C5D1 | 2 | 1.0150 (0.0113) | 1.0150 (1.0070, 1.0230) | 1.007, 1.023 | 2 | -0.0045 (0.0134) | -0.0045 (-0.0140, 0.0050) | -0.014, 0.005 |
|  | | | | | | | | | | |
|  | Control Group (N = 5) | Baseline | 5 | 1.0154 (0.0033) | 1.0160 (1.0140, 1.0160) | 1.011, 1.020 |  |  |  |  |
|  |  | C1D8 | 5 | 1.0168 (0.0066) | 1.0150 (1.0130, 1.0220) | 1.009, 1.025 | 5 | 0.0014 (0.0079) | -0.0030 (-0.0050, 0.0090) | -0.005, 0.011 |
|  |  | C2D1 | 4 | 1.0125 (0.0050) | 1.0100 (1.0100, 1.0150) | 1.010, 1.020 | 4 | -0.0018 (0.0072) | -0.0050 (-0.0060, 0.0025) | -0.006, 0.009 |
|  |  | C3D1 | 2 | 1.0205 (0.0021) | 1.0205 (1.0190, 1.0220) | 1.019, 1.022 | 2 | 0.0070 (0.0057) | 0.0070 (0.0030, 0.0110) | 0.003, 0.011 |
|  |  | C4D1 | 1 | 1.0190 (NA) | 1.0190 (1.0190, 1.0190) | 1.019, 1.019 | 1 | 0.0080 (NA) | 0.0080 (0.0080, 0.0080) | 0.008, 0.008 |
|  |  | C5D1 | 1 | 1.0130 (NA) | 1.0130 (1.0130, 1.0130) | 1.013, 1.013 | 1 | 0.0020 (NA) | 0.0020 (0.0020, 0.0020) | 0.002, 0.002 |
|  |  | End of Treatment | 1 | 1.0210 (NA) | 1.0210 (1.0210, 1.0210) | 1.021, 1.021 | 1 | 0.0070 (NA) | 0.0070 (0.0070, 0.0070) | 0.007, 0.007 |
|  | | | | | | | | | | |
|  | Total (N = 10) | Baseline | 10 | 1.0199 (0.0084) | 1.0190 (1.0160, 1.0210) | 1.011, 1.042 |  |  |  |  |
|  |  | C1D8 | 10 | 1.0201 (0.0067) | 1.0205 (1.0150, 1.0250) | 1.009, 1.032 | 10 | 0.0002 (0.0098) | -0.0005 (-0.0050, 0.0090) | -0.021, 0.012 |
|  |  | C2D1 | 8 | 1.0126 (0.0046) | 1.0110 (1.0100, 1.0160) | 1.007, 1.020 | 8 | -0.0071 (0.0108) | -0.0060 (-0.0095, -0.0030) | -0.029, 0.009 |
|  |  | C3D1 | 4 | 1.0170 (0.0044) | 1.0170 (1.0135, 1.0205) | 1.012, 1.022 | 4 | 0.0005 (0.0082) | -0.0015 (-0.0060, 0.0070) | -0.006, 0.011 |
|  |  | C4D1 | 3 | 1.0107 (0.0080) | 1.0100 (1.0030, 1.0190) | 1.003, 1.019 | 3 | -0.0060 (0.0123) | -0.0110 (-0.0150, 0.0080) | -0.015, 0.008 |
|  |  | C5D1 | 3 | 1.0143 (0.0081) | 1.0130 (1.0070, 1.0230) | 1.007, 1.023 | 3 | -0.0023 (0.0102) | 0.0020 (-0.0140, 0.0050) | -0.014, 0.005 |
|  |  | End of Treatment | 1 | 1.0210 (NA) | 1.0210 (1.0210, 1.0210) | 1.021, 1.021 | 1 | 0.0070 (NA) | 0.0070 (0.0070, 0.0070) | 0.007, 0.007 |
|  | | | | | | | | | | |
| Urine Erythrocytes (/uL), Quantitative | Treatment Group (N = 5) | Baseline | 5 | 3.640 (3.0452) | 3.600 (1.300, 6.300) | 0.00, 7.00 |  |  |  |  |
|  |  | C1D8 | 5 | 52.280 (92.7774) | 14.400 (2.200, 26.600) | 1.00, 217.20 | 5 | 48.640 (90.6716) | 10.800 (1.000, 20.300) | 0.90, 210.20 |
|  |  | C2D1 | 4 | 95.825 (164.7716) | 19.900 (3.450, 188.200) | 1.50, 342.00 | 4 | 92.850 (166.5669) | 14.600 (1.000, 184.700) | 0.20, 342.00 |
|  |  | C3D1 | 2 | 3.550 (2.6163) | 3.550 (1.700, 5.400) | 1.70, 5.40 | 2 | -0.600 (1.4142) | -0.600 (-1.600, 0.400) | -1.60, 0.40 |
|  |  | C4D1 | 2 | 13.100 (17.6777) | 13.100 (0.600, 25.600) | 0.60, 25.60 | 2 | 8.950 (13.6472) | 8.950 (-0.700, 18.600) | -0.70, 18.60 |
|  |  | C5D1 | 2 | 19.900 (24.1831) | 19.900 (2.800, 37.000) | 2.80, 37.00 | 2 | 15.750 (28.2136) | 15.750 (-4.200, 35.700) | -4.20, 35.70 |
|  | | | | | | | | | | |
|  | Control Group (N = 5) | Baseline | 5 | 2.640 (1.6861) | 2.700 (2.300, 4.000) | 0.00, 4.20 |  |  |  |  |
|  |  | C1D8 | 5 | 5.660 (6.5767) | 1.700 (1.000, 11.900) | 0.00, 13.70 | 5 | 3.020 (6.7603) | 0.000 (-2.500, 9.600) | -3.00, 11.00 |
|  |  | C2D1 | 4 | 0.925 (0.8770) | 0.900 (0.200, 1.650) | 0.00, 1.90 | 4 | -1.375 (1.3817) | -1.350 (-2.550, -0.200) | -2.80, 0.00 |
|  |  | C3D1 | 2 | 5.000 (4.5255) | 5.000 (1.800, 8.200) | 1.80, 8.20 | 2 | 2.500 (4.8083) | 2.500 (-0.900, 5.900) | -0.90, 5.90 |
|  |  | C4D1 | 1 | 4.500 (NA) | 4.500 (4.500, 4.500) | 4.50, 4.50 | 1 | 2.200 (NA) | 2.200 (2.200, 2.200) | 2.20, 2.20 |
|  |  | C5D1 | 1 | 0.800 (NA) | 0.800 (0.800, 0.800) | 0.80, 0.80 | 1 | -1.500 (NA) | -1.500 (-1.500, -1.500) | -1.50, -1.50 |
|  |  | End of Treatment | 1 | 1.100 (NA) | 1.100 (1.100, 1.100) | 1.10, 1.10 | 1 | -3.100 (NA) | -3.100 (-3.100, -3.100) | -3.10, -3.10 |
|  | | | | | | | | | | |
|  | Total (N = 10) | Baseline | 10 | 3.140 (2.3796) | 3.150 (1.300, 4.200) | 0.00, 7.00 |  |  |  |  |
|  |  | C1D8 | 10 | 28.970 (66.6976) | 7.050 (1.000, 14.400) | 0.00, 217.20 | 10 | 25.830 (65.2100) | 5.300 (0.000, 11.000) | -3.00, 210.20 |
|  |  | C2D1 | 8 | 48.375 (119.2017) | 1.700 (0.900, 19.900) | 0.00, 342.00 | 8 | 45.738 (120.1166) | 0.100 (-1.350, 14.600) | -2.80, 342.00 |
|  |  | C3D1 | 4 | 4.275 (3.1320) | 3.600 (1.750, 6.800) | 1.70, 8.20 | 4 | 0.950 (3.4025) | -0.250 (-1.250, 3.150) | -1.60, 5.90 |
|  |  | C4D1 | 3 | 10.233 (13.4500) | 4.500 (0.600, 25.600) | 0.60, 25.60 | 3 | 6.700 (10.4072) | 2.200 (-0.700, 18.600) | -0.70, 18.60 |
|  |  | C5D1 | 3 | 13.533 (20.3473) | 2.800 (0.800, 37.000) | 0.80, 37.00 | 3 | 10.000 (22.2978) | -1.500 (-4.200, 35.700) | -4.20, 35.70 |
|  |  | End of Treatment | 1 | 1.100 (NA) | 1.100 (1.100, 1.100) | 1.10, 1.10 | 1 | -3.100 (NA) | -3.100 (-3.100, -3.100) | -3.10, -3.10 |
|  | | | | | | | | | | |
| Urine Leukocytes (/uL), Quantitative | Treatment Group (N = 5) | Baseline | 5 | 6.220 (3.6492) | 5.500 (5.400, 6.300) | 1.90, 12.00 |  |  |  |  |
|  |  | C1D8 | 5 | 7.400 (5.2082) | 6.100 (4.000, 7.200) | 3.40, 16.30 | 5 | 1.180 (6.3771) | 1.500 (0.700, 1.700) | -8.00, 10.00 |
|  |  | C2D1 | 4 | 20.700 (27.9383) | 7.100 (6.500, 34.900) | 6.00, 62.60 | 4 | 14.500 (28.6616) | 2.950 (-1.600, 30.600) | -5.00, 57.10 |
|  |  | C3D1 | 2 | 3.800 (4.3841) | 3.800 (0.700, 6.900) | 0.70, 6.90 | 2 | -1.650 (4.3134) | -1.650 (-4.700, 1.400) | -4.70, 1.40 |
|  |  | C4D1 | 2 | 2.600 (2.4042) | 2.600 (0.900, 4.300) | 0.90, 4.30 | 2 | -2.850 (2.4749) | -2.850 (-4.600, -1.100) | -4.60, -1.10 |
|  |  | C5D1 | 2 | 15.350 (18.3141) | 15.350 (2.400, 28.300) | 2.40, 28.30 | 2 | 9.900 (18.2434) | 9.900 (-3.000, 22.800) | -3.00, 22.80 |
|  | | | | | | | | | | |
|  | Control Group (N = 5) | Baseline | 5 | 54.920 (70.9693) | 12.000 (8.900, 83.100) | 3.00, 167.60 |  |  |  |  |
|  |  | C1D8 | 5 | 87.120 (97.4475) | 59.200 (9.000, 132.100) | 1.00, 234.30 | 5 | 32.200 (73.2813) | -2.000 (-3.000, 50.300) | -35.50, 151.20 |
|  |  | C2D1 | 4 | 111.975 (178.4019) | 34.700 (5.400, 218.550) | 1.80, 376.70 | 4 | 44.075 (173.1876) | -5.050 (-57.150, 145.300) | -107.20, 293.60 |
|  |  | C3D1 | 2 | 134.600 (158.8162) | 134.600 (22.300, 246.900) | 22.30, 246.90 | 2 | 88.600 (106.3489) | 88.600 (13.400, 163.800) | 13.40, 163.80 |
|  |  | C4D1 | 1 | 1027.200 (NA) | 1027.200 (1027.200, 1027.200) | 1027.20, 1027.20 | 1 | 944.100 (NA) | 944.100 (944.100, 944.100) | 944.10, 944.10 |
|  |  | C5D1 | 1 | 178.800 (NA) | 178.800 (178.800, 178.800) | 178.80, 178.80 | 1 | 95.700 (NA) | 95.700 (95.700, 95.700) | 95.70, 95.70 |
|  |  | End of Treatment | 1 | 105.100 (NA) | 105.100 (105.100, 105.100) | 105.10, 105.10 | 1 | -62.500 (NA) | -62.500 (-62.500, -62.500) | -62.50, -62.50 |
|  | | | | | | | | | | |
|  | Total (N = 10) | Baseline | 10 | 30.570 (53.8816) | 7.600 (5.400, 12.000) | 1.90, 167.60 |  |  |  |  |
|  |  | C1D8 | 10 | 47.260 (77.4459) | 8.100 (4.000, 59.200) | 1.00, 234.30 | 10 | 16.690 (51.6923) | 1.100 (-3.000, 10.000) | -35.50, 151.20 |
|  |  | C2D1 | 8 | 66.338 (127.8870) | 8.100 (6.500, 61.500) | 1.80, 376.70 | 8 | 29.288 (116.0022) | -0.600 (-6.050, 30.600) | -107.20, 293.60 |
|  |  | C3D1 | 4 | 69.200 (118.8142) | 14.600 (3.800, 134.600) | 0.70, 246.90 | 4 | 43.475 (80.5683) | 7.400 (-1.650, 88.600) | -4.70, 163.80 |
|  |  | C4D1 | 3 | 344.133 (591.5555) | 4.300 (0.900, 1027.200) | 0.90, 1027.20 | 3 | 312.800 (546.7246) | -1.100 (-4.600, 944.100) | -4.60, 944.10 |
|  |  | C5D1 | 3 | 69.833 (95.2523) | 28.300 (2.400, 178.800) | 2.40, 178.80 | 3 | 38.500 (51.1888) | 22.800 (-3.000, 95.700) | -3.00, 95.70 |
|  |  | End of Treatment | 1 | 105.100 (NA) | 105.100 (105.100, 105.100) | 105.10, 105.10 | 1 | -62.500 (NA) | -62.500 (-62.500, -62.500) | -62.50, -62.50 |
|  | | | | | | | | | | |
| Urine Creatinine (g/L), Quantitative | Treatment Group (N = 5) | Baseline | 2 | 1.50 (0.707) | 1.50 (1.00, 2.00) | 1.0, 2.0 |  |  |  |  |
|  |  | C1D8 | 3 | 1.33 (0.577) | 1.00 (1.00, 2.00) | 1.0, 2.0 | 2 | -0.50 (0.707) | -0.50 (-1.00, 0.00) | -1.0, 0.0 |
|  |  | C2D1 | 3 | 0.83 (0.289) | 1.00 (0.50, 1.00) | 0.5, 1.0 | 2 | -0.75 (1.061) | -0.75 (-1.50, 0.00) | -1.5, 0.0 |
|  |  | C3D1 | 2 | 0.50 (0.000) | 0.50 (0.50, 0.50) | 0.5, 0.5 | 2 | -1.00 (0.707) | -1.00 (-1.50, -0.50) | -1.5, -0.5 |
|  |  | C4D1 | 2 | 0.30 (0.283) | 0.30 (0.10, 0.50) | 0.1, 0.5 | 2 | -1.20 (0.990) | -1.20 (-1.90, -0.50) | -1.9, -0.5 |
|  |  | C5D1 | 2 | 1.05 (1.344) | 1.05 (0.10, 2.00) | 0.1, 2.0 | 2 | -0.45 (0.636) | -0.45 (-0.90, 0.00) | -0.9, 0.0 |
|  | | | | | | | | | | |
|  | Control Group (N = 5) | Baseline | 3 | 0.67 (0.289) | 0.50 (0.50, 1.00) | 0.5, 1.0 |  |  |  |  |
|  |  | C1D8 | 2 | 0.75 (0.354) | 0.75 (0.50, 1.00) | 0.5, 1.0 | 2 | 0.00 (0.707) | 0.00 (-0.50, 0.50) | -0.5, 0.5 |
|  |  | C2D1 | 3 | 0.67 (0.289) | 0.50 (0.50, 1.00) | 0.5, 1.0 | 3 | 0.00 (0.500) | 0.00 (-0.50, 0.50) | -0.5, 0.5 |
|  |  | C3D1 | 2 | 1.00 (0.000) | 1.00 (1.00, 1.00) | 1.0, 1.0 | 2 | 0.50 (0.000) | 0.50 (0.50, 0.50) | 0.5, 0.5 |
|  |  | C4D1 | 1 | 1.00 (NA) | 1.00 (1.00, 1.00) | 1.0, 1.0 | 1 | 0.50 (NA) | 0.50 (0.50, 0.50) | 0.5, 0.5 |
|  |  | End of Treatment | 1 | 1.00 (NA) | 1.00 (1.00, 1.00) | 1.0, 1.0 | 1 | 0.00 (NA) | 0.00 (0.00, 0.00) | 0.0, 0.0 |
|  | | | | | | | | | | |
|  | Total (N = 10) | Baseline | 5 | 1.00 (0.612) | 1.00 (0.50, 1.00) | 0.5, 2.0 |  |  |  |  |
|  |  | C1D8 | 5 | 1.10 (0.548) | 1.00 (1.00, 1.00) | 0.5, 2.0 | 4 | -0.25 (0.645) | -0.25 (-0.75, 0.25) | -1.0, 0.5 |
|  |  | C2D1 | 6 | 0.75 (0.274) | 0.75 (0.50, 1.00) | 0.5, 1.0 | 5 | -0.30 (0.758) | 0.00 (-0.50, 0.00) | -1.5, 0.5 |
|  |  | C3D1 | 4 | 0.75 (0.289) | 0.75 (0.50, 1.00) | 0.5, 1.0 | 4 | -0.25 (0.957) | 0.00 (-1.00, 0.50) | -1.5, 0.5 |
|  |  | C4D1 | 3 | 0.53 (0.451) | 0.50 (0.10, 1.00) | 0.1, 1.0 | 3 | -0.63 (1.206) | -0.50 (-1.90, 0.50) | -1.9, 0.5 |
|  |  | C5D1 | 2 | 1.05 (1.344) | 1.05 (0.10, 2.00) | 0.1, 2.0 | 2 | -0.45 (0.636) | -0.45 (-0.90, 0.00) | -0.9, 0.0 |
|  |  | End of Treatment | 1 | 1.00 (NA) | 1.00 (1.00, 1.00) | 1.0, 1.0 | 1 | 0.00 (NA) | 0.00 (0.00, 0.00) | 0.0, 0.0 |
|  | | | | | | | | | | |
| Urine Creatinine, Quantitative | Treatment Group (N = 5) | Baseline | 1 | 2.00 (NA) | 2.00 (2.00, 2.00) | 2.0, 2.0 |  |  |  |  |
|  | | | | | | | | | | |
|  | Control Group (N = 5) | C1D8 | 1 | 2.00 (NA) | 2.00 (2.00, 2.00) | 2.0, 2.0 | 0 |  |  |  |
|  |  | C5D1 | 1 | 0.50 (NA) | 0.50 (0.50, 0.50) | 0.5, 0.5 | 0 |  |  |  |
|  | | | | | | | | | | |
|  | Total (N = 10) | Baseline | 1 | 2.00 (NA) | 2.00 (2.00, 2.00) | 2.0, 2.0 |  |  |  |  |
|  |  | C1D8 | 1 | 2.00 (NA) | 2.00 (2.00, 2.00) | 2.0, 2.0 | 0 |  |  |  |
|  |  | C5D1 | 1 | 0.50 (NA) | 0.50 (0.50, 0.50) | 0.5, 0.5 | 0 |  |  |  |

NA = Not applicable.

Baseline is defined as the last available assessment before the first administration of investigational drug (D-1553 or IN10018).

Only subjects with data at both baseline and the relevant post baseline visit are included in the change from baseline summary statistics.

Source Data: Listing 16.2.8.3.1

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| --- | --- | --- |
| Program: t-lb-chg.sas | DCO: 27APR2024 | Executed: 07JUL2024 20:45 |

|  |  |
| --- | --- |
| **InxMed (Shanghai) Co., Ltd.  Protocol No. IN10018-602** |  |

**Table 14.3.5.1.4.3 Summary of Coagulation Function Results - Phase II part 2 - CRC (Safety Analysis Set)**

|  | | | Observed Value | | | | Change from Baseline | | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Parameter | Group | Visit | n | Mean (STD) | Median (Q1, Q3) | Min, Max | n | Mean (STD) | Median (Q1, Q3) | Min, Max |
| Activated Partial Thromboplastin Time (s) | Treatment Group (N = 5) | Baseline | 5 | 31.560 (3.7220) | 32.000 (28.100, 33.200) | 27.80, 36.70 |  |  |  |  |
|  |  | C1D8 | 5 | 35.040 (2.5677) | 36.500 (32.300, 36.800) | 32.20, 37.40 | 5 | 3.480 (3.4010) | 3.600 (0.700, 4.200) | 0.20, 8.70 |
|  |  | C2D1 | 4 | 33.850 (2.5489) | 33.550 (31.700, 36.000) | 31.60, 36.70 | 4 | 1.350 (2.5305) | 1.650 (-0.800, 3.500) | -1.40, 3.50 |
|  |  | C3D1 | 2 | 34.250 (1.6263) | 34.250 (33.100, 35.400) | 33.10, 35.40 | 2 | 4.200 (4.3841) | 4.200 (1.100, 7.300) | 1.10, 7.30 |
|  |  | C4D1 | 2 | 34.700 (0.4243) | 34.700 (34.400, 35.000) | 34.40, 35.00 | 2 | 4.650 (2.3335) | 4.650 (3.000, 6.300) | 3.00, 6.30 |
|  |  | C5D1 | 2 | 31.300 (3.9598) | 31.300 (28.500, 34.100) | 28.50, 34.10 | 2 | 1.250 (6.7175) | 1.250 (-3.500, 6.000) | -3.50, 6.00 |
|  | | | | | | | | | | |
|  | Control Group (N = 5) | Baseline | 5 | 32.140 (2.4521) | 31.400 (30.700, 32.900) | 29.70, 36.00 |  |  |  |  |
|  |  | C1D8 | 5 | 31.580 (2.0303) | 30.200 (30.200, 32.600) | 30.20, 34.70 | 5 | -0.560 (3.0517) | 0.500 (-0.500, 1.200) | -5.80, 1.80 |
|  |  | C2D1 | 4 | 32.150 (1.7464) | 32.400 (30.700, 33.600) | 30.10, 33.70 | 4 | 0.975 (0.8884) | 0.600 (0.500, 1.450) | 0.40, 2.30 |
|  |  | C3D1 | 2 | 34.100 (2.2627) | 34.100 (32.500, 35.700) | 32.50, 35.70 | 2 | 3.050 (1.7678) | 3.050 (1.800, 4.300) | 1.80, 4.30 |
|  |  | C4D1 | 1 | 35.200 (NA) | 35.200 (35.200, 35.200) | 35.20, 35.20 | 1 | 3.800 (NA) | 3.800 (3.800, 3.800) | 3.80, 3.80 |
|  |  | C5D1 | 1 | 33.700 (NA) | 33.700 (33.700, 33.700) | 33.70, 33.70 | 1 | 2.300 (NA) | 2.300 (2.300, 2.300) | 2.30, 2.30 |
|  |  | End of Treatment | 1 | 30.800 (NA) | 30.800 (30.800, 30.800) | 30.80, 30.80 | 1 | 1.100 (NA) | 1.100 (1.100, 1.100) | 1.10, 1.10 |
|  | | | | | | | | | | |
|  | Total (N = 10) | Baseline | 10 | 31.850 (2.9871) | 31.700 (29.700, 33.200) | 27.80, 36.70 |  |  |  |  |
|  |  | C1D8 | 10 | 33.310 (2.8439) | 32.450 (30.200, 36.500) | 30.20, 37.40 | 10 | 1.460 (3.7167) | 0.950 (0.200, 3.600) | -5.80, 8.70 |
|  |  | C2D1 | 8 | 33.000 (2.2175) | 32.650 (31.450, 34.500) | 30.10, 36.70 | 8 | 1.163 (1.7671) | 0.600 (0.100, 2.900) | -1.40, 3.50 |
|  |  | C3D1 | 4 | 34.175 (1.6112) | 34.250 (32.800, 35.550) | 32.50, 35.70 | 4 | 3.625 (2.8088) | 3.050 (1.450, 5.800) | 1.10, 7.30 |
|  |  | C4D1 | 3 | 34.867 (0.4163) | 35.000 (34.400, 35.200) | 34.40, 35.20 | 3 | 4.367 (1.7214) | 3.800 (3.000, 6.300) | 3.00, 6.30 |
|  |  | C5D1 | 3 | 32.100 (3.1241) | 33.700 (28.500, 34.100) | 28.50, 34.10 | 3 | 1.600 (4.7885) | 2.300 (-3.500, 6.000) | -3.50, 6.00 |
|  |  | End of Treatment | 1 | 30.800 (NA) | 30.800 (30.800, 30.800) | 30.80, 30.80 | 1 | 1.100 (NA) | 1.100 (1.100, 1.100) | 1.10, 1.10 |
|  | | | | | | | | | | |
| Prothrombin Time (s) | Treatment Group (N = 5) | Baseline | 5 | 11.400 (1.1895) | 11.300 (10.600, 11.300) | 10.40, 13.40 |  |  |  |  |
|  |  | C1D8 | 5 | 10.680 (0.7463) | 10.500 (10.200, 10.800) | 10.00, 11.90 | 5 | -0.720 (1.2357) | -0.600 (-1.100, 0.100) | -2.60, 0.60 |
|  |  | C2D1 | 4 | 10.800 (0.5477) | 11.000 (10.450, 11.150) | 10.00, 11.20 | 4 | -0.625 (1.1529) | -0.250 (-1.350, 0.100) | -2.30, 0.30 |
|  |  | C3D1 | 2 | 10.350 (0.2121) | 10.350 (10.200, 10.500) | 10.20, 10.50 | 2 | -0.150 (0.0707) | -0.150 (-0.200, -0.100) | -0.20, -0.10 |
|  |  | C4D1 | 2 | 10.100 (0.1414) | 10.100 (10.000, 10.200) | 10.00, 10.20 | 2 | -0.400 (0.2828) | -0.400 (-0.600, -0.200) | -0.60, -0.20 |
|  |  | C5D1 | 2 | 10.650 (0.2121) | 10.650 (10.500, 10.800) | 10.50, 10.80 | 2 | 0.150 (0.3536) | 0.150 (-0.100, 0.400) | -0.10, 0.40 |
|  | | | | | | | | | | |
|  | Control Group (N = 5) | Baseline | 5 | 11.720 (1.2296) | 11.600 (10.700, 11.900) | 10.70, 13.70 |  |  |  |  |
|  |  | C1D8 | 5 | 11.200 (0.6892) | 11.400 (11.300, 11.600) | 10.00, 11.70 | 5 | -0.520 (1.2215) | -0.500 (-0.700, 0.100) | -2.40, 0.90 |
|  |  | C2D1 | 4 | 11.175 (0.8261) | 11.300 (10.550, 11.800) | 10.10, 12.00 | 4 | -0.500 (1.1576) | -0.150 (-1.350, 0.350) | -2.10, 0.40 |
|  |  | C3D1 | 2 | 10.400 (0.2828) | 10.400 (10.200, 10.600) | 10.20, 10.60 | 2 | -0.750 (0.3536) | -0.750 (-1.000, -0.500) | -1.00, -0.50 |
|  |  | C4D1 | 1 | 11.500 (NA) | 11.500 (11.500, 11.500) | 11.50, 11.50 | 1 | -0.100 (NA) | -0.100 (-0.100, -0.100) | -0.10, -0.10 |
|  |  | C5D1 | 1 | 11.100 (NA) | 11.100 (11.100, 11.100) | 11.10, 11.10 | 1 | -0.500 (NA) | -0.500 (-0.500, -0.500) | -0.50, -0.50 |
|  |  | End of Treatment | 1 | 12.000 (NA) | 12.000 (12.000, 12.000) | 12.00, 12.00 | 1 | -1.700 (NA) | -1.700 (-1.700, -1.700) | -1.70, -1.70 |
|  | | | | | | | | | | |
|  | Total (N = 10) | Baseline | 10 | 11.560 (1.1530) | 11.300 (10.700, 11.900) | 10.40, 13.70 |  |  |  |  |
|  |  | C1D8 | 10 | 10.940 (0.7306) | 11.050 (10.200, 11.600) | 10.00, 11.90 | 10 | -0.620 (1.1631) | -0.550 (-1.100, 0.100) | -2.60, 0.90 |
|  |  | C2D1 | 8 | 10.988 (0.6792) | 11.050 (10.500, 11.400) | 10.00, 12.00 | 8 | -0.563 (1.0716) | -0.250 (-1.350, 0.300) | -2.30, 0.40 |
|  |  | C3D1 | 4 | 10.375 (0.2062) | 10.350 (10.200, 10.550) | 10.20, 10.60 | 4 | -0.450 (0.4041) | -0.350 (-0.750, -0.150) | -1.00, -0.10 |
|  |  | C4D1 | 3 | 10.567 (0.8145) | 10.200 (10.000, 11.500) | 10.00, 11.50 | 3 | -0.300 (0.2646) | -0.200 (-0.600, -0.100) | -0.60, -0.10 |
|  |  | C5D1 | 3 | 10.800 (0.3000) | 10.800 (10.500, 11.100) | 10.50, 11.10 | 3 | -0.067 (0.4509) | -0.100 (-0.500, 0.400) | -0.50, 0.40 |
|  |  | End of Treatment | 1 | 12.000 (NA) | 12.000 (12.000, 12.000) | 12.00, 12.00 | 1 | -1.700 (NA) | -1.700 (-1.700, -1.700) | -1.70, -1.70 |
|  | | | | | | | | | | |
| Prothrombin Intl. Normalized Ratio | Treatment Group (N = 5) | Baseline | 5 | 1.002 (0.1277) | 0.980 (0.920, 0.990) | 0.90, 1.22 |  |  |  |  |
|  |  | C1D8 | 5 | 0.906 (0.0456) | 0.900 (0.880, 0.910) | 0.86, 0.98 | 5 | -0.096 (0.0913) | -0.090 (-0.100, -0.060) | -0.24, 0.01 |
|  |  | C2D1 | 4 | 0.948 (0.0634) | 0.960 (0.905, 0.990) | 0.86, 1.01 | 4 | -0.058 (0.1056) | -0.025 (-0.125, 0.010) | -0.21, 0.03 |
|  |  | C3D1 | 2 | 0.895 (0.0212) | 0.895 (0.880, 0.910) | 0.88, 0.91 | 2 | -0.015 (0.0071) | -0.015 (-0.020, -0.010) | -0.02, -0.01 |
|  |  | C4D1 | 2 | 0.870 (0.0141) | 0.870 (0.860, 0.880) | 0.86, 0.88 | 2 | -0.040 (0.0283) | -0.040 (-0.060, -0.020) | -0.06, -0.02 |
|  |  | C5D1 | 2 | 0.925 (0.0212) | 0.925 (0.910, 0.940) | 0.91, 0.94 | 2 | 0.015 (0.0354) | 0.015 (-0.010, 0.040) | -0.01, 0.04 |
|  | | | | | | | | | | |
|  | Control Group (N = 5) | Baseline | 5 | 1.000 (0.1204) | 0.970 (0.930, 1.010) | 0.89, 1.20 |  |  |  |  |
|  |  | C1D8 | 5 | 0.952 (0.0920) | 0.980 (0.860, 1.020) | 0.85, 1.05 | 5 | -0.048 (0.1117) | -0.040 (-0.070, 0.010) | -0.22, 0.08 |
|  |  | C2D1 | 4 | 0.983 (0.0780) | 1.005 (0.935, 1.030) | 0.87, 1.05 | 4 | -0.045 (0.1066) | -0.015 (-0.125, 0.035) | -0.19, 0.04 |
|  |  | C3D1 | 2 | 0.905 (0.0212) | 0.905 (0.890, 0.920) | 0.89, 0.92 | 2 | -0.065 (0.0354) | -0.065 (-0.090, -0.040) | -0.09, -0.04 |
|  |  | C4D1 | 1 | 1.000 (NA) | 1.000 (1.000, 1.000) | 1.00, 1.00 | 1 | -0.010 (NA) | -0.010 (-0.010, -0.010) | -0.01, -0.01 |
|  |  | C5D1 | 1 | 0.970 (NA) | 0.970 (0.970, 0.970) | 0.97, 0.97 | 1 | -0.040 (NA) | -0.040 (-0.040, -0.040) | -0.04, -0.04 |
|  |  | End of Treatment | 1 | 1.050 (NA) | 1.050 (1.050, 1.050) | 1.05, 1.05 | 1 | -0.150 (NA) | -0.150 (-0.150, -0.150) | -0.15, -0.15 |
|  | | | | | | | | | | |
|  | Total (N = 10) | Baseline | 10 | 1.001 (0.1170) | 0.975 (0.920, 1.010) | 0.89, 1.22 |  |  |  |  |
|  |  | C1D8 | 10 | 0.929 (0.0726) | 0.905 (0.860, 0.980) | 0.85, 1.05 | 10 | -0.072 (0.0994) | -0.065 (-0.100, 0.010) | -0.24, 0.08 |
|  |  | C2D1 | 8 | 0.965 (0.0685) | 0.985 (0.910, 1.010) | 0.86, 1.05 | 8 | -0.051 (0.0985) | -0.025 (-0.125, 0.030) | -0.21, 0.04 |
|  |  | C3D1 | 4 | 0.900 (0.0183) | 0.900 (0.885, 0.915) | 0.88, 0.92 | 4 | -0.040 (0.0356) | -0.030 (-0.065, -0.015) | -0.09, -0.01 |
|  |  | C4D1 | 3 | 0.913 (0.0757) | 0.880 (0.860, 1.000) | 0.86, 1.00 | 3 | -0.030 (0.0265) | -0.020 (-0.060, -0.010) | -0.06, -0.01 |
|  |  | C5D1 | 3 | 0.940 (0.0300) | 0.940 (0.910, 0.970) | 0.91, 0.97 | 3 | -0.003 (0.0404) | -0.010 (-0.040, 0.040) | -0.04, 0.04 |
|  |  | End of Treatment | 1 | 1.050 (NA) | 1.050 (1.050, 1.050) | 1.05, 1.05 | 1 | -0.150 (NA) | -0.150 (-0.150, -0.150) | -0.15, -0.15 |

NA = Not applicable.

Baseline is defined as the last available assessment before the first administration of investigational drug (D-1553 or IN10018).

Only subjects with data at both baseline and the relevant post baseline visit are included in the change from baseline summary statistics.

Source Data: Listing 16.2.8.4.1

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| Program: t-lb-chg.sas | DCO: 27APR2024 | Executed: 07JUL2024 20:45 |

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| **InxMed (Shanghai) Co., Ltd.  Protocol No. IN10018-602** |  |

**Table 14.3.5.2.3 Shift Table for Laboratory Test from Baseline to Last/Worst Post-baseline CTCAE Grade - Phase II part 2 - CRC (Safety Analysis Set)**

|  | | | | Post-baseline Grade | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Parameter | Group | Visit | Baseline Grade | 0 | 1 | 2 | 3 | 4 | Missing | Total |
| Hemoglobin (Anemia) | Treatment Group (N = 5) | Last Post-Baseline | 0 | 2 (40.0) | 1 (20.0) | 0 | 0 | 0 | 0 | 3 (60.0) |
|  |  |  | 1 | 2 (40.0) | 0 | 0 | 0 | 0 | 0 | 2 (40.0) |
|  |  |  | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 4 (80.0) | 1 (20.0) | 0 | 0 | 0 | 0 | 5 (100) |
|  | | | | | | | | | | |
|  |  | Worst Post-Baseline | 0 | 2 (40.0) | 1 (20.0) | 0 | 0 | 0 | 0 | 3 (60.0) |
|  |  |  | 1 | 2 (40.0) | 0 | 0 | 0 | 0 | 0 | 2 (40.0) |
|  |  |  | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 4 (80.0) | 1 (20.0) | 0 | 0 | 0 | 0 | 5 (100) |
|  | | | | | | | | | | |
|  | Control Group (N = 5) | Last Post-Baseline | 0 | 2 (40.0) | 0 | 0 | 0 | 0 | 0 | 2 (40.0) |
|  |  |  | 1 | 2 (40.0) | 0 | 0 | 0 | 0 | 0 | 2 (40.0) |
|  |  |  | 2 | 0 | 0 | 0 | 1 (20.0) | 0 | 0 | 1 (20.0) |
|  |  |  | 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 4 (80.0) | 0 | 0 | 1 (20.0) | 0 | 0 | 5 (100) |
|  | | | | | | | | | | |
|  |  | Worst Post-Baseline | 0 | 2 (40.0) | 0 | 0 | 0 | 0 | 0 | 2 (40.0) |
|  |  |  | 1 | 1 (20.0) | 1 (20.0) | 0 | 0 | 0 | 0 | 2 (40.0) |
|  |  |  | 2 | 0 | 0 | 0 | 1 (20.0) | 0 | 0 | 1 (20.0) |
|  |  |  | 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 3 (60.0) | 1 (20.0) | 0 | 1 (20.0) | 0 | 0 | 5 (100) |
|  | | | | | | | | | | |
| Hemoglobin (Hemoglobin increased) | Treatment Group (N = 5) | Last Post-Baseline | 0 | 5 (100) | 0 | 0 | 0 | 0 | 0 | 5 (100) |
|  |  |  | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 5 (100) | 0 | 0 | 0 | 0 | 0 | 5 (100) |
|  | | | | | | | | | | |
|  |  | Worst Post-Baseline | 0 | 5 (100) | 0 | 0 | 0 | 0 | 0 | 5 (100) |
|  |  |  | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 5 (100) | 0 | 0 | 0 | 0 | 0 | 5 (100) |
|  | | | | | | | | | | |
|  | Control Group (N = 5) | Last Post-Baseline | 0 | 5 (100) | 0 | 0 | 0 | 0 | 0 | 5 (100) |
|  |  |  | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 5 (100) | 0 | 0 | 0 | 0 | 0 | 5 (100) |
|  | | | | | | | | | | |
|  |  | Worst Post-Baseline | 0 | 5 (100) | 0 | 0 | 0 | 0 | 0 | 5 (100) |
|  |  |  | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 5 (100) | 0 | 0 | 0 | 0 | 0 | 5 (100) |
|  | | | | | | | | | | |
| Leukocytes (White blood cell decreased) | Treatment Group (N = 5) | Last Post-Baseline | 0 | 4 (80.0) | 1 (20.0) | 0 | 0 | 0 | 0 | 5 (100) |
|  |  |  | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 4 (80.0) | 1 (20.0) | 0 | 0 | 0 | 0 | 5 (100) |
|  | | | | | | | | | | |
|  |  | Worst Post-Baseline | 0 | 4 (80.0) | 0 | 1 (20.0) | 0 | 0 | 0 | 5 (100) |
|  |  |  | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 4 (80.0) | 0 | 1 (20.0) | 0 | 0 | 0 | 5 (100) |
|  | | | | | | | | | | |
|  | Control Group (N = 5) | Last Post-Baseline | 0 | 5 (100) | 0 | 0 | 0 | 0 | 0 | 5 (100) |
|  |  |  | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 5 (100) | 0 | 0 | 0 | 0 | 0 | 5 (100) |
|  | | | | | | | | | | |
|  |  | Worst Post-Baseline | 0 | 4 (80.0) | 0 | 1 (20.0) | 0 | 0 | 0 | 5 (100) |
|  |  |  | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 4 (80.0) | 0 | 1 (20.0) | 0 | 0 | 0 | 5 (100) |
|  | | | | | | | | | | |
| Leukocytes (Leukocytosis) | Treatment Group (N = 5) | Last Post-Baseline | 0 | 5 (100) | 0 | 0 | 0 | 0 | 0 | 5 (100) |
|  |  |  | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 5 (100) | 0 | 0 | 0 | 0 | 0 | 5 (100) |
|  | | | | | | | | | | |
|  |  | Worst Post-Baseline | 0 | 5 (100) | 0 | 0 | 0 | 0 | 0 | 5 (100) |
|  |  |  | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 5 (100) | 0 | 0 | 0 | 0 | 0 | 5 (100) |
|  | | | | | | | | | | |
|  | Control Group (N = 5) | Last Post-Baseline | 0 | 5 (100) | 0 | 0 | 0 | 0 | 0 | 5 (100) |
|  |  |  | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 5 (100) | 0 | 0 | 0 | 0 | 0 | 5 (100) |
|  | | | | | | | | | | |
|  |  | Worst Post-Baseline | 0 | 5 (100) | 0 | 0 | 0 | 0 | 0 | 5 (100) |
|  |  |  | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 5 (100) | 0 | 0 | 0 | 0 | 0 | 5 (100) |
|  | | | | | | | | | | |
| Neutrophils (Neutrophil count decreased) | Treatment Group (N = 5) | Last Post-Baseline | 0 | 5 (100) | 0 | 0 | 0 | 0 | 0 | 5 (100) |
|  |  |  | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 5 (100) | 0 | 0 | 0 | 0 | 0 | 5 (100) |
|  | | | | | | | | | | |
|  |  | Worst Post-Baseline | 0 | 4 (80.0) | 0 | 1 (20.0) | 0 | 0 | 0 | 5 (100) |
|  |  |  | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 4 (80.0) | 0 | 1 (20.0) | 0 | 0 | 0 | 5 (100) |
|  | | | | | | | | | | |
|  | Control Group (N = 5) | Last Post-Baseline | 0 | 5 (100) | 0 | 0 | 0 | 0 | 0 | 5 (100) |
|  |  |  | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 5 (100) | 0 | 0 | 0 | 0 | 0 | 5 (100) |
|  | | | | | | | | | | |
|  |  | Worst Post-Baseline | 0 | 4 (80.0) | 0 | 1 (20.0) | 0 | 0 | 0 | 5 (100) |
|  |  |  | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 4 (80.0) | 0 | 1 (20.0) | 0 | 0 | 0 | 5 (100) |
|  | | | | | | | | | | |
| Eosinophils (Eosinophilia) | Treatment Group (N = 5) | Last Post-Baseline | 0 | 2 (40.0) | 2 (40.0) | 0 | 0 | 0 | 0 | 4 (80.0) |
|  |  |  | 1 | 1 (20.0) | 0 | 0 | 0 | 0 | 0 | 1 (20.0) |
|  |  |  | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 3 (60.0) | 2 (40.0) | 0 | 0 | 0 | 0 | 5 (100) |
|  | | | | | | | | | | |
|  |  | Worst Post-Baseline | 0 | 2 (40.0) | 2 (40.0) | 0 | 0 | 0 | 0 | 4 (80.0) |
|  |  |  | 1 | 1 (20.0) | 0 | 0 | 0 | 0 | 0 | 1 (20.0) |
|  |  |  | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 3 (60.0) | 2 (40.0) | 0 | 0 | 0 | 0 | 5 (100) |
|  | | | | | | | | | | |
|  | Control Group (N = 5) | Last Post-Baseline | 0 | 5 (100) | 0 | 0 | 0 | 0 | 0 | 5 (100) |
|  |  |  | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 5 (100) | 0 | 0 | 0 | 0 | 0 | 5 (100) |
|  | | | | | | | | | | |
|  |  | Worst Post-Baseline | 0 | 5 (100) | 0 | 0 | 0 | 0 | 0 | 5 (100) |
|  |  |  | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 5 (100) | 0 | 0 | 0 | 0 | 0 | 5 (100) |
|  | | | | | | | | | | |
| Lymphocytes (Lymphocyte count decreased) | Treatment Group (N = 5) | Last Post-Baseline | 0 | 4 (80.0) | 0 | 0 | 0 | 0 | 0 | 4 (80.0) |
|  |  |  | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 2 | 0 | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  |  |  | 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 4 (80.0) | 1 (20.0) | 0 | 0 | 0 | 0 | 5 (100) |
|  | | | | | | | | | | |
|  |  | Worst Post-Baseline | 0 | 4 (80.0) | 0 | 0 | 0 | 0 | 0 | 4 (80.0) |
|  |  |  | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 2 | 0 | 0 | 1 (20.0) | 0 | 0 | 0 | 1 (20.0) |
|  |  |  | 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 4 (80.0) | 0 | 1 (20.0) | 0 | 0 | 0 | 5 (100) |
|  | | | | | | | | | | |
|  | Control Group (N = 5) | Last Post-Baseline | 0 | 4 (80.0) | 0 | 0 | 0 | 0 | 0 | 4 (80.0) |
|  |  |  | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 2 | 0 | 0 | 0 | 1 (20.0) | 0 | 0 | 1 (20.0) |
|  |  |  | 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 4 (80.0) | 0 | 0 | 1 (20.0) | 0 | 0 | 5 (100) |
|  | | | | | | | | | | |
|  |  | Worst Post-Baseline | 0 | 3 (60.0) | 0 | 1 (20.0) | 0 | 0 | 0 | 4 (80.0) |
|  |  |  | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 2 | 0 | 0 | 0 | 1 (20.0) | 0 | 0 | 1 (20.0) |
|  |  |  | 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 3 (60.0) | 0 | 1 (20.0) | 1 (20.0) | 0 | 0 | 5 (100) |
|  | | | | | | | | | | |
| Lymphocytes (Lymphocyte count increased) | Treatment Group (N = 5) | Last Post-Baseline | 0 | 5 (100) | 0 | 0 | 0 | 0 | 0 | 5 (100) |
|  |  |  | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 5 (100) | 0 | 0 | 0 | 0 | 0 | 5 (100) |
|  | | | | | | | | | | |
|  |  | Worst Post-Baseline | 0 | 5 (100) | 0 | 0 | 0 | 0 | 0 | 5 (100) |
|  |  |  | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 5 (100) | 0 | 0 | 0 | 0 | 0 | 5 (100) |
|  | | | | | | | | | | |
|  | Control Group (N = 5) | Last Post-Baseline | 0 | 5 (100) | 0 | 0 | 0 | 0 | 0 | 5 (100) |
|  |  |  | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 5 (100) | 0 | 0 | 0 | 0 | 0 | 5 (100) |
|  | | | | | | | | | | |
|  |  | Worst Post-Baseline | 0 | 5 (100) | 0 | 0 | 0 | 0 | 0 | 5 (100) |
|  |  |  | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 5 (100) | 0 | 0 | 0 | 0 | 0 | 5 (100) |
|  | | | | | | | | | | |
| Platelets (Platelet count decreased) | Treatment Group (N = 5) | Last Post-Baseline | 0 | 3 (60.0) | 0 | 0 | 0 | 0 | 0 | 3 (60.0) |
|  |  |  | 1 | 2 (40.0) | 0 | 0 | 0 | 0 | 0 | 2 (40.0) |
|  |  |  | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 5 (100) | 0 | 0 | 0 | 0 | 0 | 5 (100) |
|  | | | | | | | | | | |
|  |  | Worst Post-Baseline | 0 | 2 (40.0) | 1 (20.0) | 0 | 0 | 0 | 0 | 3 (60.0) |
|  |  |  | 1 | 1 (20.0) | 1 (20.0) | 0 | 0 | 0 | 0 | 2 (40.0) |
|  |  |  | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 3 (60.0) | 2 (40.0) | 0 | 0 | 0 | 0 | 5 (100) |
|  | | | | | | | | | | |
|  | Control Group (N = 5) | Last Post-Baseline | 0 | 4 (80.0) | 1 (20.0) | 0 | 0 | 0 | 0 | 5 (100) |
|  |  |  | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 4 (80.0) | 1 (20.0) | 0 | 0 | 0 | 0 | 5 (100) |
|  | | | | | | | | | | |
|  |  | Worst Post-Baseline | 0 | 4 (80.0) | 1 (20.0) | 0 | 0 | 0 | 0 | 5 (100) |
|  |  |  | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 4 (80.0) | 1 (20.0) | 0 | 0 | 0 | 0 | 5 (100) |
|  | | | | | | | | | | |
| Bilirubin (Blood bilirubin increased) | Treatment Group (N = 5) | Last Post-Baseline | 0 | 5 (100) | 0 | 0 | 0 | 0 | 0 | 5 (100) |
|  |  |  | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 5 (100) | 0 | 0 | 0 | 0 | 0 | 5 (100) |
|  | | | | | | | | | | |
|  |  | Worst Post-Baseline | 0 | 5 (100) | 0 | 0 | 0 | 0 | 0 | 5 (100) |
|  |  |  | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 5 (100) | 0 | 0 | 0 | 0 | 0 | 5 (100) |
|  | | | | | | | | | | |
|  | Control Group (N = 5) | Last Post-Baseline | 0 | 4 (80.0) | 0 | 0 | 0 | 0 | 0 | 4 (80.0) |
|  |  |  | 1 | 0 | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  |  |  | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 4 (80.0) | 1 (20.0) | 0 | 0 | 0 | 0 | 5 (100) |
|  | | | | | | | | | | |
|  |  | Worst Post-Baseline | 0 | 4 (80.0) | 0 | 0 | 0 | 0 | 0 | 4 (80.0) |
|  |  |  | 1 | 0 | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  |  |  | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 4 (80.0) | 1 (20.0) | 0 | 0 | 0 | 0 | 5 (100) |
|  | | | | | | | | | | |
| Alanine Aminotransferase (Alanine aminotransferase increased) | Treatment Group (N = 5) | Last Post-Baseline | 0 | 3 (60.0) | 2 (40.0) | 0 | 0 | 0 | 0 | 5 (100) |
|  |  |  | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 3 (60.0) | 2 (40.0) | 0 | 0 | 0 | 0 | 5 (100) |
|  | | | | | | | | | | |
|  |  | Worst Post-Baseline | 0 | 3 (60.0) | 2 (40.0) | 0 | 0 | 0 | 0 | 5 (100) |
|  |  |  | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 3 (60.0) | 2 (40.0) | 0 | 0 | 0 | 0 | 5 (100) |
|  | | | | | | | | | | |
|  | Control Group (N = 5) | Last Post-Baseline | 0 | 4 (80.0) | 0 | 0 | 0 | 0 | 0 | 4 (80.0) |
|  |  |  | 1 | 1 (20.0) | 0 | 0 | 0 | 0 | 0 | 1 (20.0) |
|  |  |  | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 5 (100) | 0 | 0 | 0 | 0 | 0 | 5 (100) |
|  | | | | | | | | | | |
|  |  | Worst Post-Baseline | 0 | 3 (60.0) | 1 (20.0) | 0 | 0 | 0 | 0 | 4 (80.0) |
|  |  |  | 1 | 1 (20.0) | 0 | 0 | 0 | 0 | 0 | 1 (20.0) |
|  |  |  | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 4 (80.0) | 1 (20.0) | 0 | 0 | 0 | 0 | 5 (100) |
|  | | | | | | | | | | |
| Aspartate Aminotransferase (Aspartate aminotransferase increased) | Treatment Group (N = 5) | Last Post-Baseline | 0 | 3 (60.0) | 1 (20.0) | 0 | 0 | 0 | 0 | 4 (80.0) |
|  |  |  | 1 | 1 (20.0) | 0 | 0 | 0 | 0 | 0 | 1 (20.0) |
|  |  |  | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 4 (80.0) | 1 (20.0) | 0 | 0 | 0 | 0 | 5 (100) |
|  | | | | | | | | | | |
|  |  | Worst Post-Baseline | 0 | 3 (60.0) | 1 (20.0) | 0 | 0 | 0 | 0 | 4 (80.0) |
|  |  |  | 1 | 1 (20.0) | 0 | 0 | 0 | 0 | 0 | 1 (20.0) |
|  |  |  | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 4 (80.0) | 1 (20.0) | 0 | 0 | 0 | 0 | 5 (100) |
|  | | | | | | | | | | |
|  | Control Group (N = 5) | Last Post-Baseline | 0 | 3 (60.0) | 0 | 0 | 0 | 0 | 0 | 3 (60.0) |
|  |  |  | 1 | 1 (20.0) | 1 (20.0) | 0 | 0 | 0 | 0 | 2 (40.0) |
|  |  |  | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 4 (80.0) | 1 (20.0) | 0 | 0 | 0 | 0 | 5 (100) |
|  | | | | | | | | | | |
|  |  | Worst Post-Baseline | 0 | 2 (40.0) | 1 (20.0) | 0 | 0 | 0 | 0 | 3 (60.0) |
|  |  |  | 1 | 1 (20.0) | 1 (20.0) | 0 | 0 | 0 | 0 | 2 (40.0) |
|  |  |  | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 3 (60.0) | 2 (40.0) | 0 | 0 | 0 | 0 | 5 (100) |
|  | | | | | | | | | | |
| Gamma Glutamyl Transferase (GGT increased) | Treatment Group (N = 5) | Last Post-Baseline | 0 | 2 (40.0) | 0 | 0 | 0 | 0 | 0 | 2 (40.0) |
|  |  |  | 1 | 2 (40.0) | 0 | 0 | 0 | 0 | 0 | 2 (40.0) |
|  |  |  | 2 | 1 (20.0) | 0 | 0 | 0 | 0 | 0 | 1 (20.0) |
|  |  |  | 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 5 (100) | 0 | 0 | 0 | 0 | 0 | 5 (100) |
|  | | | | | | | | | | |
|  |  | Worst Post-Baseline | 0 | 2 (40.0) | 0 | 0 | 0 | 0 | 0 | 2 (40.0) |
|  |  |  | 1 | 1 (20.0) | 0 | 1 (20.0) | 0 | 0 | 0 | 2 (40.0) |
|  |  |  | 2 | 1 (20.0) | 0 | 0 | 0 | 0 | 0 | 1 (20.0) |
|  |  |  | 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 4 (80.0) | 0 | 1 (20.0) | 0 | 0 | 0 | 5 (100) |
|  | | | | | | | | | | |
|  | Control Group (N = 5) | Last Post-Baseline | 0 | 2 (40.0) | 0 | 0 | 0 | 0 | 0 | 2 (40.0) |
|  |  |  | 1 | 1 (20.0) | 0 | 0 | 0 | 0 | 0 | 1 (20.0) |
|  |  |  | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 3 | 2 (40.0) | 0 | 0 | 0 | 0 | 0 | 2 (40.0) |
|  |  |  | 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 5 (100) | 0 | 0 | 0 | 0 | 0 | 5 (100) |
|  | | | | | | | | | | |
|  |  | Worst Post-Baseline | 0 | 2 (40.0) | 0 | 0 | 0 | 0 | 0 | 2 (40.0) |
|  |  |  | 1 | 1 (20.0) | 0 | 0 | 0 | 0 | 0 | 1 (20.0) |
|  |  |  | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 3 | 2 (40.0) | 0 | 0 | 0 | 0 | 0 | 2 (40.0) |
|  |  |  | 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 5 (100) | 0 | 0 | 0 | 0 | 0 | 5 (100) |
|  | | | | | | | | | | |
| Alkaline Phosphatase (Alkaline phosphatase increased) | Treatment Group (N = 5) | Last Post-Baseline | 0 | 2 (40.0) | 0 | 0 | 0 | 0 | 0 | 2 (40.0) |
|  |  |  | 1 | 3 (60.0) | 0 | 0 | 0 | 0 | 0 | 3 (60.0) |
|  |  |  | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 5 (100) | 0 | 0 | 0 | 0 | 0 | 5 (100) |
|  | | | | | | | | | | |
|  |  | Worst Post-Baseline | 0 | 2 (40.0) | 0 | 0 | 0 | 0 | 0 | 2 (40.0) |
|  |  |  | 1 | 2 (40.0) | 0 | 1 (20.0) | 0 | 0 | 0 | 3 (60.0) |
|  |  |  | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 4 (80.0) | 0 | 1 (20.0) | 0 | 0 | 0 | 5 (100) |
|  | | | | | | | | | | |
|  | Control Group (N = 5) | Last Post-Baseline | 0 | 3 (60.0) | 0 | 0 | 0 | 0 | 0 | 3 (60.0) |
|  |  |  | 1 | 1 (20.0) | 0 | 0 | 0 | 0 | 0 | 1 (20.0) |
|  |  |  | 2 | 1 (20.0) | 0 | 0 | 0 | 0 | 0 | 1 (20.0) |
|  |  |  | 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 5 (100) | 0 | 0 | 0 | 0 | 0 | 5 (100) |
|  | | | | | | | | | | |
|  |  | Worst Post-Baseline | 0 | 3 (60.0) | 0 | 0 | 0 | 0 | 0 | 3 (60.0) |
|  |  |  | 1 | 1 (20.0) | 0 | 0 | 0 | 0 | 0 | 1 (20.0) |
|  |  |  | 2 | 1 (20.0) | 0 | 0 | 0 | 0 | 0 | 1 (20.0) |
|  |  |  | 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 5 (100) | 0 | 0 | 0 | 0 | 0 | 5 (100) |
|  | | | | | | | | | | |
| Lactate Dehydrogenase (Blood lactate dehydrogenase increased) | Treatment Group (N = 5) | Last Post-Baseline | 0 | 4 (80.0) | 0 | 0 | 0 | 0 | 0 | 4 (80.0) |
|  |  |  | 1 | 0 | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  |  |  | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 4 (80.0) | 1 (20.0) | 0 | 0 | 0 | 0 | 5 (100) |
|  | | | | | | | | | | |
|  |  | Worst Post-Baseline | 0 | 3 (60.0) | 1 (20.0) | 0 | 0 | 0 | 0 | 4 (80.0) |
|  |  |  | 1 | 0 | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  |  |  | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 3 (60.0) | 2 (40.0) | 0 | 0 | 0 | 0 | 5 (100) |
|  | | | | | | | | | | |
|  | Control Group (N = 5) | Last Post-Baseline | 0 | 2 (40.0) | 0 | 0 | 0 | 0 | 0 | 2 (40.0) |
|  |  |  | 1 | 0 | 3 (60.0) | 0 | 0 | 0 | 0 | 3 (60.0) |
|  |  |  | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 2 (40.0) | 3 (60.0) | 0 | 0 | 0 | 0 | 5 (100) |
|  | | | | | | | | | | |
|  |  | Worst Post-Baseline | 0 | 1 (20.0) | 1 (20.0) | 0 | 0 | 0 | 0 | 2 (40.0) |
|  |  |  | 1 | 0 | 3 (60.0) | 0 | 0 | 0 | 0 | 3 (60.0) |
|  |  |  | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 1 (20.0) | 4 (80.0) | 0 | 0 | 0 | 0 | 5 (100) |
|  | | | | | | | | | | |
| Albumin (Hypoalbuminemia) | Treatment Group (N = 5) | Last Post-Baseline | 0 | 2 (40.0) | 1 (20.0) | 0 | 0 | 0 | 0 | 3 (60.0) |
|  |  |  | 1 | 1 (20.0) | 1 (20.0) | 0 | 0 | 0 | 0 | 2 (40.0) |
|  |  |  | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 3 (60.0) | 2 (40.0) | 0 | 0 | 0 | 0 | 5 (100) |
|  | | | | | | | | | | |
|  |  | Worst Post-Baseline | 0 | 2 (40.0) | 1 (20.0) | 0 | 0 | 0 | 0 | 3 (60.0) |
|  |  |  | 1 | 0 | 2 (40.0) | 0 | 0 | 0 | 0 | 2 (40.0) |
|  |  |  | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 2 (40.0) | 3 (60.0) | 0 | 0 | 0 | 0 | 5 (100) |
|  | | | | | | | | | | |
|  | Control Group (N = 5) | Last Post-Baseline | 0 | 3 (60.0) | 0 | 0 | 0 | 0 | 0 | 3 (60.0) |
|  |  |  | 1 | 0 | 2 (40.0) | 0 | 0 | 0 | 0 | 2 (40.0) |
|  |  |  | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 3 (60.0) | 2 (40.0) | 0 | 0 | 0 | 0 | 5 (100) |
|  | | | | | | | | | | |
|  |  | Worst Post-Baseline | 0 | 3 (60.0) | 0 | 0 | 0 | 0 | 0 | 3 (60.0) |
|  |  |  | 1 | 0 | 2 (40.0) | 0 | 0 | 0 | 0 | 2 (40.0) |
|  |  |  | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 3 (60.0) | 2 (40.0) | 0 | 0 | 0 | 0 | 5 (100) |
|  | | | | | | | | | | |
| Triglycerides (Hypertriglyceridemia) | Treatment Group (N = 5) | Last Post-Baseline | 0 | 4 (80.0) | 0 | 0 | 0 | 0 | 0 | 4 (80.0) |
|  |  |  | 1 | 0 | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  |  |  | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 4 (80.0) | 1 (20.0) | 0 | 0 | 0 | 0 | 5 (100) |
|  | | | | | | | | | | |
|  |  | Worst Post-Baseline | 0 | 4 (80.0) | 0 | 0 | 0 | 0 | 0 | 4 (80.0) |
|  |  |  | 1 | 0 | 0 | 1 (20.0) | 0 | 0 | 0 | 1 (20.0) |
|  |  |  | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 4 (80.0) | 0 | 1 (20.0) | 0 | 0 | 0 | 5 (100) |
|  | | | | | | | | | | |
|  | Control Group (N = 5) | Last Post-Baseline | 0 | 3 (60.0) | 0 | 0 | 0 | 0 | 0 | 3 (60.0) |
|  |  |  | 1 | 0 | 0 | 1 (20.0) | 0 | 0 | 0 | 1 (20.0) |
|  |  |  | 2 | 0 | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  |  |  | 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 3 (60.0) | 1 (20.0) | 1 (20.0) | 0 | 0 | 0 | 5 (100) |
|  | | | | | | | | | | |
|  |  | Worst Post-Baseline | 0 | 3 (60.0) | 0 | 0 | 0 | 0 | 0 | 3 (60.0) |
|  |  |  | 1 | 0 | 0 | 1 (20.0) | 0 | 0 | 0 | 1 (20.0) |
|  |  |  | 2 | 0 | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  |  |  | 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 3 (60.0) | 1 (20.0) | 1 (20.0) | 0 | 0 | 0 | 5 (100) |
|  | | | | | | | | | | |
| Cholesterol (Cholesterol high) | Treatment Group (N = 5) | Last Post-Baseline | 0 | 3 (60.0) | 1 (20.0) | 0 | 0 | 0 | 0 | 4 (80.0) |
|  |  |  | 1 | 1 (20.0) | 0 | 0 | 0 | 0 | 0 | 1 (20.0) |
|  |  |  | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 4 (80.0) | 1 (20.0) | 0 | 0 | 0 | 0 | 5 (100) |
|  | | | | | | | | | | |
|  |  | Worst Post-Baseline | 0 | 2 (40.0) | 2 (40.0) | 0 | 0 | 0 | 0 | 4 (80.0) |
|  |  |  | 1 | 1 (20.0) | 0 | 0 | 0 | 0 | 0 | 1 (20.0) |
|  |  |  | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 3 (60.0) | 2 (40.0) | 0 | 0 | 0 | 0 | 5 (100) |
|  | | | | | | | | | | |
|  | Control Group (N = 5) | Last Post-Baseline | 0 | 4 (80.0) | 0 | 0 | 0 | 0 | 0 | 4 (80.0) |
|  |  |  | 1 | 0 | 0 | 1 (20.0) | 0 | 0 | 0 | 1 (20.0) |
|  |  |  | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 4 (80.0) | 0 | 1 (20.0) | 0 | 0 | 0 | 5 (100) |
|  | | | | | | | | | | |
|  |  | Worst Post-Baseline | 0 | 3 (60.0) | 0 | 0 | 1 (20.0) | 0 | 0 | 4 (80.0) |
|  |  |  | 1 | 0 | 0 | 1 (20.0) | 0 | 0 | 0 | 1 (20.0) |
|  |  |  | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 3 (60.0) | 0 | 1 (20.0) | 1 (20.0) | 0 | 0 | 5 (100) |
|  | | | | | | | | | | |
| Sodium (Hyponatremia) | Treatment Group (N = 5) | Last Post-Baseline | 0 | 4 (80.0) | 0 | 0 | 0 | 0 | 0 | 4 (80.0) |
|  |  |  | 1 | 1 (20.0) | 0 | 0 | 0 | 0 | 0 | 1 (20.0) |
|  |  |  | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 5 (100) | 0 | 0 | 0 | 0 | 0 | 5 (100) |
|  | | | | | | | | | | |
|  |  | Worst Post-Baseline | 0 | 4 (80.0) | 0 | 0 | 0 | 0 | 0 | 4 (80.0) |
|  |  |  | 1 | 0 | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  |  |  | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 4 (80.0) | 1 (20.0) | 0 | 0 | 0 | 0 | 5 (100) |
|  | | | | | | | | | | |
|  | Control Group (N = 5) | Last Post-Baseline | 0 | 4 (80.0) | 0 | 0 | 0 | 0 | 0 | 4 (80.0) |
|  |  |  | 1 | 1 (20.0) | 0 | 0 | 0 | 0 | 0 | 1 (20.0) |
|  |  |  | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 5 (100) | 0 | 0 | 0 | 0 | 0 | 5 (100) |
|  | | | | | | | | | | |
|  |  | Worst Post-Baseline | 0 | 4 (80.0) | 0 | 0 | 0 | 0 | 0 | 4 (80.0) |
|  |  |  | 1 | 0 | 1 (20.0) | 0 | 0 | 0 | 0 | 1 (20.0) |
|  |  |  | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 4 (80.0) | 1 (20.0) | 0 | 0 | 0 | 0 | 5 (100) |
|  | | | | | | | | | | |
| Sodium (Hypernatremia) | Treatment Group (N = 5) | Last Post-Baseline | 0 | 5 (100) | 0 | 0 | 0 | 0 | 0 | 5 (100) |
|  |  |  | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 5 (100) | 0 | 0 | 0 | 0 | 0 | 5 (100) |
|  | | | | | | | | | | |
|  |  | Worst Post-Baseline | 0 | 5 (100) | 0 | 0 | 0 | 0 | 0 | 5 (100) |
|  |  |  | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 5 (100) | 0 | 0 | 0 | 0 | 0 | 5 (100) |
|  | | | | | | | | | | |
|  | Control Group (N = 5) | Last Post-Baseline | 0 | 5 (100) | 0 | 0 | 0 | 0 | 0 | 5 (100) |
|  |  |  | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 5 (100) | 0 | 0 | 0 | 0 | 0 | 5 (100) |
|  | | | | | | | | | | |
|  |  | Worst Post-Baseline | 0 | 5 (100) | 0 | 0 | 0 | 0 | 0 | 5 (100) |
|  |  |  | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 5 (100) | 0 | 0 | 0 | 0 | 0 | 5 (100) |
|  | | | | | | | | | | |
| Potassium (Hypokalemia) | Treatment Group (N = 5) | Last Post-Baseline | 0 | 5 (100) | 0 | 0 | 0 | 0 | 0 | 5 (100) |
|  |  |  | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 5 (100) | 0 | 0 | 0 | 0 | 0 | 5 (100) |
|  | | | | | | | | | | |
|  |  | Worst Post-Baseline | 0 | 3 (60.0) | 2 (40.0) | 0 | 0 | 0 | 0 | 5 (100) |
|  |  |  | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 3 (60.0) | 2 (40.0) | 0 | 0 | 0 | 0 | 5 (100) |
|  | | | | | | | | | | |
|  | Control Group (N = 5) | Last Post-Baseline | 0 | 5 (100) | 0 | 0 | 0 | 0 | 0 | 5 (100) |
|  |  |  | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 5 (100) | 0 | 0 | 0 | 0 | 0 | 5 (100) |
|  | | | | | | | | | | |
|  |  | Worst Post-Baseline | 0 | 4 (80.0) | 1 (20.0) | 0 | 0 | 0 | 0 | 5 (100) |
|  |  |  | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 4 (80.0) | 1 (20.0) | 0 | 0 | 0 | 0 | 5 (100) |
|  | | | | | | | | | | |
| Potassium (Hyperkalemia) | Treatment Group (N = 5) | Last Post-Baseline | 0 | 5 (100) | 0 | 0 | 0 | 0 | 0 | 5 (100) |
|  |  |  | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 5 (100) | 0 | 0 | 0 | 0 | 0 | 5 (100) |
|  | | | | | | | | | | |
|  |  | Worst Post-Baseline | 0 | 5 (100) | 0 | 0 | 0 | 0 | 0 | 5 (100) |
|  |  |  | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 5 (100) | 0 | 0 | 0 | 0 | 0 | 5 (100) |
|  | | | | | | | | | | |
|  | Control Group (N = 5) | Last Post-Baseline | 0 | 5 (100) | 0 | 0 | 0 | 0 | 0 | 5 (100) |
|  |  |  | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 5 (100) | 0 | 0 | 0 | 0 | 0 | 5 (100) |
|  | | | | | | | | | | |
|  |  | Worst Post-Baseline | 0 | 5 (100) | 0 | 0 | 0 | 0 | 0 | 5 (100) |
|  |  |  | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 5 (100) | 0 | 0 | 0 | 0 | 0 | 5 (100) |
|  | | | | | | | | | | |
| Magnesium (Hypomagnesemia) | Treatment Group (N = 5) | Last Post-Baseline | 0 | 5 (100) | 0 | 0 | 0 | 0 | 0 | 5 (100) |
|  |  |  | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 5 (100) | 0 | 0 | 0 | 0 | 0 | 5 (100) |
|  | | | | | | | | | | |
|  |  | Worst Post-Baseline | 0 | 5 (100) | 0 | 0 | 0 | 0 | 0 | 5 (100) |
|  |  |  | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 5 (100) | 0 | 0 | 0 | 0 | 0 | 5 (100) |
|  | | | | | | | | | | |
|  | Control Group (N = 5) | Last Post-Baseline | 0 | 5 (100) | 0 | 0 | 0 | 0 | 0 | 5 (100) |
|  |  |  | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 5 (100) | 0 | 0 | 0 | 0 | 0 | 5 (100) |
|  | | | | | | | | | | |
|  |  | Worst Post-Baseline | 0 | 5 (100) | 0 | 0 | 0 | 0 | 0 | 5 (100) |
|  |  |  | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 5 (100) | 0 | 0 | 0 | 0 | 0 | 5 (100) |
|  | | | | | | | | | | |
| Magnesium (Hypermagnesemia) | Treatment Group (N = 5) | Last Post-Baseline | 0 | 5 (100) | 0 | 0 | 0 | 0 | 0 | 5 (100) |
|  |  |  | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 5 (100) | 0 | 0 | 0 | 0 | 0 | 5 (100) |
|  | | | | | | | | | | |
|  |  | Worst Post-Baseline | 0 | 5 (100) | 0 | 0 | 0 | 0 | 0 | 5 (100) |
|  |  |  | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 5 (100) | 0 | 0 | 0 | 0 | 0 | 5 (100) |
|  | | | | | | | | | | |
|  | Control Group (N = 5) | Last Post-Baseline | 0 | 4 (80.0) | 1 (20.0) | 0 | 0 | 0 | 0 | 5 (100) |
|  |  |  | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 4 (80.0) | 1 (20.0) | 0 | 0 | 0 | 0 | 5 (100) |
|  | | | | | | | | | | |
|  |  | Worst Post-Baseline | 0 | 4 (80.0) | 1 (20.0) | 0 | 0 | 0 | 0 | 5 (100) |
|  |  |  | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 4 (80.0) | 1 (20.0) | 0 | 0 | 0 | 0 | 5 (100) |
|  | | | | | | | | | | |
| Calcium (Hypocalcemia) | Treatment Group (N = 5) | Last Post-Baseline | 0 | 5 (100) | 0 | 0 | 0 | 0 | 0 | 5 (100) |
|  |  |  | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 5 (100) | 0 | 0 | 0 | 0 | 0 | 5 (100) |
|  | | | | | | | | | | |
|  |  | Worst Post-Baseline | 0 | 4 (80.0) | 0 | 1 (20.0) | 0 | 0 | 0 | 5 (100) |
|  |  |  | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 4 (80.0) | 0 | 1 (20.0) | 0 | 0 | 0 | 5 (100) |
|  | | | | | | | | | | |
|  | Control Group (N = 5) | Last Post-Baseline | 0 | 5 (100) | 0 | 0 | 0 | 0 | 0 | 5 (100) |
|  |  |  | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 5 (100) | 0 | 0 | 0 | 0 | 0 | 5 (100) |
|  | | | | | | | | | | |
|  |  | Worst Post-Baseline | 0 | 5 (100) | 0 | 0 | 0 | 0 | 0 | 5 (100) |
|  |  |  | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 5 (100) | 0 | 0 | 0 | 0 | 0 | 5 (100) |
|  | | | | | | | | | | |
| Calcium (Hypercalcemia) | Treatment Group (N = 5) | Last Post-Baseline | 0 | 5 (100) | 0 | 0 | 0 | 0 | 0 | 5 (100) |
|  |  |  | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 5 (100) | 0 | 0 | 0 | 0 | 0 | 5 (100) |
|  | | | | | | | | | | |
|  |  | Worst Post-Baseline | 0 | 5 (100) | 0 | 0 | 0 | 0 | 0 | 5 (100) |
|  |  |  | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 5 (100) | 0 | 0 | 0 | 0 | 0 | 5 (100) |
|  | | | | | | | | | | |
|  | Control Group (N = 5) | Last Post-Baseline | 0 | 5 (100) | 0 | 0 | 0 | 0 | 0 | 5 (100) |
|  |  |  | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 5 (100) | 0 | 0 | 0 | 0 | 0 | 5 (100) |
|  | | | | | | | | | | |
|  |  | Worst Post-Baseline | 0 | 5 (100) | 0 | 0 | 0 | 0 | 0 | 5 (100) |
|  |  |  | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 5 (100) | 0 | 0 | 0 | 0 | 0 | 5 (100) |
|  | | | | | | | | | | |
| Creatinine (Creatinine increased) | Treatment Group (N = 5) | Last Post-Baseline | 0 | 4 (80.0) | 1 (20.0) | 0 | 0 | 0 | 0 | 5 (100) |
|  |  |  | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 4 (80.0) | 1 (20.0) | 0 | 0 | 0 | 0 | 5 (100) |
|  | | | | | | | | | | |
|  |  | Worst Post-Baseline | 0 | 4 (80.0) | 1 (20.0) | 0 | 0 | 0 | 0 | 5 (100) |
|  |  |  | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 4 (80.0) | 1 (20.0) | 0 | 0 | 0 | 0 | 5 (100) |
|  | | | | | | | | | | |
|  | Control Group (N = 5) | Last Post-Baseline | 0 | 5 (100) | 0 | 0 | 0 | 0 | 0 | 5 (100) |
|  |  |  | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 5 (100) | 0 | 0 | 0 | 0 | 0 | 5 (100) |
|  | | | | | | | | | | |
|  |  | Worst Post-Baseline | 0 | 5 (100) | 0 | 0 | 0 | 0 | 0 | 5 (100) |
|  |  |  | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 5 (100) | 0 | 0 | 0 | 0 | 0 | 5 (100) |
|  | | | | | | | | | | |
| Urate (Hyperuricemia) | Treatment Group (N = 5) | Last Post-Baseline | 0 | 5 (100) | 0 | 0 | 0 | 0 | 0 | 5 (100) |
|  |  |  | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 5 (100) | 0 | 0 | 0 | 0 | 0 | 5 (100) |
|  | | | | | | | | | | |
|  |  | Worst Post-Baseline | 0 | 4 (80.0) | 1 (20.0) | 0 | 0 | 0 | 0 | 5 (100) |
|  |  |  | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 4 (80.0) | 1 (20.0) | 0 | 0 | 0 | 0 | 5 (100) |
|  | | | | | | | | | | |
|  | Control Group (N = 5) | Last Post-Baseline | 0 | 5 (100) | 0 | 0 | 0 | 0 | 0 | 5 (100) |
|  |  |  | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 5 (100) | 0 | 0 | 0 | 0 | 0 | 5 (100) |
|  | | | | | | | | | | |
|  |  | Worst Post-Baseline | 0 | 5 (100) | 0 | 0 | 0 | 0 | 0 | 5 (100) |
|  |  |  | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 5 (100) | 0 | 0 | 0 | 0 | 0 | 5 (100) |
|  | | | | | | | | | | |
| Glucose (Hypoglycemia) | Treatment Group (N = 5) | Last Post-Baseline | 0 | 5 (100) | 0 | 0 | 0 | 0 | 0 | 5 (100) |
|  |  |  | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 5 (100) | 0 | 0 | 0 | 0 | 0 | 5 (100) |
|  | | | | | | | | | | |
|  |  | Worst Post-Baseline | 0 | 5 (100) | 0 | 0 | 0 | 0 | 0 | 5 (100) |
|  |  |  | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 5 (100) | 0 | 0 | 0 | 0 | 0 | 5 (100) |
|  | | | | | | | | | | |
|  | Control Group (N = 5) | Last Post-Baseline | 0 | 4 (80.0) | 1 (20.0) | 0 | 0 | 0 | 0 | 5 (100) |
|  |  |  | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 4 (80.0) | 1 (20.0) | 0 | 0 | 0 | 0 | 5 (100) |
|  | | | | | | | | | | |
|  |  | Worst Post-Baseline | 0 | 4 (80.0) | 1 (20.0) | 0 | 0 | 0 | 0 | 5 (100) |
|  |  |  | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 4 (80.0) | 1 (20.0) | 0 | 0 | 0 | 0 | 5 (100) |
|  | | | | | | | | | | |
| Amylase (Serum amylase increased) | Treatment Group (N = 5) | Last Post-Baseline | 0 | 4 (80.0) | 0 | 0 | 0 | 0 | 0 | 4 (80.0) |
|  |  |  | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Missing | 0 | 0 | 0 | 0 | 0 | 1 (20.0) | 1 (20.0) |
|  |  |  | Total | 4 (80.0) | 0 | 0 | 0 | 0 | 1 (20.0) | 5 (100) |
|  | | | | | | | | | | |
|  |  | Worst Post-Baseline | 0 | 4 (80.0) | 0 | 0 | 0 | 0 | 0 | 4 (80.0) |
|  |  |  | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Missing | 0 | 0 | 0 | 0 | 0 | 1 (20.0) | 1 (20.0) |
|  |  |  | Total | 4 (80.0) | 0 | 0 | 0 | 0 | 1 (20.0) | 5 (100) |
|  | | | | | | | | | | |
|  | Control Group (N = 5) | Last Post-Baseline | 0 | 3 (60.0) | 0 | 0 | 0 | 0 | 1 (20.0) | 4 (80.0) |
|  |  |  | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Missing | 0 | 0 | 0 | 0 | 0 | 1 (20.0) | 1 (20.0) |
|  |  |  | Total | 3 (60.0) | 0 | 0 | 0 | 0 | 2 (40.0) | 5 (100) |
|  | | | | | | | | | | |
|  |  | Worst Post-Baseline | 0 | 3 (60.0) | 0 | 0 | 0 | 0 | 1 (20.0) | 4 (80.0) |
|  |  |  | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Missing | 0 | 0 | 0 | 0 | 0 | 1 (20.0) | 1 (20.0) |
|  |  |  | Total | 3 (60.0) | 0 | 0 | 0 | 0 | 2 (40.0) | 5 (100) |
|  | | | | | | | | | | |
| Lipase (Lipase increased) | Treatment Group (N = 5) | Last Post-Baseline | 0 | 4 (80.0) | 0 | 0 | 0 | 0 | 0 | 4 (80.0) |
|  |  |  | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Missing | 0 | 0 | 0 | 0 | 0 | 1 (20.0) | 1 (20.0) |
|  |  |  | Total | 4 (80.0) | 0 | 0 | 0 | 0 | 1 (20.0) | 5 (100) |
|  | | | | | | | | | | |
|  |  | Worst Post-Baseline | 0 | 4 (80.0) | 0 | 0 | 0 | 0 | 0 | 4 (80.0) |
|  |  |  | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Missing | 0 | 0 | 0 | 0 | 0 | 1 (20.0) | 1 (20.0) |
|  |  |  | Total | 4 (80.0) | 0 | 0 | 0 | 0 | 1 (20.0) | 5 (100) |
|  | | | | | | | | | | |
|  | Control Group (N = 5) | Last Post-Baseline | 0 | 4 (80.0) | 0 | 0 | 0 | 0 | 0 | 4 (80.0) |
|  |  |  | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Missing | 0 | 0 | 0 | 0 | 0 | 1 (20.0) | 1 (20.0) |
|  |  |  | Total | 4 (80.0) | 0 | 0 | 0 | 0 | 1 (20.0) | 5 (100) |
|  | | | | | | | | | | |
|  |  | Worst Post-Baseline | 0 | 4 (80.0) | 0 | 0 | 0 | 0 | 0 | 4 (80.0) |
|  |  |  | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Missing | 0 | 0 | 0 | 0 | 0 | 1 (20.0) | 1 (20.0) |
|  |  |  | Total | 4 (80.0) | 0 | 0 | 0 | 0 | 1 (20.0) | 5 (100) |
|  | | | | | | | | | | |
| Creatine Kinase (CPK increased) | Treatment Group (N = 5) | Last Post-Baseline | 0 | 4 (80.0) | 0 | 0 | 0 | 0 | 0 | 4 (80.0) |
|  |  |  | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Missing | 0 | 0 | 0 | 0 | 0 | 1 (20.0) | 1 (20.0) |
|  |  |  | Total | 4 (80.0) | 0 | 0 | 0 | 0 | 1 (20.0) | 5 (100) |
|  | | | | | | | | | | |
|  |  | Worst Post-Baseline | 0 | 4 (80.0) | 0 | 0 | 0 | 0 | 0 | 4 (80.0) |
|  |  |  | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Missing | 0 | 0 | 0 | 0 | 0 | 1 (20.0) | 1 (20.0) |
|  |  |  | Total | 4 (80.0) | 0 | 0 | 0 | 0 | 1 (20.0) | 5 (100) |
|  | | | | | | | | | | |
|  | Control Group (N = 5) | Last Post-Baseline | 0 | 3 (60.0) | 1 (20.0) | 0 | 0 | 0 | 0 | 4 (80.0) |
|  |  |  | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Missing | 0 | 0 | 0 | 0 | 0 | 1 (20.0) | 1 (20.0) |
|  |  |  | Total | 3 (60.0) | 1 (20.0) | 0 | 0 | 0 | 1 (20.0) | 5 (100) |
|  | | | | | | | | | | |
|  |  | Worst Post-Baseline | 0 | 3 (60.0) | 1 (20.0) | 0 | 0 | 0 | 0 | 4 (80.0) |
|  |  |  | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Missing | 0 | 0 | 0 | 0 | 0 | 1 (20.0) | 1 (20.0) |
|  |  |  | Total | 3 (60.0) | 1 (20.0) | 0 | 0 | 0 | 1 (20.0) | 5 (100) |
|  | | | | | | | | | | |
| Activated Partial Thromboplastin Time (Activated partial thromboplastin time prolonged) | Treatment Group (N = 5) | Last Post-Baseline | 0 | 4 (80.0) | 1 (20.0) | 0 | 0 | 0 | 0 | 5 (100) |
|  |  |  | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 4 (80.0) | 1 (20.0) | 0 | 0 | 0 | 0 | 5 (100) |
|  | | | | | | | | | | |
|  |  | Worst Post-Baseline | 0 | 4 (80.0) | 1 (20.0) | 0 | 0 | 0 | 0 | 5 (100) |
|  |  |  | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 4 (80.0) | 1 (20.0) | 0 | 0 | 0 | 0 | 5 (100) |
|  | | | | | | | | | | |
|  | Control Group (N = 5) | Last Post-Baseline | 0 | 5 (100) | 0 | 0 | 0 | 0 | 0 | 5 (100) |
|  |  |  | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 5 (100) | 0 | 0 | 0 | 0 | 0 | 5 (100) |
|  | | | | | | | | | | |
|  |  | Worst Post-Baseline | 0 | 5 (100) | 0 | 0 | 0 | 0 | 0 | 5 (100) |
|  |  |  | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 5 (100) | 0 | 0 | 0 | 0 | 0 | 5 (100) |
|  | | | | | | | | | | |
| Prothrombin Intl. Normalized Ratio (INR increased) | Treatment Group (N = 5) | Last Post-Baseline | 0 | 4 (80.0) | 0 | 0 | 0 | 0 | 0 | 4 (80.0) |
|  |  |  | 1 | 1 (20.0) | 0 | 0 | 0 | 0 | 0 | 1 (20.0) |
|  |  |  | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 5 (100) | 0 | 0 | 0 | 0 | 0 | 5 (100) |
|  | | | | | | | | | | |
|  |  | Worst Post-Baseline | 0 | 4 (80.0) | 0 | 0 | 0 | 0 | 0 | 4 (80.0) |
|  |  |  | 1 | 1 (20.0) | 0 | 0 | 0 | 0 | 0 | 1 (20.0) |
|  |  |  | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 5 (100) | 0 | 0 | 0 | 0 | 0 | 5 (100) |
|  | | | | | | | | | | |
|  | Control Group (N = 5) | Last Post-Baseline | 0 | 5 (100) | 0 | 0 | 0 | 0 | 0 | 5 (100) |
|  |  |  | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 5 (100) | 0 | 0 | 0 | 0 | 0 | 5 (100) |
|  | | | | | | | | | | |
|  |  | Worst Post-Baseline | 0 | 5 (100) | 0 | 0 | 0 | 0 | 0 | 5 (100) |
|  |  |  | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 5 (100) | 0 | 0 | 0 | 0 | 0 | 5 (100) |

Grading is based on Common Terminology Criteria for Adverse Events (CTCAE) version 5.0.

Baseline is defined as the last available assessment before the first administration of investigational drug (D-1553 or IN10018).

Last post-baseline is the last value of CTCAE grade at all post-baseline visits, including any scheduled, unscheduled, EOT/early withdraw from the study and safety follow-up.

Worst post-baseline is the value of worst CTCAE grade at all post-baseline visits, including any scheduled, unscheduled, EOT/early withdraw from the study and safety follow-up.

Percentages are based on the number of subjects of each respective group in the Safety Analysis Set.

Source Data: Listing 16.2.8.1.1, 16.2.8.2.1, 16.2.8.4.1

|  |  |  |
| --- | --- | --- |
| Program: t-lb-shift-ctcae.sas | DCO: 27APR2024 | Executed: 07JUL2024 20:50 |

|  |  |
| --- | --- |
| **InxMed (Shanghai) Co., Ltd.  Protocol No. IN10018-602** |  |

**Table 14.3.5.3.2.3 Summary of Shifts from Baseline in Chemistry According to Investigator’s Assessment - Phase II part 2 - CRC (Safety Analysis Set)**

|  | | | | Post-baseline | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Parameter | Group | Visit | Baseline | Normal | Abnormal, NCS | Abnormal, CS | Missing | Total |
| Bilirubin | Treatment Group (N = 5) | Last Post-Baseline | Normal | 5 (100) | 0 | 0 | 0 | 5 (100) |
|  |  |  | Abnormal, NCS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Abnormal, CS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 5 (100) | 0 | 0 | 0 | 5 (100) |
|  | | | | | | | | |
|  |  | Worst Post-Baseline | Normal | 5 (100) | 0 | 0 | 0 | 5 (100) |
|  |  |  | Abnormal, NCS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Abnormal, CS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 5 (100) | 0 | 0 | 0 | 5 (100) |
|  | | | | | | | | |
|  | Control Group (N = 5) | Last Post-Baseline | Normal | 4 (80.0) | 0 | 0 | 0 | 4 (80.0) |
|  |  |  | Abnormal, NCS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Abnormal, CS | 0 | 0 | 1 (20.0) | 0 | 1 (20.0) |
|  |  |  | Total | 4 (80.0) | 0 | 1 (20.0) | 0 | 5 (100) |
|  | | | | | | | | |
|  |  | Worst Post-Baseline | Normal | 4 (80.0) | 0 | 0 | 0 | 4 (80.0) |
|  |  |  | Abnormal, NCS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Abnormal, CS | 0 | 0 | 1 (20.0) | 0 | 1 (20.0) |
|  |  |  | Total | 4 (80.0) | 0 | 1 (20.0) | 0 | 5 (100) |
|  | | | | | | | | |
| Direct Bilirubin | Treatment Group (N = 5) | Last Post-Baseline | Normal | 4 (80.0) | 0 | 0 | 0 | 4 (80.0) |
|  |  |  | Abnormal, NCS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Abnormal, CS | 1 (20.0) | 0 | 0 | 0 | 1 (20.0) |
|  |  |  | Total | 5 (100) | 0 | 0 | 0 | 5 (100) |
|  | | | | | | | | |
|  |  | Worst Post-Baseline | Normal | 3 (60.0) | 1 (20.0) | 0 | 0 | 4 (80.0) |
|  |  |  | Abnormal, NCS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Abnormal, CS | 1 (20.0) | 0 | 0 | 0 | 1 (20.0) |
|  |  |  | Total | 4 (80.0) | 1 (20.0) | 0 | 0 | 5 (100) |
|  | | | | | | | | |
|  | Control Group (N = 5) | Last Post-Baseline | Normal | 3 (60.0) | 0 | 1 (20.0) | 0 | 4 (80.0) |
|  |  |  | Abnormal, NCS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Abnormal, CS | 0 | 0 | 1 (20.0) | 0 | 1 (20.0) |
|  |  |  | Total | 3 (60.0) | 0 | 2 (40.0) | 0 | 5 (100) |
|  | | | | | | | | |
|  |  | Worst Post-Baseline | Normal | 3 (60.0) | 0 | 1 (20.0) | 0 | 4 (80.0) |
|  |  |  | Abnormal, NCS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Abnormal, CS | 0 | 0 | 1 (20.0) | 0 | 1 (20.0) |
|  |  |  | Total | 3 (60.0) | 0 | 2 (40.0) | 0 | 5 (100) |
|  | | | | | | | | |
| Indirect Bilirubin | Treatment Group (N = 5) | Last Post-Baseline | Normal | 5 (100) | 0 | 0 | 0 | 5 (100) |
|  |  |  | Abnormal, NCS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Abnormal, CS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 5 (100) | 0 | 0 | 0 | 5 (100) |
|  | | | | | | | | |
|  |  | Worst Post-Baseline | Normal | 5 (100) | 0 | 0 | 0 | 5 (100) |
|  |  |  | Abnormal, NCS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Abnormal, CS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 5 (100) | 0 | 0 | 0 | 5 (100) |
|  | | | | | | | | |
|  | Control Group (N = 5) | Last Post-Baseline | Normal | 5 (100) | 0 | 0 | 0 | 5 (100) |
|  |  |  | Abnormal, NCS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Abnormal, CS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 5 (100) | 0 | 0 | 0 | 5 (100) |
|  | | | | | | | | |
|  |  | Worst Post-Baseline | Normal | 5 (100) | 0 | 0 | 0 | 5 (100) |
|  |  |  | Abnormal, NCS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Abnormal, CS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 5 (100) | 0 | 0 | 0 | 5 (100) |
|  | | | | | | | | |
| Alanine Aminotransferase | Treatment Group (N = 5) | Last Post-Baseline | Normal | 3 (60.0) | 0 | 2 (40.0) | 0 | 5 (100) |
|  |  |  | Abnormal, NCS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Abnormal, CS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 3 (60.0) | 0 | 2 (40.0) | 0 | 5 (100) |
|  | | | | | | | | |
|  |  | Worst Post-Baseline | Normal | 3 (60.0) | 0 | 2 (40.0) | 0 | 5 (100) |
|  |  |  | Abnormal, NCS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Abnormal, CS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 3 (60.0) | 0 | 2 (40.0) | 0 | 5 (100) |
|  | | | | | | | | |
|  | Control Group (N = 5) | Last Post-Baseline | Normal | 4 (80.0) | 0 | 0 | 0 | 4 (80.0) |
|  |  |  | Abnormal, NCS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Abnormal, CS | 0 | 0 | 1 (20.0) | 0 | 1 (20.0) |
|  |  |  | Total | 4 (80.0) | 0 | 1 (20.0) | 0 | 5 (100) |
|  | | | | | | | | |
|  |  | Worst Post-Baseline | Normal | 3 (60.0) | 0 | 1 (20.0) | 0 | 4 (80.0) |
|  |  |  | Abnormal, NCS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Abnormal, CS | 0 | 0 | 1 (20.0) | 0 | 1 (20.0) |
|  |  |  | Total | 3 (60.0) | 0 | 2 (40.0) | 0 | 5 (100) |
|  | | | | | | | | |
| Aspartate Aminotransferase | Treatment Group (N = 5) | Last Post-Baseline | Normal | 3 (60.0) | 0 | 1 (20.0) | 0 | 4 (80.0) |
|  |  |  | Abnormal, NCS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Abnormal, CS | 0 | 0 | 1 (20.0) | 0 | 1 (20.0) |
|  |  |  | Total | 3 (60.0) | 0 | 2 (40.0) | 0 | 5 (100) |
|  | | | | | | | | |
|  |  | Worst Post-Baseline | Normal | 3 (60.0) | 0 | 1 (20.0) | 0 | 4 (80.0) |
|  |  |  | Abnormal, NCS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Abnormal, CS | 0 | 0 | 1 (20.0) | 0 | 1 (20.0) |
|  |  |  | Total | 3 (60.0) | 0 | 2 (40.0) | 0 | 5 (100) |
|  | | | | | | | | |
|  | Control Group (N = 5) | Last Post-Baseline | Normal | 3 (60.0) | 0 | 0 | 0 | 3 (60.0) |
|  |  |  | Abnormal, NCS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Abnormal, CS | 0 | 0 | 2 (40.0) | 0 | 2 (40.0) |
|  |  |  | Total | 3 (60.0) | 0 | 2 (40.0) | 0 | 5 (100) |
|  | | | | | | | | |
|  |  | Worst Post-Baseline | Normal | 2 (40.0) | 0 | 1 (20.0) | 0 | 3 (60.0) |
|  |  |  | Abnormal, NCS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Abnormal, CS | 0 | 0 | 2 (40.0) | 0 | 2 (40.0) |
|  |  |  | Total | 2 (40.0) | 0 | 3 (60.0) | 0 | 5 (100) |
|  | | | | | | | | |
| Gamma Glutamyl Transferase | Treatment Group (N = 5) | Last Post-Baseline | Normal | 2 (40.0) | 0 | 0 | 0 | 2 (40.0) |
|  |  |  | Abnormal, NCS | 1 (20.0) | 0 | 0 | 0 | 1 (20.0) |
|  |  |  | Abnormal, CS | 0 | 0 | 2 (40.0) | 0 | 2 (40.0) |
|  |  |  | Total | 3 (60.0) | 0 | 2 (40.0) | 0 | 5 (100) |
|  | | | | | | | | |
|  |  | Worst Post-Baseline | Normal | 2 (40.0) | 0 | 0 | 0 | 2 (40.0) |
|  |  |  | Abnormal, NCS | 0 | 1 (20.0) | 0 | 0 | 1 (20.0) |
|  |  |  | Abnormal, CS | 0 | 0 | 2 (40.0) | 0 | 2 (40.0) |
|  |  |  | Total | 2 (40.0) | 1 (20.0) | 2 (40.0) | 0 | 5 (100) |
|  | | | | | | | | |
|  | Control Group (N = 5) | Last Post-Baseline | Normal | 2 (40.0) | 0 | 0 | 0 | 2 (40.0) |
|  |  |  | Abnormal, NCS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Abnormal, CS | 0 | 0 | 3 (60.0) | 0 | 3 (60.0) |
|  |  |  | Total | 2 (40.0) | 0 | 3 (60.0) | 0 | 5 (100) |
|  | | | | | | | | |
|  |  | Worst Post-Baseline | Normal | 2 (40.0) | 0 | 0 | 0 | 2 (40.0) |
|  |  |  | Abnormal, NCS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Abnormal, CS | 0 | 0 | 3 (60.0) | 0 | 3 (60.0) |
|  |  |  | Total | 2 (40.0) | 0 | 3 (60.0) | 0 | 5 (100) |
|  | | | | | | | | |
| Alkaline Phosphatase | Treatment Group (N = 5) | Last Post-Baseline | Normal | 2 (40.0) | 0 | 0 | 0 | 2 (40.0) |
|  |  |  | Abnormal, NCS | 1 (20.0) | 0 | 0 | 0 | 1 (20.0) |
|  |  |  | Abnormal, CS | 0 | 0 | 2 (40.0) | 0 | 2 (40.0) |
|  |  |  | Total | 3 (60.0) | 0 | 2 (40.0) | 0 | 5 (100) |
|  | | | | | | | | |
|  |  | Worst Post-Baseline | Normal | 2 (40.0) | 0 | 0 | 0 | 2 (40.0) |
|  |  |  | Abnormal, NCS | 0 | 1 (20.0) | 0 | 0 | 1 (20.0) |
|  |  |  | Abnormal, CS | 0 | 0 | 2 (40.0) | 0 | 2 (40.0) |
|  |  |  | Total | 2 (40.0) | 1 (20.0) | 2 (40.0) | 0 | 5 (100) |
|  | | | | | | | | |
|  | Control Group (N = 5) | Last Post-Baseline | Normal | 3 (60.0) | 0 | 0 | 0 | 3 (60.0) |
|  |  |  | Abnormal, NCS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Abnormal, CS | 0 | 0 | 2 (40.0) | 0 | 2 (40.0) |
|  |  |  | Total | 3 (60.0) | 0 | 2 (40.0) | 0 | 5 (100) |
|  | | | | | | | | |
|  |  | Worst Post-Baseline | Normal | 3 (60.0) | 0 | 0 | 0 | 3 (60.0) |
|  |  |  | Abnormal, NCS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Abnormal, CS | 0 | 0 | 2 (40.0) | 0 | 2 (40.0) |
|  |  |  | Total | 3 (60.0) | 0 | 2 (40.0) | 0 | 5 (100) |
|  | | | | | | | | |
| Lactate Dehydrogenase | Treatment Group (N = 5) | Last Post-Baseline | Normal | 4 (80.0) | 0 | 0 | 0 | 4 (80.0) |
|  |  |  | Abnormal, NCS | 0 | 1 (20.0) | 0 | 0 | 1 (20.0) |
|  |  |  | Abnormal, CS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 4 (80.0) | 1 (20.0) | 0 | 0 | 5 (100) |
|  | | | | | | | | |
|  |  | Worst Post-Baseline | Normal | 3 (60.0) | 1 (20.0) | 0 | 0 | 4 (80.0) |
|  |  |  | Abnormal, NCS | 0 | 1 (20.0) | 0 | 0 | 1 (20.0) |
|  |  |  | Abnormal, CS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 3 (60.0) | 2 (40.0) | 0 | 0 | 5 (100) |
|  | | | | | | | | |
|  | Control Group (N = 5) | Last Post-Baseline | Normal | 2 (40.0) | 0 | 0 | 0 | 2 (40.0) |
|  |  |  | Abnormal, NCS | 0 | 2 (40.0) | 0 | 0 | 2 (40.0) |
|  |  |  | Abnormal, CS | 0 | 0 | 1 (20.0) | 0 | 1 (20.0) |
|  |  |  | Total | 2 (40.0) | 2 (40.0) | 1 (20.0) | 0 | 5 (100) |
|  | | | | | | | | |
|  |  | Worst Post-Baseline | Normal | 1 (20.0) | 0 | 1 (20.0) | 0 | 2 (40.0) |
|  |  |  | Abnormal, NCS | 0 | 2 (40.0) | 0 | 0 | 2 (40.0) |
|  |  |  | Abnormal, CS | 0 | 0 | 1 (20.0) | 0 | 1 (20.0) |
|  |  |  | Total | 1 (20.0) | 2 (40.0) | 2 (40.0) | 0 | 5 (100) |
|  | | | | | | | | |
| Protein | Treatment Group (N = 5) | Last Post-Baseline | Normal | 4 (80.0) | 0 | 0 | 0 | 4 (80.0) |
|  |  |  | Abnormal, NCS | 1 (20.0) | 0 | 0 | 0 | 1 (20.0) |
|  |  |  | Abnormal, CS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 5 (100) | 0 | 0 | 0 | 5 (100) |
|  | | | | | | | | |
|  |  | Worst Post-Baseline | Normal | 3 (60.0) | 1 (20.0) | 0 | 0 | 4 (80.0) |
|  |  |  | Abnormal, NCS | 0 | 1 (20.0) | 0 | 0 | 1 (20.0) |
|  |  |  | Abnormal, CS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 3 (60.0) | 2 (40.0) | 0 | 0 | 5 (100) |
|  | | | | | | | | |
|  | Control Group (N = 5) | Last Post-Baseline | Normal | 5 (100) | 0 | 0 | 0 | 5 (100) |
|  |  |  | Abnormal, NCS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Abnormal, CS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 5 (100) | 0 | 0 | 0 | 5 (100) |
|  | | | | | | | | |
|  |  | Worst Post-Baseline | Normal | 5 (100) | 0 | 0 | 0 | 5 (100) |
|  |  |  | Abnormal, NCS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Abnormal, CS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 5 (100) | 0 | 0 | 0 | 5 (100) |
|  | | | | | | | | |
| Albumin | Treatment Group (N = 5) | Last Post-Baseline | Normal | 2 (40.0) | 0 | 1 (20.0) | 0 | 3 (60.0) |
|  |  |  | Abnormal, NCS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Abnormal, CS | 1 (20.0) | 0 | 1 (20.0) | 0 | 2 (40.0) |
|  |  |  | Total | 3 (60.0) | 0 | 2 (40.0) | 0 | 5 (100) |
|  | | | | | | | | |
|  |  | Worst Post-Baseline | Normal | 2 (40.0) | 0 | 1 (20.0) | 0 | 3 (60.0) |
|  |  |  | Abnormal, NCS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Abnormal, CS | 0 | 0 | 2 (40.0) | 0 | 2 (40.0) |
|  |  |  | Total | 2 (40.0) | 0 | 3 (60.0) | 0 | 5 (100) |
|  | | | | | | | | |
|  | Control Group (N = 5) | Last Post-Baseline | Normal | 3 (60.0) | 0 | 0 | 0 | 3 (60.0) |
|  |  |  | Abnormal, NCS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Abnormal, CS | 0 | 0 | 2 (40.0) | 0 | 2 (40.0) |
|  |  |  | Total | 3 (60.0) | 0 | 2 (40.0) | 0 | 5 (100) |
|  | | | | | | | | |
|  |  | Worst Post-Baseline | Normal | 3 (60.0) | 0 | 0 | 0 | 3 (60.0) |
|  |  |  | Abnormal, NCS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Abnormal, CS | 0 | 0 | 2 (40.0) | 0 | 2 (40.0) |
|  |  |  | Total | 3 (60.0) | 0 | 2 (40.0) | 0 | 5 (100) |
|  | | | | | | | | |
| Triglycerides | Treatment Group (N = 5) | Last Post-Baseline | Normal | 4 (80.0) | 0 | 0 | 0 | 4 (80.0) |
|  |  |  | Abnormal, NCS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Abnormal, CS | 0 | 0 | 1 (20.0) | 0 | 1 (20.0) |
|  |  |  | Total | 4 (80.0) | 0 | 1 (20.0) | 0 | 5 (100) |
|  | | | | | | | | |
|  |  | Worst Post-Baseline | Normal | 4 (80.0) | 0 | 0 | 0 | 4 (80.0) |
|  |  |  | Abnormal, NCS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Abnormal, CS | 0 | 0 | 1 (20.0) | 0 | 1 (20.0) |
|  |  |  | Total | 4 (80.0) | 0 | 1 (20.0) | 0 | 5 (100) |
|  | | | | | | | | |
|  | Control Group (N = 5) | Last Post-Baseline | Normal | 2 (40.0) | 0 | 1 (20.0) | 0 | 3 (60.0) |
|  |  |  | Abnormal, NCS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Abnormal, CS | 0 | 0 | 2 (40.0) | 0 | 2 (40.0) |
|  |  |  | Total | 2 (40.0) | 0 | 3 (60.0) | 0 | 5 (100) |
|  | | | | | | | | |
|  |  | Worst Post-Baseline | Normal | 1 (20.0) | 0 | 2 (40.0) | 0 | 3 (60.0) |
|  |  |  | Abnormal, NCS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Abnormal, CS | 0 | 0 | 2 (40.0) | 0 | 2 (40.0) |
|  |  |  | Total | 1 (20.0) | 0 | 4 (80.0) | 0 | 5 (100) |
|  | | | | | | | | |
| Cholesterol | Treatment Group (N = 5) | Last Post-Baseline | Normal | 3 (60.0) | 0 | 1 (20.0) | 0 | 4 (80.0) |
|  |  |  | Abnormal, NCS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Abnormal, CS | 1 (20.0) | 0 | 0 | 0 | 1 (20.0) |
|  |  |  | Total | 4 (80.0) | 0 | 1 (20.0) | 0 | 5 (100) |
|  | | | | | | | | |
|  |  | Worst Post-Baseline | Normal | 2 (40.0) | 0 | 2 (40.0) | 0 | 4 (80.0) |
|  |  |  | Abnormal, NCS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Abnormal, CS | 1 (20.0) | 0 | 0 | 0 | 1 (20.0) |
|  |  |  | Total | 3 (60.0) | 0 | 2 (40.0) | 0 | 5 (100) |
|  | | | | | | | | |
|  | Control Group (N = 5) | Last Post-Baseline | Normal | 3 (60.0) | 0 | 0 | 0 | 3 (60.0) |
|  |  |  | Abnormal, NCS | 0 | 1 (20.0) | 0 | 0 | 1 (20.0) |
|  |  |  | Abnormal, CS | 0 | 0 | 1 (20.0) | 0 | 1 (20.0) |
|  |  |  | Total | 3 (60.0) | 1 (20.0) | 1 (20.0) | 0 | 5 (100) |
|  | | | | | | | | |
|  |  | Worst Post-Baseline | Normal | 2 (40.0) | 1 (20.0) | 0 | 0 | 3 (60.0) |
|  |  |  | Abnormal, NCS | 0 | 1 (20.0) | 0 | 0 | 1 (20.0) |
|  |  |  | Abnormal, CS | 0 | 0 | 1 (20.0) | 0 | 1 (20.0) |
|  |  |  | Total | 2 (40.0) | 2 (40.0) | 1 (20.0) | 0 | 5 (100) |
|  | | | | | | | | |
| Sodium | Treatment Group (N = 5) | Last Post-Baseline | Normal | 4 (80.0) | 0 | 0 | 0 | 4 (80.0) |
|  |  |  | Abnormal, NCS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Abnormal, CS | 1 (20.0) | 0 | 0 | 0 | 1 (20.0) |
|  |  |  | Total | 5 (100) | 0 | 0 | 0 | 5 (100) |
|  | | | | | | | | |
|  |  | Worst Post-Baseline | Normal | 4 (80.0) | 0 | 0 | 0 | 4 (80.0) |
|  |  |  | Abnormal, NCS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Abnormal, CS | 0 | 0 | 1 (20.0) | 0 | 1 (20.0) |
|  |  |  | Total | 4 (80.0) | 0 | 1 (20.0) | 0 | 5 (100) |
|  | | | | | | | | |
|  | Control Group (N = 5) | Last Post-Baseline | Normal | 4 (80.0) | 0 | 0 | 0 | 4 (80.0) |
|  |  |  | Abnormal, NCS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Abnormal, CS | 1 (20.0) | 0 | 0 | 0 | 1 (20.0) |
|  |  |  | Total | 5 (100) | 0 | 0 | 0 | 5 (100) |
|  | | | | | | | | |
|  |  | Worst Post-Baseline | Normal | 4 (80.0) | 0 | 0 | 0 | 4 (80.0) |
|  |  |  | Abnormal, NCS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Abnormal, CS | 0 | 0 | 1 (20.0) | 0 | 1 (20.0) |
|  |  |  | Total | 4 (80.0) | 0 | 1 (20.0) | 0 | 5 (100) |
|  | | | | | | | | |
| Potassium | Treatment Group (N = 5) | Last Post-Baseline | Normal | 5 (100) | 0 | 0 | 0 | 5 (100) |
|  |  |  | Abnormal, NCS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Abnormal, CS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 5 (100) | 0 | 0 | 0 | 5 (100) |
|  | | | | | | | | |
|  |  | Worst Post-Baseline | Normal | 3 (60.0) | 1 (20.0) | 1 (20.0) | 0 | 5 (100) |
|  |  |  | Abnormal, NCS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Abnormal, CS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 3 (60.0) | 1 (20.0) | 1 (20.0) | 0 | 5 (100) |
|  | | | | | | | | |
|  | Control Group (N = 5) | Last Post-Baseline | Normal | 5 (100) | 0 | 0 | 0 | 5 (100) |
|  |  |  | Abnormal, NCS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Abnormal, CS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 5 (100) | 0 | 0 | 0 | 5 (100) |
|  | | | | | | | | |
|  |  | Worst Post-Baseline | Normal | 4 (80.0) | 0 | 1 (20.0) | 0 | 5 (100) |
|  |  |  | Abnormal, NCS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Abnormal, CS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 4 (80.0) | 0 | 1 (20.0) | 0 | 5 (100) |
|  | | | | | | | | |
| Magnesium | Treatment Group (N = 5) | Last Post-Baseline | Normal | 5 (100) | 0 | 0 | 0 | 5 (100) |
|  |  |  | Abnormal, NCS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Abnormal, CS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 5 (100) | 0 | 0 | 0 | 5 (100) |
|  | | | | | | | | |
|  |  | Worst Post-Baseline | Normal | 5 (100) | 0 | 0 | 0 | 5 (100) |
|  |  |  | Abnormal, NCS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Abnormal, CS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 5 (100) | 0 | 0 | 0 | 5 (100) |
|  | | | | | | | | |
|  | Control Group (N = 5) | Last Post-Baseline | Normal | 4 (80.0) | 0 | 1 (20.0) | 0 | 5 (100) |
|  |  |  | Abnormal, NCS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Abnormal, CS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 4 (80.0) | 0 | 1 (20.0) | 0 | 5 (100) |
|  | | | | | | | | |
|  |  | Worst Post-Baseline | Normal | 4 (80.0) | 0 | 1 (20.0) | 0 | 5 (100) |
|  |  |  | Abnormal, NCS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Abnormal, CS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 4 (80.0) | 0 | 1 (20.0) | 0 | 5 (100) |
|  | | | | | | | | |
| Chloride | Treatment Group (N = 5) | Last Post-Baseline | Normal | 5 (100) | 0 | 0 | 0 | 5 (100) |
|  |  |  | Abnormal, NCS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Abnormal, CS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 5 (100) | 0 | 0 | 0 | 5 (100) |
|  | | | | | | | | |
|  |  | Worst Post-Baseline | Normal | 5 (100) | 0 | 0 | 0 | 5 (100) |
|  |  |  | Abnormal, NCS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Abnormal, CS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 5 (100) | 0 | 0 | 0 | 5 (100) |
|  | | | | | | | | |
|  | Control Group (N = 5) | Last Post-Baseline | Normal | 4 (80.0) | 0 | 0 | 0 | 4 (80.0) |
|  |  |  | Abnormal, NCS | 1 (20.0) | 0 | 0 | 0 | 1 (20.0) |
|  |  |  | Abnormal, CS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 5 (100) | 0 | 0 | 0 | 5 (100) |
|  | | | | | | | | |
|  |  | Worst Post-Baseline | Normal | 4 (80.0) | 0 | 0 | 0 | 4 (80.0) |
|  |  |  | Abnormal, NCS | 1 (20.0) | 0 | 0 | 0 | 1 (20.0) |
|  |  |  | Abnormal, CS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 5 (100) | 0 | 0 | 0 | 5 (100) |
|  | | | | | | | | |
| Calcium | Treatment Group (N = 5) | Last Post-Baseline | Normal | 5 (100) | 0 | 0 | 0 | 5 (100) |
|  |  |  | Abnormal, NCS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Abnormal, CS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 5 (100) | 0 | 0 | 0 | 5 (100) |
|  | | | | | | | | |
|  |  | Worst Post-Baseline | Normal | 4 (80.0) | 1 (20.0) | 0 | 0 | 5 (100) |
|  |  |  | Abnormal, NCS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Abnormal, CS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 4 (80.0) | 1 (20.0) | 0 | 0 | 5 (100) |
|  | | | | | | | | |
|  | Control Group (N = 5) | Last Post-Baseline | Normal | 5 (100) | 0 | 0 | 0 | 5 (100) |
|  |  |  | Abnormal, NCS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Abnormal, CS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 5 (100) | 0 | 0 | 0 | 5 (100) |
|  | | | | | | | | |
|  |  | Worst Post-Baseline | Normal | 5 (100) | 0 | 0 | 0 | 5 (100) |
|  |  |  | Abnormal, NCS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Abnormal, CS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 5 (100) | 0 | 0 | 0 | 5 (100) |
|  | | | | | | | | |
| Phosphorus | Treatment Group (N = 5) | Last Post-Baseline | Normal | 3 (60.0) | 0 | 1 (20.0) | 0 | 4 (80.0) |
|  |  |  | Abnormal, NCS | 1 (20.0) | 0 | 0 | 0 | 1 (20.0) |
|  |  |  | Abnormal, CS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 4 (80.0) | 0 | 1 (20.0) | 0 | 5 (100) |
|  | | | | | | | | |
|  |  | Worst Post-Baseline | Normal | 2 (40.0) | 1 (20.0) | 1 (20.0) | 0 | 4 (80.0) |
|  |  |  | Abnormal, NCS | 1 (20.0) | 0 | 0 | 0 | 1 (20.0) |
|  |  |  | Abnormal, CS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 3 (60.0) | 1 (20.0) | 1 (20.0) | 0 | 5 (100) |
|  | | | | | | | | |
|  | Control Group (N = 5) | Last Post-Baseline | Normal | 4 (80.0) | 0 | 0 | 0 | 4 (80.0) |
|  |  |  | Abnormal, NCS | 0 | 1 (20.0) | 0 | 0 | 1 (20.0) |
|  |  |  | Abnormal, CS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 4 (80.0) | 1 (20.0) | 0 | 0 | 5 (100) |
|  | | | | | | | | |
|  |  | Worst Post-Baseline | Normal | 3 (60.0) | 1 (20.0) | 0 | 0 | 4 (80.0) |
|  |  |  | Abnormal, NCS | 0 | 1 (20.0) | 0 | 0 | 1 (20.0) |
|  |  |  | Abnormal, CS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 3 (60.0) | 2 (40.0) | 0 | 0 | 5 (100) |
|  | | | | | | | | |
| Urea | Treatment Group (N = 5) | Last Post-Baseline | Normal | 4 (80.0) | 0 | 0 | 0 | 4 (80.0) |
|  |  |  | Abnormal, NCS | 1 (20.0) | 0 | 0 | 0 | 1 (20.0) |
|  |  |  | Abnormal, CS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 5 (100) | 0 | 0 | 0 | 5 (100) |
|  | | | | | | | | |
|  |  | Worst Post-Baseline | Normal | 3 (60.0) | 1 (20.0) | 0 | 0 | 4 (80.0) |
|  |  |  | Abnormal, NCS | 0 | 1 (20.0) | 0 | 0 | 1 (20.0) |
|  |  |  | Abnormal, CS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 3 (60.0) | 2 (40.0) | 0 | 0 | 5 (100) |
|  | | | | | | | | |
|  | Control Group (N = 5) | Last Post-Baseline | Normal | 4 (80.0) | 0 | 0 | 0 | 4 (80.0) |
|  |  |  | Abnormal, NCS | 1 (20.0) | 0 | 0 | 0 | 1 (20.0) |
|  |  |  | Abnormal, CS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 5 (100) | 0 | 0 | 0 | 5 (100) |
|  | | | | | | | | |
|  |  | Worst Post-Baseline | Normal | 4 (80.0) | 0 | 0 | 0 | 4 (80.0) |
|  |  |  | Abnormal, NCS | 1 (20.0) | 0 | 0 | 0 | 1 (20.0) |
|  |  |  | Abnormal, CS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 5 (100) | 0 | 0 | 0 | 5 (100) |
|  | | | | | | | | |
| Urea Nitrogen | Treatment Group (N = 5) | Last Post-Baseline | Normal | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Abnormal, NCS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Abnormal, CS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Missing | 0 | 0 | 0 | 5 (100) | 5 (100) |
|  |  |  | Total | 0 | 0 | 0 | 5 (100) | 5 (100) |
|  | | | | | | | | |
|  |  | Worst Post-Baseline | Normal | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Abnormal, NCS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Abnormal, CS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Missing | 0 | 0 | 0 | 5 (100) | 5 (100) |
|  |  |  | Total | 0 | 0 | 0 | 5 (100) | 5 (100) |
|  | | | | | | | | |
|  | Control Group (N = 5) | Last Post-Baseline | Normal | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Abnormal, NCS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Abnormal, CS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Missing | 0 | 0 | 0 | 5 (100) | 5 (100) |
|  |  |  | Total | 0 | 0 | 0 | 5 (100) | 5 (100) |
|  | | | | | | | | |
|  |  | Worst Post-Baseline | Normal | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Abnormal, NCS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Abnormal, CS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Missing | 0 | 0 | 0 | 5 (100) | 5 (100) |
|  |  |  | Total | 0 | 0 | 0 | 5 (100) | 5 (100) |
|  | | | | | | | | |
| Creatinine | Treatment Group (N = 5) | Last Post-Baseline | Normal | 4 (80.0) | 0 | 1 (20.0) | 0 | 5 (100) |
|  |  |  | Abnormal, NCS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Abnormal, CS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 4 (80.0) | 0 | 1 (20.0) | 0 | 5 (100) |
|  | | | | | | | | |
|  |  | Worst Post-Baseline | Normal | 3 (60.0) | 1 (20.0) | 1 (20.0) | 0 | 5 (100) |
|  |  |  | Abnormal, NCS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Abnormal, CS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 3 (60.0) | 1 (20.0) | 1 (20.0) | 0 | 5 (100) |
|  | | | | | | | | |
|  | Control Group (N = 5) | Last Post-Baseline | Normal | 3 (60.0) | 2 (40.0) | 0 | 0 | 5 (100) |
|  |  |  | Abnormal, NCS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Abnormal, CS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 3 (60.0) | 2 (40.0) | 0 | 0 | 5 (100) |
|  | | | | | | | | |
|  |  | Worst Post-Baseline | Normal | 3 (60.0) | 2 (40.0) | 0 | 0 | 5 (100) |
|  |  |  | Abnormal, NCS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Abnormal, CS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 3 (60.0) | 2 (40.0) | 0 | 0 | 5 (100) |
|  | | | | | | | | |
| Urate | Treatment Group (N = 5) | Last Post-Baseline | Normal | 5 (100) | 0 | 0 | 0 | 5 (100) |
|  |  |  | Abnormal, NCS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Abnormal, CS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 5 (100) | 0 | 0 | 0 | 5 (100) |
|  | | | | | | | | |
|  |  | Worst Post-Baseline | Normal | 4 (80.0) | 0 | 1 (20.0) | 0 | 5 (100) |
|  |  |  | Abnormal, NCS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Abnormal, CS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 4 (80.0) | 0 | 1 (20.0) | 0 | 5 (100) |
|  | | | | | | | | |
|  | Control Group (N = 5) | Last Post-Baseline | Normal | 4 (80.0) | 0 | 0 | 0 | 4 (80.0) |
|  |  |  | Abnormal, NCS | 1 (20.0) | 0 | 0 | 0 | 1 (20.0) |
|  |  |  | Abnormal, CS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 5 (100) | 0 | 0 | 0 | 5 (100) |
|  | | | | | | | | |
|  |  | Worst Post-Baseline | Normal | 4 (80.0) | 0 | 0 | 0 | 4 (80.0) |
|  |  |  | Abnormal, NCS | 0 | 1 (20.0) | 0 | 0 | 1 (20.0) |
|  |  |  | Abnormal, CS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 4 (80.0) | 1 (20.0) | 0 | 0 | 5 (100) |
|  | | | | | | | | |
| Glucose | Treatment Group (N = 5) | Last Post-Baseline | Normal | 5 (100) | 0 | 0 | 0 | 5 (100) |
|  |  |  | Abnormal, NCS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Abnormal, CS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 5 (100) | 0 | 0 | 0 | 5 (100) |
|  | | | | | | | | |
|  |  | Worst Post-Baseline | Normal | 4 (80.0) | 0 | 1 (20.0) | 0 | 5 (100) |
|  |  |  | Abnormal, NCS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Abnormal, CS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 4 (80.0) | 0 | 1 (20.0) | 0 | 5 (100) |
|  | | | | | | | | |
|  | Control Group (N = 5) | Last Post-Baseline | Normal | 3 (60.0) | 1 (20.0) | 0 | 0 | 4 (80.0) |
|  |  |  | Abnormal, NCS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Abnormal, CS | 1 (20.0) | 0 | 0 | 0 | 1 (20.0) |
|  |  |  | Total | 4 (80.0) | 1 (20.0) | 0 | 0 | 5 (100) |
|  | | | | | | | | |
|  |  | Worst Post-Baseline | Normal | 1 (20.0) | 1 (20.0) | 2 (40.0) | 0 | 4 (80.0) |
|  |  |  | Abnormal, NCS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Abnormal, CS | 1 (20.0) | 0 | 0 | 0 | 1 (20.0) |
|  |  |  | Total | 2 (40.0) | 1 (20.0) | 2 (40.0) | 0 | 5 (100) |
|  | | | | | | | | |
| Amylase | Treatment Group (N = 5) | Last Post-Baseline | Normal | 4 (80.0) | 0 | 0 | 0 | 4 (80.0) |
|  |  |  | Abnormal, NCS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Abnormal, CS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Missing | 0 | 0 | 0 | 1 (20.0) | 1 (20.0) |
|  |  |  | Total | 4 (80.0) | 0 | 0 | 1 (20.0) | 5 (100) |
|  | | | | | | | | |
|  |  | Worst Post-Baseline | Normal | 4 (80.0) | 0 | 0 | 0 | 4 (80.0) |
|  |  |  | Abnormal, NCS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Abnormal, CS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Missing | 0 | 0 | 0 | 1 (20.0) | 1 (20.0) |
|  |  |  | Total | 4 (80.0) | 0 | 0 | 1 (20.0) | 5 (100) |
|  | | | | | | | | |
|  | Control Group (N = 5) | Last Post-Baseline | Normal | 2 (40.0) | 0 | 0 | 1 (20.0) | 3 (60.0) |
|  |  |  | Abnormal, NCS | 1 (20.0) | 0 | 0 | 0 | 1 (20.0) |
|  |  |  | Abnormal, CS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Missing | 0 | 0 | 0 | 1 (20.0) | 1 (20.0) |
|  |  |  | Total | 3 (60.0) | 0 | 0 | 2 (40.0) | 5 (100) |
|  | | | | | | | | |
|  |  | Worst Post-Baseline | Normal | 2 (40.0) | 0 | 0 | 1 (20.0) | 3 (60.0) |
|  |  |  | Abnormal, NCS | 1 (20.0) | 0 | 0 | 0 | 1 (20.0) |
|  |  |  | Abnormal, CS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Missing | 0 | 0 | 0 | 1 (20.0) | 1 (20.0) |
|  |  |  | Total | 3 (60.0) | 0 | 0 | 2 (40.0) | 5 (100) |
|  | | | | | | | | |
| Lipase | Treatment Group (N = 5) | Last Post-Baseline | Normal | 4 (80.0) | 0 | 0 | 0 | 4 (80.0) |
|  |  |  | Abnormal, NCS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Abnormal, CS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Missing | 0 | 0 | 0 | 1 (20.0) | 1 (20.0) |
|  |  |  | Total | 4 (80.0) | 0 | 0 | 1 (20.0) | 5 (100) |
|  | | | | | | | | |
|  |  | Worst Post-Baseline | Normal | 3 (60.0) | 1 (20.0) | 0 | 0 | 4 (80.0) |
|  |  |  | Abnormal, NCS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Abnormal, CS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Missing | 0 | 0 | 0 | 1 (20.0) | 1 (20.0) |
|  |  |  | Total | 3 (60.0) | 1 (20.0) | 0 | 1 (20.0) | 5 (100) |
|  | | | | | | | | |
|  | Control Group (N = 5) | Last Post-Baseline | Normal | 4 (80.0) | 0 | 0 | 0 | 4 (80.0) |
|  |  |  | Abnormal, NCS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Abnormal, CS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Missing | 0 | 0 | 0 | 1 (20.0) | 1 (20.0) |
|  |  |  | Total | 4 (80.0) | 0 | 0 | 1 (20.0) | 5 (100) |
|  | | | | | | | | |
|  |  | Worst Post-Baseline | Normal | 4 (80.0) | 0 | 0 | 0 | 4 (80.0) |
|  |  |  | Abnormal, NCS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Abnormal, CS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Missing | 0 | 0 | 0 | 1 (20.0) | 1 (20.0) |
|  |  |  | Total | 4 (80.0) | 0 | 0 | 1 (20.0) | 5 (100) |
|  | | | | | | | | |
| Creatine Kinase | Treatment Group (N = 5) | Last Post-Baseline | Normal | 4 (80.0) | 0 | 0 | 0 | 4 (80.0) |
|  |  |  | Abnormal, NCS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Abnormal, CS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Missing | 0 | 0 | 0 | 1 (20.0) | 1 (20.0) |
|  |  |  | Total | 4 (80.0) | 0 | 0 | 1 (20.0) | 5 (100) |
|  | | | | | | | | |
|  |  | Worst Post-Baseline | Normal | 4 (80.0) | 0 | 0 | 0 | 4 (80.0) |
|  |  |  | Abnormal, NCS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Abnormal, CS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Missing | 0 | 0 | 0 | 1 (20.0) | 1 (20.0) |
|  |  |  | Total | 4 (80.0) | 0 | 0 | 1 (20.0) | 5 (100) |
|  | | | | | | | | |
|  | Control Group (N = 5) | Last Post-Baseline | Normal | 3 (60.0) | 0 | 1 (20.0) | 0 | 4 (80.0) |
|  |  |  | Abnormal, NCS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Abnormal, CS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Missing | 0 | 0 | 0 | 1 (20.0) | 1 (20.0) |
|  |  |  | Total | 3 (60.0) | 0 | 1 (20.0) | 1 (20.0) | 5 (100) |
|  | | | | | | | | |
|  |  | Worst Post-Baseline | Normal | 3 (60.0) | 0 | 1 (20.0) | 0 | 4 (80.0) |
|  |  |  | Abnormal, NCS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Abnormal, CS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Missing | 0 | 0 | 0 | 1 (20.0) | 1 (20.0) |
|  |  |  | Total | 3 (60.0) | 0 | 1 (20.0) | 1 (20.0) | 5 (100) |

Baseline is defined as the last available assessment before the first administration of investigational drug (D-1553 or IN10018).

Last post-baseline is the last value of investigator's assessment at all post-baseline visits, including any scheduled, unscheduled, EOT/early withdraw from the study and safety follow-up.

Worst post-baseline is the value of worst investigator's assessment at all post-baseline visits, including any scheduled, unscheduled, EOT/early withdraw from the study and safety follow-up.

Percentages are based on the number of subjects of each respective group in the Safety Analysis Set.

Source Data: Listing 16.2.8.2.1

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| Program: t-lb-shift.sas | DCO: 27APR2024 | Executed: 07JUL2024 20:50 |

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| **InxMed (Shanghai) Co., Ltd.  Protocol No. IN10018-602** |  |

**Table 14.3.5.3.3.3 Summary of Shifts from Baseline in Urinalysis According to Investigator’s Assessment - Phase II part 2 - CRC (Safety Analysis Set)**

|  | | | | Post-baseline | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Parameter | Group | Visit | Baseline | Normal | Abnormal, NCS | Abnormal, CS | Missing | Total |
| pH | Treatment Group (N = 5) | Last Post-Baseline | Normal | 5 (100) | 0 | 0 | 0 | 5 (100) |
|  |  |  | Abnormal, NCS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Abnormal, CS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 5 (100) | 0 | 0 | 0 | 5 (100) |
|  | | | | | | | | |
|  |  | Worst Post-Baseline | Normal | 5 (100) | 0 | 0 | 0 | 5 (100) |
|  |  |  | Abnormal, NCS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Abnormal, CS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 5 (100) | 0 | 0 | 0 | 5 (100) |
|  | | | | | | | | |
|  | Control Group (N = 5) | Last Post-Baseline | Normal | 5 (100) | 0 | 0 | 0 | 5 (100) |
|  |  |  | Abnormal, NCS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Abnormal, CS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 5 (100) | 0 | 0 | 0 | 5 (100) |
|  | | | | | | | | |
|  |  | Worst Post-Baseline | Normal | 5 (100) | 0 | 0 | 0 | 5 (100) |
|  |  |  | Abnormal, NCS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Abnormal, CS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 5 (100) | 0 | 0 | 0 | 5 (100) |
|  | | | | | | | | |
| Specific Gravity | Treatment Group (N = 5) | Last Post-Baseline | Normal | 4 (80.0) | 0 | 0 | 0 | 4 (80.0) |
|  |  |  | Abnormal, NCS | 1 (20.0) | 0 | 0 | 0 | 1 (20.0) |
|  |  |  | Abnormal, CS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 5 (100) | 0 | 0 | 0 | 5 (100) |
|  | | | | | | | | |
|  |  | Worst Post-Baseline | Normal | 3 (60.0) | 1 (20.0) | 0 | 0 | 4 (80.0) |
|  |  |  | Abnormal, NCS | 1 (20.0) | 0 | 0 | 0 | 1 (20.0) |
|  |  |  | Abnormal, CS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 4 (80.0) | 1 (20.0) | 0 | 0 | 5 (100) |
|  | | | | | | | | |
|  | Control Group (N = 5) | Last Post-Baseline | Normal | 5 (100) | 0 | 0 | 0 | 5 (100) |
|  |  |  | Abnormal, NCS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Abnormal, CS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 5 (100) | 0 | 0 | 0 | 5 (100) |
|  | | | | | | | | |
|  |  | Worst Post-Baseline | Normal | 5 (100) | 0 | 0 | 0 | 5 (100) |
|  |  |  | Abnormal, NCS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Abnormal, CS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 5 (100) | 0 | 0 | 0 | 5 (100) |
|  | | | | | | | | |
| Protein | Treatment Group (N = 5) | Last Post-Baseline | Normal | 1 (20.0) | 1 (20.0) | 1 (20.0) | 0 | 3 (60.0) |
|  |  |  | Abnormal, NCS | 1 (20.0) | 0 | 0 | 0 | 1 (20.0) |
|  |  |  | Abnormal, CS | 1 (20.0) | 0 | 0 | 0 | 1 (20.0) |
|  |  |  | Total | 3 (60.0) | 1 (20.0) | 1 (20.0) | 0 | 5 (100) |
|  | | | | | | | | |
|  |  | Worst Post-Baseline | Normal | 1 (20.0) | 0 | 2 (40.0) | 0 | 3 (60.0) |
|  |  |  | Abnormal, NCS | 0 | 0 | 1 (20.0) | 0 | 1 (20.0) |
|  |  |  | Abnormal, CS | 0 | 0 | 1 (20.0) | 0 | 1 (20.0) |
|  |  |  | Total | 1 (20.0) | 0 | 4 (80.0) | 0 | 5 (100) |
|  | | | | | | | | |
|  | Control Group (N = 5) | Last Post-Baseline | Normal | 3 (60.0) | 0 | 0 | 0 | 3 (60.0) |
|  |  |  | Abnormal, NCS | 1 (20.0) | 0 | 0 | 0 | 1 (20.0) |
|  |  |  | Abnormal, CS | 0 | 1 (20.0) | 0 | 0 | 1 (20.0) |
|  |  |  | Total | 4 (80.0) | 1 (20.0) | 0 | 0 | 5 (100) |
|  | | | | | | | | |
|  |  | Worst Post-Baseline | Normal | 1 (20.0) | 2 (40.0) | 0 | 0 | 3 (60.0) |
|  |  |  | Abnormal, NCS | 1 (20.0) | 0 | 0 | 0 | 1 (20.0) |
|  |  |  | Abnormal, CS | 0 | 1 (20.0) | 0 | 0 | 1 (20.0) |
|  |  |  | Total | 2 (40.0) | 3 (60.0) | 0 | 0 | 5 (100) |
|  | | | | | | | | |
| Glucose | Treatment Group (N = 5) | Last Post-Baseline | Normal | 5 (100) | 0 | 0 | 0 | 5 (100) |
|  |  |  | Abnormal, NCS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Abnormal, CS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 5 (100) | 0 | 0 | 0 | 5 (100) |
|  | | | | | | | | |
|  |  | Worst Post-Baseline | Normal | 5 (100) | 0 | 0 | 0 | 5 (100) |
|  |  |  | Abnormal, NCS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Abnormal, CS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 5 (100) | 0 | 0 | 0 | 5 (100) |
|  | | | | | | | | |
|  | Control Group (N = 5) | Last Post-Baseline | Normal | 5 (100) | 0 | 0 | 0 | 5 (100) |
|  |  |  | Abnormal, NCS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Abnormal, CS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 5 (100) | 0 | 0 | 0 | 5 (100) |
|  | | | | | | | | |
|  |  | Worst Post-Baseline | Normal | 5 (100) | 0 | 0 | 0 | 5 (100) |
|  |  |  | Abnormal, NCS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Abnormal, CS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 5 (100) | 0 | 0 | 0 | 5 (100) |
|  | | | | | | | | |
| Ketones | Treatment Group (N = 5) | Last Post-Baseline | Normal | 5 (100) | 0 | 0 | 0 | 5 (100) |
|  |  |  | Abnormal, NCS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Abnormal, CS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 5 (100) | 0 | 0 | 0 | 5 (100) |
|  | | | | | | | | |
|  |  | Worst Post-Baseline | Normal | 5 (100) | 0 | 0 | 0 | 5 (100) |
|  |  |  | Abnormal, NCS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Abnormal, CS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 5 (100) | 0 | 0 | 0 | 5 (100) |
|  | | | | | | | | |
|  | Control Group (N = 5) | Last Post-Baseline | Normal | 5 (100) | 0 | 0 | 0 | 5 (100) |
|  |  |  | Abnormal, NCS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Abnormal, CS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 5 (100) | 0 | 0 | 0 | 5 (100) |
|  | | | | | | | | |
|  |  | Worst Post-Baseline | Normal | 5 (100) | 0 | 0 | 0 | 5 (100) |
|  |  |  | Abnormal, NCS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Abnormal, CS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 5 (100) | 0 | 0 | 0 | 5 (100) |
|  | | | | | | | | |
| Erythrocytes | Treatment Group (N = 5) | Last Post-Baseline | Normal | 4 (80.0) | 0 | 1 (20.0) | 0 | 5 (100) |
|  |  |  | Abnormal, NCS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Abnormal, CS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 4 (80.0) | 0 | 1 (20.0) | 0 | 5 (100) |
|  | | | | | | | | |
|  |  | Worst Post-Baseline | Normal | 3 (60.0) | 1 (20.0) | 1 (20.0) | 0 | 5 (100) |
|  |  |  | Abnormal, NCS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Abnormal, CS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 3 (60.0) | 1 (20.0) | 1 (20.0) | 0 | 5 (100) |
|  | | | | | | | | |
|  | Control Group (N = 5) | Last Post-Baseline | Normal | 5 (100) | 0 | 0 | 0 | 5 (100) |
|  |  |  | Abnormal, NCS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Abnormal, CS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 5 (100) | 0 | 0 | 0 | 5 (100) |
|  | | | | | | | | |
|  |  | Worst Post-Baseline | Normal | 5 (100) | 0 | 0 | 0 | 5 (100) |
|  |  |  | Abnormal, NCS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Abnormal, CS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 5 (100) | 0 | 0 | 0 | 5 (100) |
|  | | | | | | | | |
| Leukocytes | Treatment Group (N = 5) | Last Post-Baseline | Normal | 5 (100) | 0 | 0 | 0 | 5 (100) |
|  |  |  | Abnormal, NCS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Abnormal, CS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 5 (100) | 0 | 0 | 0 | 5 (100) |
|  | | | | | | | | |
|  |  | Worst Post-Baseline | Normal | 4 (80.0) | 1 (20.0) | 0 | 0 | 5 (100) |
|  |  |  | Abnormal, NCS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Abnormal, CS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 4 (80.0) | 1 (20.0) | 0 | 0 | 5 (100) |
|  | | | | | | | | |
|  | Control Group (N = 5) | Last Post-Baseline | Normal | 3 (60.0) | 0 | 0 | 0 | 3 (60.0) |
|  |  |  | Abnormal, NCS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Abnormal, CS | 0 | 0 | 2 (40.0) | 0 | 2 (40.0) |
|  |  |  | Total | 3 (60.0) | 0 | 2 (40.0) | 0 | 5 (100) |
|  | | | | | | | | |
|  |  | Worst Post-Baseline | Normal | 2 (40.0) | 1 (20.0) | 0 | 0 | 3 (60.0) |
|  |  |  | Abnormal, NCS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Abnormal, CS | 0 | 0 | 2 (40.0) | 0 | 2 (40.0) |
|  |  |  | Total | 2 (40.0) | 1 (20.0) | 2 (40.0) | 0 | 5 (100) |
|  | | | | | | | | |
| Bilirubin | Treatment Group (N = 5) | Last Post-Baseline | Normal | 5 (100) | 0 | 0 | 0 | 5 (100) |
|  |  |  | Abnormal, NCS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Abnormal, CS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 5 (100) | 0 | 0 | 0 | 5 (100) |
|  | | | | | | | | |
|  |  | Worst Post-Baseline | Normal | 5 (100) | 0 | 0 | 0 | 5 (100) |
|  |  |  | Abnormal, NCS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Abnormal, CS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 5 (100) | 0 | 0 | 0 | 5 (100) |
|  | | | | | | | | |
|  | Control Group (N = 5) | Last Post-Baseline | Normal | 5 (100) | 0 | 0 | 0 | 5 (100) |
|  |  |  | Abnormal, NCS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Abnormal, CS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 5 (100) | 0 | 0 | 0 | 5 (100) |
|  | | | | | | | | |
|  |  | Worst Post-Baseline | Normal | 5 (100) | 0 | 0 | 0 | 5 (100) |
|  |  |  | Abnormal, NCS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Abnormal, CS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Total | 5 (100) | 0 | 0 | 0 | 5 (100) |
|  | | | | | | | | |
| Creatinine | Treatment Group (N = 5) | Last Post-Baseline | Normal | 3 (60.0) | 0 | 0 | 0 | 3 (60.0) |
|  |  |  | Abnormal, NCS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Abnormal, CS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Missing | 0 | 0 | 0 | 2 (40.0) | 2 (40.0) |
|  |  |  | Total | 3 (60.0) | 0 | 0 | 2 (40.0) | 5 (100) |
|  | | | | | | | | |
|  |  | Worst Post-Baseline | Normal | 3 (60.0) | 0 | 0 | 0 | 3 (60.0) |
|  |  |  | Abnormal, NCS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Abnormal, CS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Missing | 0 | 0 | 0 | 2 (40.0) | 2 (40.0) |
|  |  |  | Total | 3 (60.0) | 0 | 0 | 2 (40.0) | 5 (100) |
|  | | | | | | | | |
|  | Control Group (N = 5) | Last Post-Baseline | Normal | 3 (60.0) | 0 | 0 | 0 | 3 (60.0) |
|  |  |  | Abnormal, NCS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Abnormal, CS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Missing | 0 | 0 | 0 | 2 (40.0) | 2 (40.0) |
|  |  |  | Total | 3 (60.0) | 0 | 0 | 2 (40.0) | 5 (100) |
|  | | | | | | | | |
|  |  | Worst Post-Baseline | Normal | 3 (60.0) | 0 | 0 | 0 | 3 (60.0) |
|  |  |  | Abnormal, NCS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Abnormal, CS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Missing | 0 | 0 | 0 | 2 (40.0) | 2 (40.0) |
|  |  |  | Total | 3 (60.0) | 0 | 0 | 2 (40.0) | 5 (100) |
|  | | | | | | | | |
| Protein/Creatinine | Treatment Group (N = 5) | Last Post-Baseline | Normal | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Abnormal, NCS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Abnormal, CS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Missing | 0 | 0 | 0 | 5 (100) | 5 (100) |
|  |  |  | Total | 0 | 0 | 0 | 5 (100) | 5 (100) |
|  | | | | | | | | |
|  |  | Worst Post-Baseline | Normal | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Abnormal, NCS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Abnormal, CS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Missing | 0 | 0 | 0 | 5 (100) | 5 (100) |
|  |  |  | Total | 0 | 0 | 0 | 5 (100) | 5 (100) |
|  | | | | | | | | |
|  | Control Group (N = 5) | Last Post-Baseline | Normal | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Abnormal, NCS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Abnormal, CS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Missing | 0 | 0 | 0 | 5 (100) | 5 (100) |
|  |  |  | Total | 0 | 0 | 0 | 5 (100) | 5 (100) |
|  | | | | | | | | |
|  |  | Worst Post-Baseline | Normal | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Abnormal, NCS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Abnormal, CS | 0 | 0 | 0 | 0 | 0 |
|  |  |  | Missing | 0 | 0 | 0 | 5 (100) | 5 (100) |
|  |  |  | Total | 0 | 0 | 0 | 5 (100) | 5 (100) |

Baseline is defined as the last available assessment before the first administration of investigational drug (D-1553 or IN10018).

Last post-baseline is the last value of investigator's assessment at all post-baseline visits, including any scheduled, unscheduled, EOT/early withdraw from the study and safety follow-up.

Worst post-baseline is the value of worst investigator's assessment at all post-baseline visits, including any scheduled, unscheduled, EOT/early withdraw from the study and safety follow-up.

Percentages are based on the number of subjects of each respective group in the Safety Analysis Set.

Source Data: Listing 16.2.8.3.1

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| Program: t-lb-shift.sas | DCO: 27APR2024 | Executed: 07JUL2024 20:50 |

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| **InxMed (Shanghai) Co., Ltd.  Protocol No. IN10018-602** |  |

**Table 14.3.5.3.4.3 Summary of Shifts from Baseline in Coagulation Function According to Investigator’s Assessment - Phase II part 2 - CRC (Safety Analysis Set)**

|  | | | | Post-baseline | | | |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Parameter | Group | Visit | Baseline | Normal | Abnormal, NCS | Abnormal, CS | Total |
| Activated Partial Thromboplastin Time | Treatment Group (N = 5) | Last Post-Baseline | Normal | 4 (80.0) | 1 (20.0) | 0 | 5 (100) |
|  |  |  | Abnormal, NCS | 0 | 0 | 0 | 0 |
|  |  |  | Abnormal, CS | 0 | 0 | 0 | 0 |
|  |  |  | Total | 4 (80.0) | 1 (20.0) | 0 | 5 (100) |
|  | | | | | | | |
|  |  | Worst Post-Baseline | Normal | 4 (80.0) | 1 (20.0) | 0 | 5 (100) |
|  |  |  | Abnormal, NCS | 0 | 0 | 0 | 0 |
|  |  |  | Abnormal, CS | 0 | 0 | 0 | 0 |
|  |  |  | Total | 4 (80.0) | 1 (20.0) | 0 | 5 (100) |
|  | | | | | | | |
|  | Control Group (N = 5) | Last Post-Baseline | Normal | 5 (100) | 0 | 0 | 5 (100) |
|  |  |  | Abnormal, NCS | 0 | 0 | 0 | 0 |
|  |  |  | Abnormal, CS | 0 | 0 | 0 | 0 |
|  |  |  | Total | 5 (100) | 0 | 0 | 5 (100) |
|  | | | | | | | |
|  |  | Worst Post-Baseline | Normal | 5 (100) | 0 | 0 | 5 (100) |
|  |  |  | Abnormal, NCS | 0 | 0 | 0 | 0 |
|  |  |  | Abnormal, CS | 0 | 0 | 0 | 0 |
|  |  |  | Total | 5 (100) | 0 | 0 | 5 (100) |
|  | | | | | | | |
| Prothrombin Time | Treatment Group (N = 5) | Last Post-Baseline | Normal | 5 (100) | 0 | 0 | 5 (100) |
|  |  |  | Abnormal, NCS | 0 | 0 | 0 | 0 |
|  |  |  | Abnormal, CS | 0 | 0 | 0 | 0 |
|  |  |  | Total | 5 (100) | 0 | 0 | 5 (100) |
|  | | | | | | | |
|  |  | Worst Post-Baseline | Normal | 5 (100) | 0 | 0 | 5 (100) |
|  |  |  | Abnormal, NCS | 0 | 0 | 0 | 0 |
|  |  |  | Abnormal, CS | 0 | 0 | 0 | 0 |
|  |  |  | Total | 5 (100) | 0 | 0 | 5 (100) |
|  | | | | | | | |
|  | Control Group (N = 5) | Last Post-Baseline | Normal | 5 (100) | 0 | 0 | 5 (100) |
|  |  |  | Abnormal, NCS | 0 | 0 | 0 | 0 |
|  |  |  | Abnormal, CS | 0 | 0 | 0 | 0 |
|  |  |  | Total | 5 (100) | 0 | 0 | 5 (100) |
|  | | | | | | | |
|  |  | Worst Post-Baseline | Normal | 5 (100) | 0 | 0 | 5 (100) |
|  |  |  | Abnormal, NCS | 0 | 0 | 0 | 0 |
|  |  |  | Abnormal, CS | 0 | 0 | 0 | 0 |
|  |  |  | Total | 5 (100) | 0 | 0 | 5 (100) |
|  | | | | | | | |
| Prothrombin Intl. Normalized Ratio | Treatment Group (N = 5) | Last Post-Baseline | Normal | 5 (100) | 0 | 0 | 5 (100) |
|  |  |  | Abnormal, NCS | 0 | 0 | 0 | 0 |
|  |  |  | Abnormal, CS | 0 | 0 | 0 | 0 |
|  |  |  | Total | 5 (100) | 0 | 0 | 5 (100) |
|  | | | | | | | |
|  |  | Worst Post-Baseline | Normal | 5 (100) | 0 | 0 | 5 (100) |
|  |  |  | Abnormal, NCS | 0 | 0 | 0 | 0 |
|  |  |  | Abnormal, CS | 0 | 0 | 0 | 0 |
|  |  |  | Total | 5 (100) | 0 | 0 | 5 (100) |
|  | | | | | | | |
|  | Control Group (N = 5) | Last Post-Baseline | Normal | 5 (100) | 0 | 0 | 5 (100) |
|  |  |  | Abnormal, NCS | 0 | 0 | 0 | 0 |
|  |  |  | Abnormal, CS | 0 | 0 | 0 | 0 |
|  |  |  | Total | 5 (100) | 0 | 0 | 5 (100) |
|  | | | | | | | |
|  |  | Worst Post-Baseline | Normal | 5 (100) | 0 | 0 | 5 (100) |
|  |  |  | Abnormal, NCS | 0 | 0 | 0 | 0 |
|  |  |  | Abnormal, CS | 0 | 0 | 0 | 0 |
|  |  |  | Total | 5 (100) | 0 | 0 | 5 (100) |

Baseline is defined as the last available assessment before the first administration of investigational drug (D-1553 or IN10018).

Last post-baseline is the last value of investigator's assessment at all post-baseline visits, including any scheduled, unscheduled, EOT/early withdraw from the study and safety follow-up.

Worst post-baseline is the value of worst investigator's assessment at all post-baseline visits, including any scheduled, unscheduled, EOT/early withdraw from the study and safety follow-up.

Percentages are based on the number of subjects of each respective group in the Safety Analysis Set.

Source Data: Listing 16.2.8.4.1

|  |  |  |
| --- | --- | --- |
| Program: t-lb-shift.sas | DCO: 27APR2024 | Executed: 07JUL2024 20:50 |

|  |  |
| --- | --- |
| **InxMed (Shanghai) Co., Ltd.  Protocol No. IN10018-602** |  |

**Table 14.3.5.4.3 Summary of Subjects with At Least One Level Increase in CTCAE Grade by Abnormality - Phase II part 2 - CRC (Safety Analysis Set)**

|  | Treatment Group (N = 5) n (%) | Control Group (N = 5) n (%) | Total (N = 10) n (%) |
| --- | --- | --- | --- |
| Subjects with At Least One Level Increase in CTCAE Grade | 5 (100) | 5 (100) | 10 (100) |
|  | | | |
| Cholesterol high | 2 (40.0) | 2 (40.0) | 4 (40.0) |
| Alanine aminotransferase increased | 2 (40.0) | 1 (20.0) | 3 (30.0) |
| Aspartate aminotransferase increased | 1 (20.0) | 2 (40.0) | 3 (30.0) |
| Blood lactate dehydrogenase increased | 1 (20.0) | 2 (40.0) | 3 (30.0) |
| Hypokalemia | 2 (40.0) | 1 (20.0) | 3 (30.0) |
| Lymphocyte count decreased | 1 (20.0) | 2 (40.0) | 3 (30.0) |
| Anemia | 1 (20.0) | 1 (20.0) | 2 (20.0) |
| Eosinophilia | 2 (40.0) | 0 | 2 (20.0) |
| Hypertriglyceridemia | 1 (20.0) | 1 (20.0) | 2 (20.0) |
| Hypoalbuminemia | 2 (40.0) | 0 | 2 (20.0) |
| Neutrophil count decreased | 1 (20.0) | 1 (20.0) | 2 (20.0) |
| Platelet count decreased | 1 (20.0) | 1 (20.0) | 2 (20.0) |
| White blood cell decreased | 1 (20.0) | 1 (20.0) | 2 (20.0) |
| Activated partial thromboplastin time prolonged | 1 (20.0) | 0 | 1 (10.0) |
| Alkaline phosphatase increased | 1 (20.0) | 0 | 1 (10.0) |
| Blood bilirubin increased | 0 | 1 (20.0) | 1 (10.0) |
| CPK increased | 0 | 1 (20.0) | 1 (10.0) |
| Creatinine increased | 1 (20.0) | 0 | 1 (10.0) |
| GGT increased | 1 (20.0) | 0 | 1 (10.0) |
| Hypermagnesemia | 0 | 1 (20.0) | 1 (10.0) |
| Hyperuricemia | 1 (20.0) | 0 | 1 (10.0) |
| Hypocalcemia | 1 (20.0) | 0 | 1 (10.0) |
| Hypoglycemia | 0 | 1 (20.0) | 1 (10.0) |
| Hyponatremia | 1 (20.0) | 0 | 1 (10.0) |

Percentages are based on the number of subjects of each respective group in the Safety Analysis Set.

Source Data: Listing 16.2.8.5.1

|  |  |  |
| --- | --- | --- |
| Program: t-lb-ctcae-inc.sas | DCO: 27APR2024 | Executed: 07JUL2024 20:50 |

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| --- | --- |
| **InxMed (Shanghai) Co., Ltd.  Protocol No. IN10018-602** |  |

**Table 14.3.5.5.3 Summary of Subjects with At least One Abnormal Chemistry Result Related to Liver Function Abnormality - Phase II part 2 - CRC (Safety Analysis Set)**

|  | Treatment Group (N = 5) n (%) | Control Group (N = 5) n (%) | Total (N = 10) n (%) |
| --- | --- | --- | --- |
| Alanine Transaminase (ALT) |  |  |  |
| Subjects with non-missing value | 5 | 5 | 10 |
| ≥ 3×ULN | 0 | 0 | 0 |
|  | | | |
| Aspartate Transaminase (AST) |  |  |  |
| Subjects with non-missing value | 5 | 5 | 10 |
| ≥ 3×ULN | 0 | 0 | 0 |
|  | | | |
| ALT and/or AST |  |  |  |
| Subjects with non-missing value | 5 | 5 | 10 |
| ≥ 3×ULN | 0 | 0 | 0 |
|  | | | |
| ALT |  |  |  |
| Subjects with non-missing value | 5 | 5 | 10 |
| ≥ 8×ULN | 0 | 0 | 0 |
|  | | | |
| AST |  |  |  |
| Subjects with non-missing value | 5 | 5 | 10 |
| ≥ 8×ULN | 0 | 0 | 0 |
|  | | | |
| ALT and/or AST |  |  |  |
| Subjects with non-missing value | 5 | 5 | 10 |
| ≥ 8×ULN | 0 | 0 | 0 |
|  | | | |
| Total Bilirubin (TBIL) |  |  |  |
| Subjects with non-missing value | 5 | 5 | 10 |
| ≥ 2×ULN | 0 | 0 | 0 |
|  | | | |
| TBIL |  |  |  |
| Subjects with non-missing value | 5 | 5 | 10 |
| ≥ 3×ULN | 0 | 0 | 0 |

Percentages are based on the number of subjects of each respective group in the Safety Analysis Set.

Source Data: Listing 16.2.8.2.1, 16.2.8.2.2

|  |  |  |
| --- | --- | --- |
| Program: t-lb-liver.sas | DCO: 27APR2024 | Executed: 07JUL2024 20:50 |

|  |  |
| --- | --- |
| **InxMed (Shanghai) Co., Ltd.  Protocol No. IN10018-602** |  |

**Table 14.3.5.5.6 Summary of Subjects with At least One Abnormal Chemistry Result Related to Liver Function Abnormality in the Subjects with Relevent Normal Baseline - Phase II part 2 - CRC (Safety Analysis Set)**

|  | Treatment Group (N = 5) n (%) | Control Group (N = 5) n (%) | Total (N = 10) n (%) |
| --- | --- | --- | --- |
| Alanine Transaminase (ALT) |  |  |  |
| Subjects with non-missing value | 5 | 4 | 9 |
| ≥ 3×ULN | 0 | 0 | 0 |
|  | | | |
| Aspartate Transaminase (AST) |  |  |  |
| Subjects with non-missing value | 4 | 3 | 7 |
| ≥ 3×ULN | 0 | 0 | 0 |
|  | | | |
| ALT and/or AST |  |  |  |
| Subjects with non-missing value | 5 | 4 | 9 |
| ≥ 3×ULN | 0 | 0 | 0 |
|  | | | |
| ALT |  |  |  |
| Subjects with non-missing value | 5 | 4 | 9 |
| ≥ 8×ULN | 0 | 0 | 0 |
|  | | | |
| AST |  |  |  |
| Subjects with non-missing value | 4 | 3 | 7 |
| ≥ 8×ULN | 0 | 0 | 0 |
|  | | | |
| ALT and/or AST |  |  |  |
| Subjects with non-missing value | 5 | 4 | 9 |
| ≥ 8×ULN | 0 | 0 | 0 |
|  | | | |
| Total Bilirubin (TBIL) |  |  |  |
| Subjects with non-missing value | 5 | 4 | 9 |
| ≥ 2×ULN | 0 | 0 | 0 |
|  | | | |
| TBIL |  |  |  |
| Subjects with non-missing value | 5 | 4 | 9 |
| ≥ 3×ULN | 0 | 0 | 0 |

Percentages are based on the number of subjects who has a relevant normal baseline liver function of each respective group in the Safety Analysis Set.

Source Data: Listing 16.2.8.2.1, 16.2.8.2.2

|  |  |  |
| --- | --- | --- |
| Program: t-lb-liver.sas | DCO: 27APR2024 | Executed: 07JUL2024 20:50 |

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| --- | --- |
| **InxMed (Shanghai) Co., Ltd.  Protocol No. IN10018-602** |  |

**Table 14.3.5.5.9 Summary of Subjects with At least One Abnormal Chemistry Result Related to Liver Function Abnormality in the Subjects with Relevent Abnormal Baseline - Phase II part 2 - CRC (Safety Analysis Set)**

|  | Treatment Group (N = 5) n (%) | Control Group (N = 5) n (%) | Total (N = 10) n (%) |
| --- | --- | --- | --- |
| Alanine Transaminase (ALT) |  |  |  |
| Subjects with non-missing value | 0 | 1 | 1 |
| ≥ 3×ULN | 0 | 0 | 0 |
|  | | | |
| Aspartate Transaminase (AST) |  |  |  |
| Subjects with non-missing value | 1 | 2 | 3 |
| ≥ 3×ULN | 0 | 0 | 0 |
|  | | | |
| ALT and/or AST |  |  |  |
| Subjects with non-missing value | 1 | 2 | 3 |
| ≥ 3×ULN | 0 | 0 | 0 |
|  | | | |
| ALT |  |  |  |
| Subjects with non-missing value | 0 | 1 | 1 |
| ≥ 8×ULN | 0 | 0 | 0 |
|  | | | |
| AST |  |  |  |
| Subjects with non-missing value | 1 | 2 | 3 |
| ≥ 8×ULN | 0 | 0 | 0 |
|  | | | |
| ALT and/or AST |  |  |  |
| Subjects with non-missing value | 1 | 2 | 3 |
| ≥ 8×ULN | 0 | 0 | 0 |
|  | | | |
| Total Bilirubin (TBIL) |  |  |  |
| Subjects with non-missing value | 0 | 1 | 1 |
| ≥ 2×ULN | 0 | 0 | 0 |
|  | | | |
| TBIL |  |  |  |
| Subjects with non-missing value | 0 | 1 | 1 |
| ≥ 3×ULN | 0 | 0 | 0 |

Percentages are based on the number of subjects who has a relevant abnormal baseline liver function of each respective group in the Safety Analysis Set.

Source Data: Listing 16.2.8.2.1, 16.2.8.2.2

|  |  |  |
| --- | --- | --- |
| Program: t-lb-liver.sas | DCO: 27APR2024 | Executed: 07JUL2024 20:50 |

|  |  |
| --- | --- |
| **InxMed (Shanghai) Co., Ltd.  Protocol No. IN10018-602** |  |

**Table 14.3.6.3 Summary of Vital Sign Results - Phase II part 2 - CRC (Safety Analysis Set)**

|  | | | Observed Value | | | |  | Change from Baseline | | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Parameter | Group | Visit | n | Mean (STD) | Median (Q1, Q3) | Min, Max |  | n | Mean (STD) | Median (Q1, Q3) | Min, Max |
| Systolic Blood Pressure (mmHg) | Treatment Group (N = 5) | Baseline | 5 | 122.2 (9.23) | 118.0 (116.0, 130.0) | 113, 134 |  | 0 |  |  |  |
|  |  | C1D1 Postdose | 5 | 125.0 (13.10) | 121.0 (120.0, 121.0) | 115, 148 |  | 5 | 2.8 (11.39) | 3.0 (2.0, 5.0) | -14, 18 |
|  |  | C2D1 Predose | 4 | 115.0 (18.06) | 106.5 (105.0, 125.0) | 105, 142 |  | 4 | -8.8 (16.76) | -9.0 (-19.5, 2.0) | -29, 12 |
|  |  | C2D1 Postdose | 4 | 120.8 (13.25) | 116.5 (112.5, 129.0) | 110, 140 |  | 4 | -3.0 (14.99) | 1.0 (-13.5, 7.5) | -24, 10 |
|  |  | C3D1 Predose | 2 | 123.5 (4.95) | 123.5 (120.0, 127.0) | 120, 127 |  | 2 | 2.0 (7.07) | 2.0 (-3.0, 7.0) | -3, 7 |
|  |  | C3D1 Postdose | 2 | 119.0 (0.00) | 119.0 (119.0, 119.0) | 119, 119 |  | 2 | -2.5 (12.02) | -2.5 (-11.0, 6.0) | -11, 6 |
|  |  | C4D1 Predose | 2 | 116.0 (16.97) | 116.0 (104.0, 128.0) | 104, 128 |  | 2 | -5.5 (4.95) | -5.5 (-9.0, -2.0) | -9, -2 |
|  |  | C4D1 Postdose | 2 | 122.5 (4.95) | 122.5 (119.0, 126.0) | 119, 126 |  | 2 | 1.0 (16.97) | 1.0 (-11.0, 13.0) | -11, 13 |
|  |  | C5D1 Predose | 2 | 110.5 (7.78) | 110.5 (105.0, 116.0) | 105, 116 |  | 2 | -11.0 (4.24) | -11.0 (-14.0, -8.0) | -14, -8 |
|  |  | C5D1 Postdose | 2 | 106.5 (6.36) | 106.5 (102.0, 111.0) | 102, 111 |  | 2 | -15.0 (18.38) | -15.0 (-28.0, -2.0) | -28, -2 |
|  | | | | | | | | | | | |
|  | Control Group (N = 5) | Baseline | 5 | 117.2 (11.43) | 111.0 (110.0, 124.0) | 107, 134 |  | 0 |  |  |  |
|  |  | C1D1 Postdose | 5 | 118.2 (12.21) | 116.0 (116.0, 121.0) | 102, 136 |  | 5 | 1.0 (4.85) | 2.0 (-3.0, 5.0) | -5, 6 |
|  |  | C2D1 Predose | 4 | 126.5 (17.75) | 131.5 (113.5, 139.5) | 102, 141 |  | 4 | 6.8 (16.32) | 2.5 (-3.5, 17.0) | -8, 30 |
|  |  | C2D1 Postdose | 4 | 125.5 (13.96) | 128.5 (116.5, 134.5) | 106, 139 |  | 4 | 5.8 (15.20) | -0.5 (-4.0, 15.5) | -4, 28 |
|  |  | C3D1 Predose | 2 | 127.0 (12.73) | 127.0 (118.0, 136.0) | 118, 136 |  | 2 | 5.0 (29.70) | 5.0 (-16.0, 26.0) | -16, 26 |
|  |  | C3D1 Postdose | 2 | 132.5 (0.71) | 132.5 (132.0, 133.0) | 132, 133 |  | 2 | 10.5 (17.68) | 10.5 (-2.0, 23.0) | -2, 23 |
|  |  | C4D1 Predose | 1 | 118.0 (NA) | 118.0 (118.0, 118.0) | 118, 118 |  | 1 | 8.0 (NA) | 8.0 (8.0, 8.0) | 8, 8 |
|  |  | C4D1 Postdose | 1 | 119.0 (NA) | 119.0 (119.0, 119.0) | 119, 119 |  | 1 | 9.0 (NA) | 9.0 (9.0, 9.0) | 9, 9 |
|  |  | C5D1 Predose | 1 | 123.0 (NA) | 123.0 (123.0, 123.0) | 123, 123 |  | 1 | 13.0 (NA) | 13.0 (13.0, 13.0) | 13, 13 |
|  |  | C5D1 Postdose | 1 | 127.0 (NA) | 127.0 (127.0, 127.0) | 127, 127 |  | 1 | 17.0 (NA) | 17.0 (17.0, 17.0) | 17, 17 |
|  |  | End of Treatment | 1 | 133.0 (NA) | 133.0 (133.0, 133.0) | 133, 133 |  | 1 | 22.0 (NA) | 22.0 (22.0, 22.0) | 22, 22 |
|  | | | | | | | | | | | |
|  | Total (N = 10) | Baseline | 10 | 119.7 (10.14) | 117.0 (111.0, 130.0) | 107, 134 |  | 0 |  |  |  |
|  |  | C1D1 Postdose | 10 | 121.6 (12.47) | 120.5 (116.0, 121.0) | 102, 148 |  | 10 | 1.9 (8.31) | 2.5 (-3.0, 5.0) | -14, 18 |
|  |  | C2D1 Predose | 8 | 120.8 (17.68) | 116.5 (105.0, 139.5) | 102, 142 |  | 8 | -1.0 (17.41) | -3.5 (-9.0, 8.0) | -29, 30 |
|  |  | C2D1 Postdose | 8 | 123.1 (12.86) | 122.5 (112.5, 134.5) | 106, 140 |  | 8 | 1.4 (14.74) | 0.0 (-4.0, 7.5) | -24, 28 |
|  |  | C3D1 Predose | 4 | 125.3 (8.14) | 123.5 (119.0, 131.5) | 118, 136 |  | 4 | 3.5 (17.71) | 2.0 (-9.5, 16.5) | -16, 26 |
|  |  | C3D1 Postdose | 4 | 125.8 (7.80) | 125.5 (119.0, 132.5) | 119, 133 |  | 4 | 4.0 (14.45) | 2.0 (-6.5, 14.5) | -11, 23 |
|  |  | C4D1 Predose | 3 | 116.7 (12.06) | 118.0 (104.0, 128.0) | 104, 128 |  | 3 | -1.0 (8.54) | -2.0 (-9.0, 8.0) | -9, 8 |
|  |  | C4D1 Postdose | 3 | 121.3 (4.04) | 119.0 (119.0, 126.0) | 119, 126 |  | 3 | 3.7 (12.86) | 9.0 (-11.0, 13.0) | -11, 13 |
|  |  | C5D1 Predose | 3 | 114.7 (9.07) | 116.0 (105.0, 123.0) | 105, 123 |  | 3 | -3.0 (14.18) | -8.0 (-14.0, 13.0) | -14, 13 |
|  |  | C5D1 Postdose | 3 | 113.3 (12.66) | 111.0 (102.0, 127.0) | 102, 127 |  | 3 | -4.3 (22.59) | -2.0 (-28.0, 17.0) | -28, 17 |
|  |  | End of Treatment | 1 | 133.0 (NA) | 133.0 (133.0, 133.0) | 133, 133 |  | 1 | 22.0 (NA) | 22.0 (22.0, 22.0) | 22, 22 |
|  | | | | | | | | | | | |
| Diastolic Blood Pressure (mmHg) | Treatment Group (N = 5) | Baseline | 5 | 83.0 (7.97) | 82.0 (77.0, 89.0) | 74, 93 |  | 0 |  |  |  |
|  |  | C1D1 Postdose | 5 | 80.6 (5.68) | 82.0 (81.0, 83.0) | 71, 86 |  | 5 | -2.4 (7.40) | -3.0 (-6.0, -1.0) | -11, 9 |
|  |  | C2D1 Predose | 4 | 76.3 (14.06) | 71.0 (68.0, 84.5) | 66, 97 |  | 4 | -9.0 (14.35) | -8.5 (-18.5, 0.5) | -27, 8 |
|  |  | C2D1 Postdose | 4 | 79.8 (15.78) | 73.5 (70.0, 89.5) | 69, 103 |  | 4 | -5.5 (15.52) | -6.0 (-15.0, 4.0) | -24, 14 |
|  |  | C3D1 Predose | 2 | 75.5 (14.85) | 75.5 (65.0, 86.0) | 65, 86 |  | 2 | -7.5 (6.36) | -7.5 (-12.0, -3.0) | -12, -3 |
|  |  | C3D1 Postdose | 2 | 72.0 (9.90) | 72.0 (65.0, 79.0) | 65, 79 |  | 2 | -11.0 (1.41) | -11.0 (-12.0, -10.0) | -12, -10 |
|  |  | C4D1 Predose | 2 | 73.0 (9.90) | 73.0 (66.0, 80.0) | 66, 80 |  | 2 | -10.0 (1.41) | -10.0 (-11.0, -9.0) | -11, -9 |
|  |  | C4D1 Postdose | 2 | 80.0 (8.49) | 80.0 (74.0, 86.0) | 74, 86 |  | 2 | -3.0 (0.00) | -3.0 (-3.0, -3.0) | -3, -3 |
|  |  | C5D1 Predose | 2 | 70.0 (7.07) | 70.0 (65.0, 75.0) | 65, 75 |  | 2 | -13.0 (1.41) | -13.0 (-14.0, -12.0) | -14, -12 |
|  |  | C5D1 Postdose | 2 | 82.0 (8.49) | 82.0 (76.0, 88.0) | 76, 88 |  | 2 | -1.0 (0.00) | -1.0 (-1.0, -1.0) | -1, -1 |
|  | | | | | | | | | | | |
|  | Control Group (N = 5) | Baseline | 5 | 74.4 (7.44) | 70.0 (69.0, 82.0) | 68, 83 |  | 0 |  |  |  |
|  |  | C1D1 Postdose | 5 | 74.8 (7.50) | 78.0 (69.0, 79.0) | 65, 83 |  | 5 | 0.4 (4.93) | 1.0 (-4.0, 1.0) | -4, 8 |
|  |  | C2D1 Predose | 4 | 79.0 (6.48) | 80.5 (74.5, 83.5) | 70, 85 |  | 4 | 3.3 (8.10) | 0.5 (-2.0, 8.5) | -3, 15 |
|  |  | C2D1 Postdose | 4 | 77.5 (7.05) | 78.0 (71.5, 83.5) | 70, 84 |  | 4 | 1.8 (9.00) | 1.5 (-4.0, 7.5) | -9, 13 |
|  |  | C3D1 Predose | 2 | 74.5 (7.78) | 74.5 (69.0, 80.0) | 69, 80 |  | 2 | -0.5 (17.68) | -0.5 (-13.0, 12.0) | -13, 12 |
|  |  | C3D1 Postdose | 2 | 74.0 (2.83) | 74.0 (72.0, 76.0) | 72, 76 |  | 2 | -1.0 (12.73) | -1.0 (-10.0, 8.0) | -10, 8 |
|  |  | C4D1 Predose | 1 | 71.0 (NA) | 71.0 (71.0, 71.0) | 71, 71 |  | 1 | 3.0 (NA) | 3.0 (3.0, 3.0) | 3, 3 |
|  |  | C4D1 Postdose | 1 | 73.0 (NA) | 73.0 (73.0, 73.0) | 73, 73 |  | 1 | 5.0 (NA) | 5.0 (5.0, 5.0) | 5, 5 |
|  |  | C5D1 Predose | 1 | 78.0 (NA) | 78.0 (78.0, 78.0) | 78, 78 |  | 1 | 10.0 (NA) | 10.0 (10.0, 10.0) | 10, 10 |
|  |  | C5D1 Postdose | 1 | 79.0 (NA) | 79.0 (79.0, 79.0) | 79, 79 |  | 1 | 11.0 (NA) | 11.0 (11.0, 11.0) | 11, 11 |
|  |  | End of Treatment | 1 | 83.0 (NA) | 83.0 (83.0, 83.0) | 83, 83 |  | 1 | 13.0 (NA) | 13.0 (13.0, 13.0) | 13, 13 |
|  | | | | | | | | | | | |
|  | Total (N = 10) | Baseline | 10 | 78.7 (8.56) | 79.5 (70.0, 83.0) | 68, 93 |  | 0 |  |  |  |
|  |  | C1D1 Postdose | 10 | 77.7 (6.98) | 80.0 (71.0, 83.0) | 65, 86 |  | 10 | -1.0 (6.11) | -2.0 (-4.0, 1.0) | -11, 9 |
|  |  | C2D1 Predose | 8 | 77.6 (10.24) | 75.5 (70.0, 83.5) | 66, 97 |  | 8 | -2.9 (12.62) | -2.0 (-8.5, 5.0) | -27, 15 |
|  |  | C2D1 Postdose | 8 | 78.6 (11.38) | 74.5 (70.5, 83.5) | 69, 103 |  | 8 | -1.9 (12.37) | -2.5 (-7.5, 7.5) | -24, 14 |
|  |  | C3D1 Predose | 4 | 75.0 (9.70) | 74.5 (67.0, 83.0) | 65, 86 |  | 4 | -4.0 (11.58) | -7.5 (-12.5, 4.5) | -13, 12 |
|  |  | C3D1 Postdose | 4 | 73.0 (6.06) | 74.0 (68.5, 77.5) | 65, 79 |  | 4 | -6.0 (9.38) | -10.0 (-11.0, -1.0) | -12, 8 |
|  |  | C4D1 Predose | 3 | 72.3 (7.09) | 71.0 (66.0, 80.0) | 66, 80 |  | 3 | -5.7 (7.57) | -9.0 (-11.0, 3.0) | -11, 3 |
|  |  | C4D1 Postdose | 3 | 77.7 (7.23) | 74.0 (73.0, 86.0) | 73, 86 |  | 3 | -0.3 (4.62) | -3.0 (-3.0, 5.0) | -3, 5 |
|  |  | C5D1 Predose | 3 | 72.7 (6.81) | 75.0 (65.0, 78.0) | 65, 78 |  | 3 | -5.3 (13.32) | -12.0 (-14.0, 10.0) | -14, 10 |
|  |  | C5D1 Postdose | 3 | 81.0 (6.24) | 79.0 (76.0, 88.0) | 76, 88 |  | 3 | 3.0 (6.93) | -1.0 (-1.0, 11.0) | -1, 11 |
|  |  | End of Treatment | 1 | 83.0 (NA) | 83.0 (83.0, 83.0) | 83, 83 |  | 1 | 13.0 (NA) | 13.0 (13.0, 13.0) | 13, 13 |
|  | | | | | | | | | | | |
| Pulse Rate (beats/min) | Treatment Group (N = 5) | Baseline | 5 | 80.6 (11.15) | 84.0 (77.0, 88.0) | 63, 91 |  | 0 |  |  |  |
|  |  | C1D1 Postdose | 5 | 79.6 (11.13) | 83.0 (79.0, 85.0) | 61, 90 |  | 5 | -1.0 (1.87) | -1.0 (-2.0, -1.0) | -3, 2 |
|  |  | C2D1 Predose | 4 | 77.0 (11.20) | 79.0 (68.0, 86.0) | 63, 87 |  | 4 | -1.0 (10.17) | 0.0 (-8.5, 6.5) | -14, 10 |
|  |  | C2D1 Postdose | 4 | 79.0 (11.22) | 79.5 (71.0, 87.0) | 65, 92 |  | 4 | 1.0 (12.06) | 1.0 (-9.0, 11.0) | -12, 14 |
|  |  | C3D1 Predose | 2 | 78.5 (2.12) | 78.5 (77.0, 80.0) | 77, 80 |  | 2 | 5.0 (12.73) | 5.0 (-4.0, 14.0) | -4, 14 |
|  |  | C3D1 Postdose | 2 | 78.5 (0.71) | 78.5 (78.0, 79.0) | 78, 79 |  | 2 | 5.0 (15.56) | 5.0 (-6.0, 16.0) | -6, 16 |
|  |  | C4D1 Predose | 2 | 76.5 (13.44) | 76.5 (67.0, 86.0) | 67, 86 |  | 2 | 3.0 (1.41) | 3.0 (2.0, 4.0) | 2, 4 |
|  |  | C4D1 Postdose | 2 | 76.5 (7.78) | 76.5 (71.0, 82.0) | 71, 82 |  | 2 | 3.0 (7.07) | 3.0 (-2.0, 8.0) | -2, 8 |
|  |  | C5D1 Predose | 2 | 86.0 (18.38) | 86.0 (73.0, 99.0) | 73, 99 |  | 2 | 12.5 (3.54) | 12.5 (10.0, 15.0) | 10, 15 |
|  |  | C5D1 Postdose | 2 | 85.0 (18.38) | 85.0 (72.0, 98.0) | 72, 98 |  | 2 | 11.5 (3.54) | 11.5 (9.0, 14.0) | 9, 14 |
|  | | | | | | | | | | | |
|  | Control Group (N = 5) | Baseline | 5 | 81.6 (3.78) | 82.0 (80.0, 85.0) | 76, 85 |  | 0 |  |  |  |
|  |  | C1D1 Postdose | 5 | 81.0 (5.05) | 84.0 (79.0, 84.0) | 73, 85 |  | 5 | -0.6 (2.88) | -1.0 (-3.0, 0.0) | -3, 4 |
|  |  | C2D1 Predose | 4 | 83.5 (2.38) | 83.5 (81.5, 85.5) | 81, 86 |  | 4 | 0.5 (3.11) | 1.5 (-1.5, 2.5) | -4, 3 |
|  |  | C2D1 Postdose | 4 | 85.8 (2.22) | 86.0 (84.0, 87.5) | 83, 88 |  | 4 | 2.8 (3.30) | 4.0 (0.5, 5.0) | -2, 5 |
|  |  | C3D1 Predose | 2 | 89.0 (1.41) | 89.0 (88.0, 90.0) | 88, 90 |  | 2 | 6.5 (4.95) | 6.5 (3.0, 10.0) | 3, 10 |
|  |  | C3D1 Postdose | 2 | 87.5 (3.54) | 87.5 (85.0, 90.0) | 85, 90 |  | 2 | 5.0 (7.07) | 5.0 (0.0, 10.0) | 0, 10 |
|  |  | C4D1 Predose | 1 | 82.0 (NA) | 82.0 (82.0, 82.0) | 82, 82 |  | 1 | -3.0 (NA) | -3.0 (-3.0, -3.0) | -3, -3 |
|  |  | C4D1 Postdose | 1 | 86.0 (NA) | 86.0 (86.0, 86.0) | 86, 86 |  | 1 | 1.0 (NA) | 1.0 (1.0, 1.0) | 1, 1 |
|  |  | C5D1 Predose | 1 | 89.0 (NA) | 89.0 (89.0, 89.0) | 89, 89 |  | 1 | 4.0 (NA) | 4.0 (4.0, 4.0) | 4, 4 |
|  |  | C5D1 Postdose | 1 | 88.0 (NA) | 88.0 (88.0, 88.0) | 88, 88 |  | 1 | 3.0 (NA) | 3.0 (3.0, 3.0) | 3, 3 |
|  |  | End of Treatment | 1 | 103.0 (NA) | 103.0 (103.0, 103.0) | 103, 103 |  | 1 | 18.0 (NA) | 18.0 (18.0, 18.0) | 18, 18 |
|  | | | | | | | | | | | |
|  | Total (N = 10) | Baseline | 10 | 81.1 (7.87) | 83.0 (77.0, 85.0) | 63, 91 |  | 0 |  |  |  |
|  |  | C1D1 Postdose | 10 | 80.3 (8.18) | 83.5 (79.0, 85.0) | 61, 90 |  | 10 | -0.8 (2.30) | -1.0 (-3.0, 0.0) | -3, 4 |
|  |  | C2D1 Predose | 8 | 80.3 (8.26) | 83.5 (77.0, 85.5) | 63, 87 |  | 8 | -0.3 (7.01) | 1.5 (-3.5, 3.0) | -14, 10 |
|  |  | C2D1 Postdose | 8 | 82.4 (8.31) | 84.0 (79.5, 87.5) | 65, 92 |  | 8 | 1.9 (8.24) | 4.0 (-4.0, 6.5) | -12, 14 |
|  |  | C3D1 Predose | 4 | 83.8 (6.24) | 84.0 (78.5, 89.0) | 77, 90 |  | 4 | 5.8 (7.93) | 6.5 (-0.5, 12.0) | -4, 14 |
|  |  | C3D1 Postdose | 4 | 83.0 (5.60) | 82.0 (78.5, 87.5) | 78, 90 |  | 4 | 5.0 (9.87) | 5.0 (-3.0, 13.0) | -6, 16 |
|  |  | C4D1 Predose | 3 | 78.3 (10.02) | 82.0 (67.0, 86.0) | 67, 86 |  | 3 | 1.0 (3.61) | 2.0 (-3.0, 4.0) | -3, 4 |
|  |  | C4D1 Postdose | 3 | 79.7 (7.77) | 82.0 (71.0, 86.0) | 71, 86 |  | 3 | 2.3 (5.13) | 1.0 (-2.0, 8.0) | -2, 8 |
|  |  | C5D1 Predose | 3 | 87.0 (13.11) | 89.0 (73.0, 99.0) | 73, 99 |  | 3 | 9.7 (5.51) | 10.0 (4.0, 15.0) | 4, 15 |
|  |  | C5D1 Postdose | 3 | 86.0 (13.11) | 88.0 (72.0, 98.0) | 72, 98 |  | 3 | 8.7 (5.51) | 9.0 (3.0, 14.0) | 3, 14 |
|  |  | End of Treatment | 1 | 103.0 (NA) | 103.0 (103.0, 103.0) | 103, 103 |  | 1 | 18.0 (NA) | 18.0 (18.0, 18.0) | 18, 18 |
|  | | | | | | | | | | | |
| Respiratory Rate (breaths/min) | Treatment Group (N = 5) | Baseline | 5 | 18.4 (0.89) | 18.0 (18.0, 18.0) | 18, 20 |  | 0 |  |  |  |
|  |  | C1D1 Postdose | 5 | 18.6 (0.89) | 18.0 (18.0, 19.0) | 18, 20 |  | 5 | 0.2 (0.45) | 0.0 (0.0, 0.0) | 0, 1 |
|  |  | C2D1 Predose | 4 | 17.8 (0.50) | 18.0 (17.5, 18.0) | 17, 18 |  | 4 | -0.3 (0.50) | 0.0 (-0.5, 0.0) | -1, 0 |
|  |  | C2D1 Postdose | 4 | 18.0 (1.41) | 18.5 (17.0, 19.0) | 16, 19 |  | 4 | 0.0 (1.41) | 0.5 (-1.0, 1.0) | -2, 1 |
|  |  | C3D1 Predose | 2 | 19.0 (0.00) | 19.0 (19.0, 19.0) | 19, 19 |  | 2 | 1.0 (0.00) | 1.0 (1.0, 1.0) | 1, 1 |
|  |  | C3D1 Postdose | 2 | 17.5 (0.71) | 17.5 (17.0, 18.0) | 17, 18 |  | 2 | -0.5 (0.71) | -0.5 (-1.0, 0.0) | -1, 0 |
|  |  | C4D1 Predose | 2 | 18.0 (0.00) | 18.0 (18.0, 18.0) | 18, 18 |  | 2 | 0.0 (0.00) | 0.0 (0.0, 0.0) | 0, 0 |
|  |  | C4D1 Postdose | 2 | 17.0 (0.00) | 17.0 (17.0, 17.0) | 17, 17 |  | 2 | -1.0 (0.00) | -1.0 (-1.0, -1.0) | -1, -1 |
|  |  | C5D1 Predose | 2 | 18.0 (0.00) | 18.0 (18.0, 18.0) | 18, 18 |  | 2 | 0.0 (0.00) | 0.0 (0.0, 0.0) | 0, 0 |
|  |  | C5D1 Postdose | 2 | 17.5 (0.71) | 17.5 (17.0, 18.0) | 17, 18 |  | 2 | -0.5 (0.71) | -0.5 (-1.0, 0.0) | -1, 0 |
|  | | | | | | | | | | | |
|  | Control Group (N = 5) | Baseline | 5 | 18.4 (0.89) | 18.0 (18.0, 18.0) | 18, 20 |  | 0 |  |  |  |
|  |  | C1D1 Postdose | 5 | 18.4 (1.14) | 18.0 (18.0, 19.0) | 17, 20 |  | 5 | 0.0 (0.71) | 0.0 (0.0, 0.0) | -1, 1 |
|  |  | C2D1 Predose | 4 | 17.8 (0.96) | 17.5 (17.0, 18.5) | 17, 19 |  | 4 | -0.3 (0.96) | -0.5 (-1.0, 0.5) | -1, 1 |
|  |  | C2D1 Postdose | 4 | 18.0 (0.00) | 18.0 (18.0, 18.0) | 18, 18 |  | 4 | 0.0 (0.00) | 0.0 (0.0, 0.0) | 0, 0 |
|  |  | C3D1 Predose | 2 | 18.0 (0.00) | 18.0 (18.0, 18.0) | 18, 18 |  | 2 | 0.0 (0.00) | 0.0 (0.0, 0.0) | 0, 0 |
|  |  | C3D1 Postdose | 2 | 17.0 (0.00) | 17.0 (17.0, 17.0) | 17, 17 |  | 2 | -1.0 (0.00) | -1.0 (-1.0, -1.0) | -1, -1 |
|  |  | C4D1 Predose | 1 | 17.0 (NA) | 17.0 (17.0, 17.0) | 17, 17 |  | 1 | -1.0 (NA) | -1.0 (-1.0, -1.0) | -1, -1 |
|  |  | C4D1 Postdose | 1 | 18.0 (NA) | 18.0 (18.0, 18.0) | 18, 18 |  | 1 | 0.0 (NA) | 0.0 (0.0, 0.0) | 0, 0 |
|  |  | C5D1 Predose | 1 | 17.0 (NA) | 17.0 (17.0, 17.0) | 17, 17 |  | 1 | -1.0 (NA) | -1.0 (-1.0, -1.0) | -1, -1 |
|  |  | C5D1 Postdose | 1 | 17.0 (NA) | 17.0 (17.0, 17.0) | 17, 17 |  | 1 | -1.0 (NA) | -1.0 (-1.0, -1.0) | -1, -1 |
|  |  | End of Treatment | 1 | 20.0 (NA) | 20.0 (20.0, 20.0) | 20, 20 |  | 1 | 2.0 (NA) | 2.0 (2.0, 2.0) | 2, 2 |
|  | | | | | | | | | | | |
|  | Total (N = 10) | Baseline | 10 | 18.4 (0.84) | 18.0 (18.0, 18.0) | 18, 20 |  | 0 |  |  |  |
|  |  | C1D1 Postdose | 10 | 18.5 (0.97) | 18.0 (18.0, 19.0) | 17, 20 |  | 10 | 0.1 (0.57) | 0.0 (0.0, 0.0) | -1, 1 |
|  |  | C2D1 Predose | 8 | 17.8 (0.71) | 18.0 (17.0, 18.0) | 17, 19 |  | 8 | -0.3 (0.71) | 0.0 (-1.0, 0.0) | -1, 1 |
|  |  | C2D1 Postdose | 8 | 18.0 (0.93) | 18.0 (18.0, 18.5) | 16, 19 |  | 8 | 0.0 (0.93) | 0.0 (0.0, 0.5) | -2, 1 |
|  |  | C3D1 Predose | 4 | 18.5 (0.58) | 18.5 (18.0, 19.0) | 18, 19 |  | 4 | 0.5 (0.58) | 0.5 (0.0, 1.0) | 0, 1 |
|  |  | C3D1 Postdose | 4 | 17.3 (0.50) | 17.0 (17.0, 17.5) | 17, 18 |  | 4 | -0.8 (0.50) | -1.0 (-1.0, -0.5) | -1, 0 |
|  |  | C4D1 Predose | 3 | 17.7 (0.58) | 18.0 (17.0, 18.0) | 17, 18 |  | 3 | -0.3 (0.58) | 0.0 (-1.0, 0.0) | -1, 0 |
|  |  | C4D1 Postdose | 3 | 17.3 (0.58) | 17.0 (17.0, 18.0) | 17, 18 |  | 3 | -0.7 (0.58) | -1.0 (-1.0, 0.0) | -1, 0 |
|  |  | C5D1 Predose | 3 | 17.7 (0.58) | 18.0 (17.0, 18.0) | 17, 18 |  | 3 | -0.3 (0.58) | 0.0 (-1.0, 0.0) | -1, 0 |
|  |  | C5D1 Postdose | 3 | 17.3 (0.58) | 17.0 (17.0, 18.0) | 17, 18 |  | 3 | -0.7 (0.58) | -1.0 (-1.0, 0.0) | -1, 0 |
|  |  | End of Treatment | 1 | 20.0 (NA) | 20.0 (20.0, 20.0) | 20, 20 |  | 1 | 2.0 (NA) | 2.0 (2.0, 2.0) | 2, 2 |
|  | | | | | | | | | | | |
| Temperature (C) | Treatment Group (N = 5) | Baseline | 5 | 36.62 (0.432) | 36.60 (36.30, 37.00) | 36.1, 37.1 |  | 0 |  |  |  |
|  |  | C1D1 Postdose | 5 | 36.66 (0.385) | 36.80 (36.30, 37.00) | 36.2, 37.0 |  | 5 | 0.04 (0.114) | 0.00 (0.00, 0.10) | -0.1, 0.2 |
|  |  | C2D1 Predose | 4 | 36.85 (0.520) | 36.90 (36.45, 37.25) | 36.2, 37.4 |  | 4 | 0.15 (0.404) | 0.25 (-0.15, 0.45) | -0.4, 0.5 |
|  |  | C2D1 Postdose | 4 | 36.85 (0.342) | 36.90 (36.60, 37.10) | 36.4, 37.2 |  | 4 | 0.15 (0.311) | 0.25 (-0.05, 0.35) | -0.3, 0.4 |
|  |  | C3D1 Predose | 2 | 36.90 (0.283) | 36.90 (36.70, 37.10) | 36.7, 37.1 |  | 2 | 0.10 (0.000) | 0.10 (0.10, 0.10) | 0.1, 0.1 |
|  |  | C3D1 Postdose | 2 | 36.75 (0.071) | 36.75 (36.70, 36.80) | 36.7, 36.8 |  | 2 | -0.05 (0.354) | -0.05 (-0.30, 0.20) | -0.3, 0.2 |
|  |  | C4D1 Predose | 2 | 36.65 (0.071) | 36.65 (36.60, 36.70) | 36.6, 36.7 |  | 2 | -0.15 (0.212) | -0.15 (-0.30, 0.00) | -0.3, 0.0 |
|  |  | C4D1 Postdose | 2 | 36.60 (0.000) | 36.60 (36.60, 36.60) | 36.6, 36.6 |  | 2 | -0.20 (0.283) | -0.20 (-0.40, 0.00) | -0.4, 0.0 |
|  |  | C5D1 Predose | 2 | 36.75 (0.212) | 36.75 (36.60, 36.90) | 36.6, 36.9 |  | 2 | -0.05 (0.071) | -0.05 (-0.10, 0.00) | -0.1, 0.0 |
|  |  | C5D1 Postdose | 2 | 36.45 (0.071) | 36.45 (36.40, 36.50) | 36.4, 36.5 |  | 2 | -0.35 (0.354) | -0.35 (-0.60, -0.10) | -0.6, -0.1 |
|  | | | | | | | | | | | |
|  | Control Group (N = 5) | Baseline | 5 | 36.58 (0.356) | 36.50 (36.30, 36.90) | 36.2, 37.0 |  | 0 |  |  |  |
|  |  | C1D1 Postdose | 5 | 36.70 (0.374) | 36.50 (36.40, 37.00) | 36.4, 37.2 |  | 5 | 0.12 (0.084) | 0.10 (0.10, 0.20) | 0.0, 0.2 |
|  |  | C2D1 Predose | 4 | 36.75 (0.436) | 36.85 (36.40, 37.10) | 36.2, 37.1 |  | 4 | 0.10 (0.082) | 0.10 (0.05, 0.15) | 0.0, 0.2 |
|  |  | C2D1 Postdose | 4 | 36.75 (0.465) | 36.65 (36.45, 37.05) | 36.3, 37.4 |  | 4 | 0.10 (0.245) | 0.10 (-0.05, 0.25) | -0.2, 0.4 |
|  |  | C3D1 Predose | 2 | 37.05 (0.212) | 37.05 (36.90, 37.20) | 36.9, 37.2 |  | 2 | 0.10 (0.141) | 0.10 (0.00, 0.20) | 0.0, 0.2 |
|  |  | C3D1 Postdose | 2 | 37.00 (0.141) | 37.00 (36.90, 37.10) | 36.9, 37.1 |  | 2 | 0.05 (0.071) | 0.05 (0.00, 0.10) | 0.0, 0.1 |
|  |  | C4D1 Predose | 1 | 36.80 (NA) | 36.80 (36.80, 36.80) | 36.8, 36.8 |  | 1 | -0.10 (NA) | -0.10 (-0.10, -0.10) | -0.1, -0.1 |
|  |  | C4D1 Postdose | 1 | 37.10 (NA) | 37.10 (37.10, 37.10) | 37.1, 37.1 |  | 1 | 0.20 (NA) | 0.20 (0.20, 0.20) | 0.2, 0.2 |
|  |  | C5D1 Predose | 1 | 37.20 (NA) | 37.20 (37.20, 37.20) | 37.2, 37.2 |  | 1 | 0.30 (NA) | 0.30 (0.30, 0.30) | 0.3, 0.3 |
|  |  | C5D1 Postdose | 1 | 37.10 (NA) | 37.10 (37.10, 37.10) | 37.1, 37.1 |  | 1 | 0.20 (NA) | 0.20 (0.20, 0.20) | 0.2, 0.2 |
|  |  | End of Treatment | 1 | 37.30 (NA) | 37.30 (37.30, 37.30) | 37.3, 37.3 |  | 1 | 0.80 (NA) | 0.80 (0.80, 0.80) | 0.8, 0.8 |
|  | | | | | | | | | | | |
|  | Total (N = 10) | Baseline | 10 | 36.60 (0.374) | 36.55 (36.30, 37.00) | 36.1, 37.1 |  | 0 |  |  |  |
|  |  | C1D1 Postdose | 10 | 36.68 (0.358) | 36.65 (36.40, 37.00) | 36.2, 37.2 |  | 10 | 0.08 (0.103) | 0.10 (0.00, 0.20) | -0.1, 0.2 |
|  |  | C2D1 Predose | 8 | 36.80 (0.447) | 36.90 (36.40, 37.10) | 36.2, 37.4 |  | 8 | 0.13 (0.271) | 0.10 (0.05, 0.30) | -0.4, 0.5 |
|  |  | C2D1 Postdose | 8 | 36.80 (0.382) | 36.75 (36.50, 37.10) | 36.3, 37.4 |  | 8 | 0.13 (0.260) | 0.15 (-0.05, 0.35) | -0.3, 0.4 |
|  |  | C3D1 Predose | 4 | 36.98 (0.222) | 37.00 (36.80, 37.15) | 36.7, 37.2 |  | 4 | 0.10 (0.082) | 0.10 (0.05, 0.15) | 0.0, 0.2 |
|  |  | C3D1 Postdose | 4 | 36.88 (0.171) | 36.85 (36.75, 37.00) | 36.7, 37.1 |  | 4 | 0.00 (0.216) | 0.05 (-0.15, 0.15) | -0.3, 0.2 |
|  |  | C4D1 Predose | 3 | 36.70 (0.100) | 36.70 (36.60, 36.80) | 36.6, 36.8 |  | 3 | -0.13 (0.153) | -0.10 (-0.30, 0.00) | -0.3, 0.0 |
|  |  | C4D1 Postdose | 3 | 36.77 (0.289) | 36.60 (36.60, 37.10) | 36.6, 37.1 |  | 3 | -0.07 (0.306) | 0.00 (-0.40, 0.20) | -0.4, 0.2 |
|  |  | C5D1 Predose | 3 | 36.90 (0.300) | 36.90 (36.60, 37.20) | 36.6, 37.2 |  | 3 | 0.07 (0.208) | 0.00 (-0.10, 0.30) | -0.1, 0.3 |
|  |  | C5D1 Postdose | 3 | 36.67 (0.379) | 36.50 (36.40, 37.10) | 36.4, 37.1 |  | 3 | -0.17 (0.404) | -0.10 (-0.60, 0.20) | -0.6, 0.2 |
|  |  | End of Treatment | 1 | 37.30 (NA) | 37.30 (37.30, 37.30) | 37.3, 37.3 |  | 1 | 0.80 (NA) | 0.80 (0.80, 0.80) | 0.8, 0.8 |

NA = Not applicable.

Baseline is defined as the last available assessment before the first administration of investigational drug (D-1553 or IN10018).

Only subjects with data at both baseline and the relevant post baseline visit are included in the change from baseline summary statistics.

Source Data: Listing 16.2.9

|  |  |  |
| --- | --- | --- |
| Program: t-vs-chg.sas | DCO: 27APR2024 | Executed: 07JUL2024 20:52 |

|  |  |
| --- | --- |
| **InxMed (Shanghai) Co., Ltd.  Protocol No. IN10018-602** |  |

**Table 14.3.7.3 Summary of Shifts from Baseline to Last/Worst Post-baseline in ECOG Assessment - Phase II part 2 - CRC (Safety Analysis Set)**

|  | | | Post-baseline | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Group | Visit | Baseline | 0 | 1 | 2 |  | 3 | 4 | Missing | Total |
| Treatment Group (N = 5) | Last Post-Baseline | 1 | 0 | 4 (80.0) | 0 |  | 0 | 0 | 1 (20.0) | 5 (100) |
|  |  | Total | 0 | 4 (80.0) | 0 |  | 0 | 0 | 1 (20.0) | 5 (100) |
|  | | | | | | | | | | |
|  | Worst Post-Baseline | 1 | 0 | 4 (80.0) | 0 |  | 0 | 0 | 1 (20.0) | 5 (100) |
|  |  | Total | 0 | 4 (80.0) | 0 |  | 0 | 0 | 1 (20.0) | 5 (100) |
|  | | | | | | | | | | |
| Control Group (N = 5) | Last Post-Baseline | 1 | 0 | 4 (80.0) | 0 |  | 0 | 0 | 1 (20.0) | 5 (100) |
|  |  | Total | 0 | 4 (80.0) | 0 |  | 0 | 0 | 1 (20.0) | 5 (100) |
|  | | | | | | | | | | |
|  | Worst Post-Baseline | 1 | 0 | 4 (80.0) | 0 |  | 0 | 0 | 1 (20.0) | 5 (100) |
|  |  | Total | 0 | 4 (80.0) | 0 |  | 0 | 0 | 1 (20.0) | 5 (100) |

Baseline is defined as the last available assessment before the first administration of investigational drug (D-1553 or IN10018).

Last post-baseline is the last value of ECOG at all post-baseline visits, including any scheduled, unscheduled, EOT/early withdraw from the study and safety follow-up.

Worst post-baseline is the value of worst ECOG at all post-baseline visits, including any scheduled, unscheduled, EOT/early withdraw from the study and safety follow-up.

Percentages are based on the number of subjects of each respective group in the Safety Analysis Set.

Source Data: Listing 16.2.10

|  |  |  |
| --- | --- | --- |
| Program: t-rs-ecog-shift.sas | DCO: 27APR2024 | Executed: 07JUL2024 20:52 |

|  |  |
| --- | --- |
| **InxMed (Shanghai) Co., Ltd.  Protocol No. IN10018-602** |  |

**Table 14.3.8.1.3 Summary of 12-Lead ECG Parameters - Phase II part 2 - CRC (Safety Analysis Set)**

|  | | | Observed Value | | | |  | Change from Baseline | | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Parameter | Group | Visit | n | Mean (STD) | Median (Q1, Q3) | Min, Max |  | n | Mean (STD) | Median (Q1, Q3) | Min, Max |
| Heart Rate (beats/min) | Treatment Group (N = 5) | Baseline | 5 | 73.6 (16.27) | 77.0 (67.0, 85.0) | 49, 90 |  | 0 |  |  |  |
|  |  | C1D1 | 5 | 67.8 (9.91) | 68.0 (59.0, 72.0) | 58, 82 |  | 5 | -5.8 (9.04) | -9.0 (-9.0, -8.0) | -13, 10 |
|  |  | C1D8 | 5 | 66.4 (14.43) | 61.0 (54.0, 77.0) | 54, 86 |  | 5 | -7.2 (8.23) | -8.0 (-13.0, -4.0) | -16, 5 |
|  |  | C2D1 | 4 | 68.5 (9.71) | 64.0 (63.0, 74.0) | 63, 83 |  | 4 | -4.3 (14.01) | -5.5 (-13.5, 5.0) | -20, 14 |
|  |  | C3D1 | 2 | 62.5 (4.95) | 62.5 (59.0, 66.0) | 59, 66 |  | 2 | -4.5 (20.51) | -4.5 (-19.0, 10.0) | -19, 10 |
|  |  | C4D1 | 2 | 70.5 (6.36) | 70.5 (66.0, 75.0) | 66, 75 |  | 2 | 3.5 (19.09) | 3.5 (-10.0, 17.0) | -10, 17 |
|  |  | C5D1 | 2 | 67.5 (6.36) | 67.5 (63.0, 72.0) | 63, 72 |  | 2 | 0.5 (19.09) | 0.5 (-13.0, 14.0) | -13, 14 |
|  | | | | | | | | | | | |
|  | Control Group (N = 5) | Baseline | 5 | 78.6 (9.10) | 75.0 (73.0, 85.0) | 69, 91 |  | 0 |  |  |  |
|  |  | C1D1 | 5 | 80.6 (11.44) | 77.0 (76.0, 80.0) | 70, 100 |  | 5 | 2.0 (16.00) | 3.0 (-11.0, 8.0) | -15, 25 |
|  |  | C1D8 | 5 | 84.2 (11.65) | 79.0 (79.0, 80.0) | 78, 105 |  | 5 | 5.6 (16.23) | 7.0 (-6.0, 9.0) | -12, 30 |
|  |  | C2D1 | 4 | 79.5 (7.85) | 81.5 (73.5, 85.5) | 69, 86 |  | 4 | 2.5 (6.45) | 2.5 (-2.5, 7.5) | -5, 10 |
|  |  | C3D1 | 2 | 74.0 (4.24) | 74.0 (71.0, 77.0) | 71, 77 |  | 2 | 3.0 (1.41) | 3.0 (2.0, 4.0) | 2, 4 |
|  |  | C4D1 | 1 | 72.0 (NA) | 72.0 (72.0, 72.0) | 72, 72 |  | 1 | 3.0 (NA) | 3.0 (3.0, 3.0) | 3, 3 |
|  |  | C5D1 | 1 | 76.0 (NA) | 76.0 (76.0, 76.0) | 76, 76 |  | 1 | 7.0 (NA) | 7.0 (7.0, 7.0) | 7, 7 |
|  |  | End of Treatment | 1 | 100.0 (NA) | 100.0 (100.0, 100.0) | 100, 100 |  | 1 | 9.0 (NA) | 9.0 (9.0, 9.0) | 9, 9 |
|  | | | | | | | | | | | |
|  | Total (N = 10) | Baseline | 10 | 76.1 (12.71) | 76.0 (69.0, 85.0) | 49, 91 |  | 0 |  |  |  |
|  |  | C1D1 | 10 | 74.2 (12.14) | 74.0 (68.0, 80.0) | 58, 100 |  | 10 | -1.9 (12.92) | -8.5 (-11.0, 8.0) | -15, 25 |
|  |  | C1D8 | 10 | 75.3 (15.52) | 78.5 (61.0, 80.0) | 54, 105 |  | 10 | -0.8 (13.88) | -5.0 (-12.0, 7.0) | -16, 30 |
|  |  | C2D1 | 8 | 74.0 (10.07) | 73.5 (64.0, 84.0) | 63, 86 |  | 8 | -0.9 (10.72) | -2.0 (-6.0, 7.5) | -20, 14 |
|  |  | C3D1 | 4 | 68.3 (7.63) | 68.5 (62.5, 74.0) | 59, 77 |  | 4 | -0.8 (12.63) | 3.0 (-8.5, 7.0) | -19, 10 |
|  |  | C4D1 | 3 | 71.0 (4.58) | 72.0 (66.0, 75.0) | 66, 75 |  | 3 | 3.3 (13.50) | 3.0 (-10.0, 17.0) | -10, 17 |
|  |  | C5D1 | 3 | 70.3 (6.66) | 72.0 (63.0, 76.0) | 63, 76 |  | 3 | 2.7 (14.01) | 7.0 (-13.0, 14.0) | -13, 14 |
|  |  | End of Treatment | 1 | 100.0 (NA) | 100.0 (100.0, 100.0) | 100, 100 |  | 1 | 9.0 (NA) | 9.0 (9.0, 9.0) | 9, 9 |
|  | | | | | | | | | | | |
| PR Interval (ms) | Treatment Group (N = 5) | Baseline | 5 | 148.8 (16.04) | 144.0 (142.0, 148.0) | 134, 176 |  | 0 |  |  |  |
|  |  | C1D1 | 5 | 162.4 (20.61) | 174.0 (142.0, 178.0) | 138, 180 |  | 5 | 13.6 (16.70) | 8.0 (4.0, 30.0) | -6, 32 |
|  |  | C1D8 | 5 | 169.2 (20.62) | 160.0 (160.0, 182.0) | 146, 198 |  | 5 | 20.4 (11.70) | 16.0 (12.0, 22.0) | 12, 40 |
|  |  | C2D1 | 4 | 174.0 (22.21) | 174.0 (155.0, 193.0) | 152, 196 |  | 4 | 25.0 (15.53) | 19.0 (16.0, 34.0) | 14, 48 |
|  |  | C3D1 | 2 | 191.0 (52.33) | 191.0 (154.0, 228.0) | 154, 228 |  | 2 | 36.0 (22.63) | 36.0 (20.0, 52.0) | 20, 52 |
|  |  | C4D1 | 2 | 183.0 (43.84) | 183.0 (152.0, 214.0) | 152, 214 |  | 2 | 28.0 (14.14) | 28.0 (18.0, 38.0) | 18, 38 |
|  |  | C5D1 | 2 | 179.0 (41.01) | 179.0 (150.0, 208.0) | 150, 208 |  | 2 | 24.0 (11.31) | 24.0 (16.0, 32.0) | 16, 32 |
|  | | | | | | | | | | | |
|  | Control Group (N = 5) | Baseline | 5 | 172.0 (33.56) | 176.0 (142.0, 180.0) | 140, 222 |  | 0 |  |  |  |
|  |  | C1D1 | 5 | 170.8 (20.72) | 170.0 (158.0, 180.0) | 146, 200 |  | 5 | -1.2 (15.27) | 4.0 (-10.0, 4.0) | -22, 18 |
|  |  | C1D8 | 5 | 172.0 (30.95) | 166.0 (156.0, 176.0) | 140, 222 |  | 5 | 0.0 (16.55) | -2.0 (-4.0, 0.0) | -20, 26 |
|  |  | C2D1 | 4 | 178.0 (25.66) | 177.0 (160.0, 196.0) | 148, 210 |  | 4 | -2.0 (9.38) | -1.0 (-10.0, 6.0) | -12, 6 |
|  |  | C3D1 | 2 | 194.0 (8.49) | 194.0 (188.0, 200.0) | 188, 200 |  | 2 | -5.0 (24.04) | -5.0 (-22.0, 12.0) | -22, 12 |
|  |  | C4D1 | 1 | 230.0 (NA) | 230.0 (230.0, 230.0) | 230, 230 |  | 1 | 8.0 (NA) | 8.0 (8.0, 8.0) | 8, 8 |
|  |  | C5D1 | 1 | 200.0 (NA) | 200.0 (200.0, 200.0) | 200, 200 |  | 1 | -22.0 (NA) | -22.0 (-22.0, -22.0) | -22, -22 |
|  |  | End of Treatment | 1 | 134.0 (NA) | 134.0 (134.0, 134.0) | 134, 134 |  | 1 | -8.0 (NA) | -8.0 (-8.0, -8.0) | -8, -8 |
|  | | | | | | | | | | | |
|  | Total (N = 10) | Baseline | 10 | 160.4 (27.65) | 146.0 (142.0, 176.0) | 134, 222 |  | 0 |  |  |  |
|  |  | C1D1 | 10 | 166.6 (19.98) | 172.0 (146.0, 180.0) | 138, 200 |  | 10 | 6.2 (16.98) | 4.0 (-6.0, 18.0) | -22, 32 |
|  |  | C1D8 | 10 | 170.6 (24.84) | 163.0 (156.0, 182.0) | 140, 222 |  | 10 | 10.2 (17.27) | 12.0 (-2.0, 22.0) | -20, 40 |
|  |  | C2D1 | 8 | 176.0 (22.32) | 177.0 (155.0, 193.0) | 148, 210 |  | 8 | 11.5 (18.69) | 10.0 (-1.0, 19.0) | -12, 48 |
|  |  | C3D1 | 4 | 192.5 (30.65) | 194.0 (171.0, 214.0) | 154, 228 |  | 4 | 15.5 (30.39) | 16.0 (-5.0, 36.0) | -22, 52 |
|  |  | C4D1 | 3 | 198.7 (41.20) | 214.0 (152.0, 230.0) | 152, 230 |  | 3 | 21.3 (15.28) | 18.0 (8.0, 38.0) | 8, 38 |
|  |  | C5D1 | 3 | 186.0 (31.43) | 200.0 (150.0, 208.0) | 150, 208 |  | 3 | 8.7 (27.74) | 16.0 (-22.0, 32.0) | -22, 32 |
|  |  | End of Treatment | 1 | 134.0 (NA) | 134.0 (134.0, 134.0) | 134, 134 |  | 1 | -8.0 (NA) | -8.0 (-8.0, -8.0) | -8, -8 |
|  | | | | | | | | | | | |
| QRS Interval (ms) | Treatment Group (N = 5) | Baseline | 5 | 88.0 (4.00) | 90.0 (86.0, 90.0) | 82, 92 |  | 0 |  |  |  |
|  |  | C1D1 | 5 | 87.6 (2.97) | 88.0 (86.0, 88.0) | 84, 92 |  | 5 | -0.4 (3.58) | 2.0 (-2.0, 2.0) | -6, 2 |
|  |  | C1D8 | 5 | 90.0 (7.48) | 88.0 (84.0, 92.0) | 84, 102 |  | 5 | 2.0 (7.07) | 2.0 (2.0, 2.0) | -8, 12 |
|  |  | C2D1 | 4 | 85.0 (2.00) | 84.0 (84.0, 86.0) | 84, 88 |  | 4 | -2.5 (4.12) | -2.0 (-5.0, 0.0) | -8, 2 |
|  |  | C3D1 | 2 | 91.0 (1.41) | 91.0 (90.0, 92.0) | 90, 92 |  | 2 | 2.0 (5.66) | 2.0 (-2.0, 6.0) | -2, 6 |
|  |  | C4D1 | 2 | 90.0 (0.00) | 90.0 (90.0, 90.0) | 90, 90 |  | 2 | 1.0 (4.24) | 1.0 (-2.0, 4.0) | -2, 4 |
|  |  | C5D1 | 2 | 89.0 (1.41) | 89.0 (88.0, 90.0) | 88, 90 |  | 2 | 0.0 (2.83) | 0.0 (-2.0, 2.0) | -2, 2 |
|  | | | | | | | | | | | |
|  | Control Group (N = 5) | Baseline | 5 | 99.6 (23.38) | 96.0 (82.0, 102.0) | 80, 138 |  | 0 |  |  |  |
|  |  | C1D1 | 5 | 104.4 (25.63) | 92.0 (84.0, 128.0) | 82, 136 |  | 5 | 4.8 (16.04) | 0.0 (-2.0, 4.0) | -10, 32 |
|  |  | C1D8 | 5 | 102.4 (24.47) | 96.0 (82.0, 124.0) | 78, 132 |  | 5 | 2.8 (14.32) | -2.0 (-6.0, 0.0) | -6, 28 |
|  |  | C2D1 | 4 | 113.5 (21.38) | 116.0 (96.0, 131.0) | 88, 134 |  | 4 | 9.5 (15.78) | 5.0 (-1.0, 20.0) | -4, 32 |
|  |  | C3D1 | 2 | 84.0 (8.49) | 84.0 (78.0, 90.0) | 78, 90 |  | 2 | -7.0 (7.07) | -7.0 (-12.0, -2.0) | -12, -2 |
|  |  | C4D1 | 1 | 100.0 (NA) | 100.0 (100.0, 100.0) | 100, 100 |  | 1 | -2.0 (NA) | -2.0 (-2.0, -2.0) | -2, -2 |
|  |  | C5D1 | 1 | 98.0 (NA) | 98.0 (98.0, 98.0) | 98, 98 |  | 1 | -4.0 (NA) | -4.0 (-4.0, -4.0) | -4, -4 |
|  |  | End of Treatment | 1 | 136.0 (NA) | 136.0 (136.0, 136.0) | 136, 136 |  | 1 | -2.0 (NA) | -2.0 (-2.0, -2.0) | -2, -2 |
|  | | | | | | | | | | | |
|  | Total (N = 10) | Baseline | 10 | 93.8 (16.96) | 90.0 (82.0, 96.0) | 80, 138 |  | 0 |  |  |  |
|  |  | C1D1 | 10 | 96.0 (19.34) | 88.0 (84.0, 92.0) | 82, 136 |  | 10 | 2.2 (11.29) | 1.0 (-2.0, 2.0) | -10, 32 |
|  |  | C1D8 | 10 | 96.2 (18.27) | 90.0 (84.0, 102.0) | 78, 132 |  | 10 | 2.4 (10.66) | 1.0 (-6.0, 2.0) | -8, 28 |
|  |  | C2D1 | 8 | 99.3 (20.73) | 88.0 (84.0, 116.0) | 84, 134 |  | 8 | 3.5 (12.46) | 0.0 (-3.0, 5.0) | -8, 32 |
|  |  | C3D1 | 4 | 87.5 (6.40) | 90.0 (84.0, 91.0) | 78, 92 |  | 4 | -2.5 (7.37) | -2.0 (-7.0, 2.0) | -12, 6 |
|  |  | C4D1 | 3 | 93.3 (5.77) | 90.0 (90.0, 100.0) | 90, 100 |  | 3 | 0.0 (3.46) | -2.0 (-2.0, 4.0) | -2, 4 |
|  |  | C5D1 | 3 | 92.0 (5.29) | 90.0 (88.0, 98.0) | 88, 98 |  | 3 | -1.3 (3.06) | -2.0 (-4.0, 2.0) | -4, 2 |
|  |  | End of Treatment | 1 | 136.0 (NA) | 136.0 (136.0, 136.0) | 136, 136 |  | 1 | -2.0 (NA) | -2.0 (-2.0, -2.0) | -2, -2 |
|  | | | | | | | | | | | |
| QT Interval (ms) | Treatment Group (N = 5) | Baseline | 5 | 383.2 (30.22) | 370.0 (368.0, 380.0) | 362, 436 |  | 0 |  |  |  |
|  |  | C1D1 | 5 | 378.0 (15.36) | 376.0 (364.0, 386.0) | 364, 400 |  | 5 | -5.2 (18.03) | 2.0 (-6.0, 6.0) | -36, 8 |
|  |  | C1D8 | 5 | 399.2 (20.03) | 390.0 (388.0, 404.0) | 382, 432 |  | 5 | 16.0 (14.63) | 18.0 (10.0, 20.0) | -4, 36 |
|  |  | C2D1 | 4 | 399.0 (18.94) | 399.0 (386.0, 412.0) | 376, 422 |  | 4 | 12.5 (18.57) | 18.0 (0.0, 25.0) | -14, 28 |
|  |  | C3D1 | 2 | 433.0 (9.90) | 433.0 (426.0, 440.0) | 426, 440 |  | 2 | 25.0 (49.50) | 25.0 (-10.0, 60.0) | -10, 60 |
|  |  | C4D1 | 2 | 402.0 (8.49) | 402.0 (396.0, 408.0) | 396, 408 |  | 2 | -6.0 (31.11) | -6.0 (-28.0, 16.0) | -28, 16 |
|  |  | C5D1 | 2 | 410.5 (7.78) | 410.5 (405.0, 416.0) | 405, 416 |  | 2 | 2.5 (31.82) | 2.5 (-20.0, 25.0) | -20, 25 |
|  | | | | | | | | | | | |
|  | Control Group (N = 5) | Baseline | 5 | 387.2 (16.77) | 382.0 (380.0, 400.0) | 366, 408 |  | 0 |  |  |  |
|  |  | C1D1 | 5 | 391.6 (16.76) | 400.0 (388.0, 400.0) | 364, 406 |  | 5 | 4.4 (23.93) | -8.0 (-12.0, 18.0) | -16, 40 |
|  |  | C1D8 | 5 | 378.0 (18.87) | 376.0 (370.0, 392.0) | 352, 400 |  | 5 | -9.2 (22.03) | -16.0 (-28.0, 10.0) | -30, 18 |
|  |  | C2D1 | 4 | 391.5 (6.61) | 391.0 (387.0, 396.0) | 384, 400 |  | 4 | -1.0 (9.59) | -2.0 (-9.0, 7.0) | -10, 10 |
|  |  | C3D1 | 2 | 397.5 (10.61) | 397.5 (390.0, 405.0) | 390, 405 |  | 2 | -6.5 (4.95) | -6.5 (-10.0, -3.0) | -10, -3 |
|  |  | C4D1 | 1 | 386.0 (NA) | 386.0 (386.0, 386.0) | 386, 386 |  | 1 | -22.0 (NA) | -22.0 (-22.0, -22.0) | -22, -22 |
|  |  | C5D1 | 1 | 400.0 (NA) | 400.0 (400.0, 400.0) | 400, 400 |  | 1 | -8.0 (NA) | -8.0 (-8.0, -8.0) | -8, -8 |
|  |  | End of Treatment | 1 | 350.0 (NA) | 350.0 (350.0, 350.0) | 350, 350 |  | 1 | -32.0 (NA) | -32.0 (-32.0, -32.0) | -32, -32 |
|  | | | | | | | | | | | |
|  | Total (N = 10) | Baseline | 10 | 385.2 (23.14) | 380.0 (368.0, 400.0) | 362, 436 |  | 0 |  |  |  |
|  |  | C1D1 | 10 | 384.8 (16.77) | 387.0 (364.0, 400.0) | 364, 406 |  | 10 | -0.4 (20.61) | -2.0 (-12.0, 8.0) | -36, 40 |
|  |  | C1D8 | 10 | 388.6 (21.48) | 389.0 (376.0, 400.0) | 352, 432 |  | 10 | 3.4 (22.07) | 10.0 (-16.0, 18.0) | -30, 36 |
|  |  | C2D1 | 8 | 395.3 (13.73) | 394.0 (387.0, 401.0) | 376, 422 |  | 8 | 5.8 (15.47) | 7.0 (-9.0, 18.0) | -14, 28 |
|  |  | C3D1 | 4 | 415.3 (22.14) | 415.5 (397.5, 433.0) | 390, 440 |  | 4 | 9.3 (33.99) | -6.5 (-10.0, 28.5) | -10, 60 |
|  |  | C4D1 | 3 | 396.7 (11.02) | 396.0 (386.0, 408.0) | 386, 408 |  | 3 | -11.3 (23.86) | -22.0 (-28.0, 16.0) | -28, 16 |
|  |  | C5D1 | 3 | 407.0 (8.19) | 405.0 (400.0, 416.0) | 400, 416 |  | 3 | -1.0 (23.30) | -8.0 (-20.0, 25.0) | -20, 25 |
|  |  | End of Treatment | 1 | 350.0 (NA) | 350.0 (350.0, 350.0) | 350, 350 |  | 1 | -32.0 (NA) | -32.0 (-32.0, -32.0) | -32, -32 |
|  | | | | | | | | | | | |
| QTcF Interval (ms) | Treatment Group (N = 5) | Baseline | 5 | 406.266 (16.4841) | 407.810 (401.750, 413.830) | 381.65, 426.29 |  | 0 |  |  |  |
|  |  | C1D1 | 5 | 392.484 (16.2339) | 397.790 (379.350, 403.520) | 371.82, 409.94 |  | 5 | -13.782 (5.5383) | -10.310 (-16.350, -10.020) | -22.40, -9.83 |
|  |  | C1D8 | 5 | 410.240 (18.8983) | 417.240 (390.190, 423.460) | 390.12, 430.19 |  | 5 | 3.974 (11.1109) | 8.540 (-2.830, 9.430) | -11.63, 16.36 |
|  |  | C2D1 | 4 | 415.635 (11.0375) | 415.630 (407.595, 423.675) | 402.43, 428.85 |  | 4 | 8.240 (16.4090) | 12.725 (-4.430, 20.910) | -13.53, 21.04 |
|  |  | C3D1 | 2 | 438.850 (21.5102) | 438.850 (423.640, 454.060) | 423.64, 454.06 |  | 2 | 21.800 (8.4429) | 21.800 (15.830, 27.770) | 15.83, 27.77 |
|  |  | C4D1 | 2 | 423.650 (3.6911) | 423.650 (421.040, 426.260) | 421.04, 426.26 |  | 2 | 6.600 (9.3762) | 6.600 (-0.030, 13.230) | -0.03, 13.23 |
|  |  | C5D1 | 2 | 426.435 (5.2114) | 426.435 (422.750, 430.120) | 422.75, 430.12 |  | 2 | 9.385 (7.8560) | 9.385 (3.830, 14.940) | 3.83, 14.94 |
|  | | | | | | | | | | | |
|  | Control Group (N = 5) | Baseline | 5 | 422.382 (12.3809) | 426.740 (410.580, 427.260) | 409.04, 438.29 |  | 0 |  |  |  |
|  |  | C1D1 | 5 | 430.332 (7.6487) | 430.840 (427.190, 434.320) | 419.48, 439.83 |  | 5 | 7.950 (11.6194) | 7.060 (1.540, 16.610) | -7.26, 21.80 |
|  |  | C1D8 | 5 | 421.486 (12.4662) | 423.390 (411.730, 427.450) | 406.85, 438.01 |  | 5 | -0.896 (12.2368) | 0.190 (-0.280, 1.150) | -19.89, 14.35 |
|  |  | C2D1 | 4 | 429.093 (9.5643) | 428.020 (422.075, 436.110) | 418.88, 441.45 |  | 4 | 3.760 (12.8843) | 0.845 (-4.925, 12.445) | -8.38, 21.73 |
|  |  | C3D1 | 2 | 425.795 (3.3022) | 425.795 (423.460, 428.130) | 423.46, 428.13 |  | 2 | -1.205 (2.9345) | -1.205 (-3.280, 0.870) | -3.28, 0.87 |
|  |  | C4D1 | 1 | 409.940 (NA) | 409.940 (409.940, 409.940) | 409.94, 409.94 |  | 1 | -17.320 (NA) | -17.320 (-17.320, -17.320) | -17.32, -17.32 |
|  |  | C5D1 | 1 | 432.450 (NA) | 432.450 (432.450, 432.450) | 432.45, 432.45 |  | 1 | 5.190 (NA) | 5.190 (5.190, 5.190) | 5.19, 5.19 |
|  |  | End of Treatment | 1 | 414.260 (NA) | 414.260 (414.260, 414.260) | 414.26, 414.26 |  | 1 | -24.030 (NA) | -24.030 (-24.030, -24.030) | -24.03, -24.03 |
|  | | | | | | | | | | | |
|  | Total (N = 10) | Baseline | 10 | 414.324 (16.1567) | 412.205 (407.810, 426.740) | 381.65, 438.29 |  | 0 |  |  |  |
|  |  | C1D1 | 10 | 411.408 (23.2602) | 414.710 (397.790, 430.840) | 371.82, 439.83 |  | 10 | -2.916 (14.3117) | -8.545 (-10.310, 7.060) | -22.40, 21.80 |
|  |  | C1D8 | 10 | 415.863 (16.2152) | 420.315 (406.850, 427.450) | 390.12, 438.01 |  | 10 | 1.539 (11.3140) | 0.670 (-2.830, 9.430) | -19.89, 16.36 |
|  |  | C2D1 | 8 | 422.364 (11.9649) | 422.075 (415.630, 429.810) | 402.43, 441.45 |  | 8 | 6.000 (13.8663) | 3.915 (-4.925, 20.910) | -13.53, 21.73 |
|  |  | C3D1 | 4 | 432.323 (14.6518) | 425.885 (423.550, 441.095) | 423.46, 454.06 |  | 4 | 10.298 (14.2492) | 8.350 (-1.205, 21.800) | -3.28, 27.77 |
|  |  | C4D1 | 3 | 419.080 (8.3347) | 421.040 (409.940, 426.260) | 409.94, 426.26 |  | 3 | -1.373 (15.3192) | -0.030 (-17.320, 13.230) | -17.32, 13.23 |
|  |  | C5D1 | 3 | 428.440 (5.0635) | 430.120 (422.750, 432.450) | 422.75, 432.45 |  | 3 | 7.987 (6.0600) | 5.190 (3.830, 14.940) | 3.83, 14.94 |
|  |  | End of Treatment | 1 | 414.260 (NA) | 414.260 (414.260, 414.260) | 414.26, 414.26 |  | 1 | -24.030 (NA) | -24.030 (-24.030, -24.030) | -24.03, -24.03 |
|  | | | | | | | | | | | |
| RR Interval (ms) | Treatment Group (N = 5) | Baseline | 5 | 854.4 (224.25) | 779.0 (706.0, 896.0) | 667, 1224 |  | 0 |  |  |  |
|  |  | C1D1 | 5 | 899.6 (127.16) | 882.0 (833.0, 1017.0) | 732, 1034 |  | 5 | 45.2 (143.74) | 103.0 (65.0, 127.0) | -207, 138 |
|  |  | C1D8 | 5 | 936.6 (190.29) | 984.0 (779.0, 1111.0) | 698, 1111 |  | 5 | 82.2 (135.58) | 73.0 (31.0, 205.0) | -113, 215 |
|  |  | C2D1 | 4 | 887.5 (110.52) | 937.5 (823.0, 952.0) | 723, 952 |  | 4 | 14.3 (205.37) | 56.0 (-108.0, 136.5) | -272, 217 |
|  |  | C3D1 | 2 | 963.0 (76.37) | 963.0 (909.0, 1017.0) | 909, 1017 |  | 2 | -2.0 (289.91) | -2.0 (-207.0, 203.0) | -207, 203 |
|  |  | C4D1 | 2 | 854.5 (77.07) | 854.5 (800.0, 909.0) | 800, 909 |  | 2 | -110.5 (289.21) | -110.5 (-315.0, 94.0) | -315, 94 |
|  |  | C5D1 | 2 | 892.5 (84.15) | 892.5 (833.0, 952.0) | 833, 952 |  | 2 | -72.5 (282.14) | -72.5 (-272.0, 127.0) | -272, 127 |
|  | | | | | | | | | | | |
|  | Control Group (N = 5) | Baseline | 5 | 771.4 (86.62) | 800.0 (706.0, 822.0) | 659, 870 |  | 0 |  |  |  |
|  |  | C1D1 | 5 | 755.0 (95.11) | 779.0 (750.0, 789.0) | 600, 857 |  | 5 | -16.4 (140.63) | -33.0 (-91.0, 91.0) | -200, 151 |
|  |  | C1D8 | 5 | 721.6 (84.46) | 759.0 (750.0, 759.0) | 571, 769 |  | 5 | -49.8 (130.61) | -72.0 (-101.0, 53.0) | -229, 100 |
|  |  | C2D1 | 4 | 760.8 (79.45) | 737.5 (702.0, 819.5) | 698, 870 |  | 4 | -27.0 (58.45) | -26.5 (-73.5, 19.5) | -94, 39 |
|  |  | C3D1 | 2 | 812.0 (46.67) | 812.0 (779.0, 845.0) | 779, 845 |  | 2 | -34.0 (12.73) | -34.0 (-43.0, -25.0) | -43, -25 |
|  |  | C4D1 | 1 | 833.0 (NA) | 833.0 (833.0, 833.0) | 833, 833 |  | 1 | -37.0 (NA) | -37.0 (-37.0, -37.0) | -37, -37 |
|  |  | C5D1 | 1 | 789.0 (NA) | 789.0 (789.0, 789.0) | 789, 789 |  | 1 | -81.0 (NA) | -81.0 (-81.0, -81.0) | -81, -81 |
|  |  | End of Treatment | 1 | 600.0 (NA) | 600.0 (600.0, 600.0) | 600, 600 |  | 1 | -59.0 (NA) | -59.0 (-59.0, -59.0) | -59, -59 |
|  | | | | | | | | | | | |
|  | Total (N = 10) | Baseline | 10 | 812.9 (166.13) | 789.5 (706.0, 870.0) | 659, 1224 |  | 0 |  |  |  |
|  |  | C1D1 | 10 | 827.3 (130.44) | 811.0 (750.0, 882.0) | 600, 1034 |  | 10 | 14.4 (137.93) | 78.0 (-91.0, 127.0) | -207, 151 |
|  |  | C1D8 | 10 | 829.1 (179.18) | 764.0 (750.0, 984.0) | 571, 1111 |  | 10 | 16.2 (143.50) | 42.0 (-101.0, 100.0) | -229, 215 |
|  |  | C2D1 | 8 | 824.1 (111.94) | 819.5 (714.5, 937.5) | 698, 952 |  | 8 | -6.4 (141.52) | 19.5 (-73.5, 56.0) | -272, 217 |
|  |  | C3D1 | 4 | 887.5 (101.34) | 877.0 (812.0, 963.0) | 779, 1017 |  | 4 | -18.0 (168.56) | -34.0 (-125.0, 89.0) | -207, 203 |
|  |  | C4D1 | 3 | 847.3 (55.90) | 833.0 (800.0, 909.0) | 800, 909 |  | 3 | -86.0 (208.86) | -37.0 (-315.0, 94.0) | -315, 94 |
|  |  | C5D1 | 3 | 858.0 (84.33) | 833.0 (789.0, 952.0) | 789, 952 |  | 3 | -75.3 (199.56) | -81.0 (-272.0, 127.0) | -272, 127 |
|  |  | End of Treatment | 1 | 600.0 (NA) | 600.0 (600.0, 600.0) | 600, 600 |  | 1 | -59.0 (NA) | -59.0 (-59.0, -59.0) | -59, -59 |

NA = Not applicable.

Baseline is defined as the last available assessment before the first administration of investigational drug (D-1553 or IN10018).

Only subjects with data at both baseline and the relevant post baseline visit are included in the change from baseline summary statistics.

Source Data: Listing 16.2.11.1

|  |  |  |
| --- | --- | --- |
| Program: t-eg-chg.sas | DCO: 27APR2024 | Executed: 07JUL2024 20:52 |

|  |  |
| --- | --- |
| **InxMed (Shanghai) Co., Ltd.  Protocol No. IN10018-602** |  |

**Table 14.3.8.2.3 Summary of Shifts from Baseline in 12-Lead ECG According to Investigator’s Assessment - Phase II part 2 - CRC (Safety Analysis Set)**

|  | | | | Post-baseline | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Parameter | Group | Visit | Baseline | Normal | Abnormal, NCS | Abnormal, CS |  | Total |
| ECG Interpretation | Treatment Group (N = 5) | Last Post-Baseline | Normal | 1 (20.0) | 1 (20.0) | 0 |  | 2 (40.0) |
|  |  |  | Abnormal, NCS | 1 (20.0) | 1 (20.0) | 0 |  | 2 (40.0) |
|  |  |  | Abnormal, CS | 0 | 0 | 1 (20.0) |  | 1 (20.0) |
|  |  |  | Total | 2 (40.0) | 2 (40.0) | 1 (20.0) |  | 5 (100) |
|  | | | | | | | | |
|  |  | Worst Post-Baseline | Normal | 0 | 1 (20.0) | 1 (20.0) |  | 2 (40.0) |
|  |  |  | Abnormal, NCS | 0 | 0 | 2 (40.0) |  | 2 (40.0) |
|  |  |  | Abnormal, CS | 0 | 0 | 1 (20.0) |  | 1 (20.0) |
|  |  |  | Total | 0 | 1 (20.0) | 4 (80.0) |  | 5 (100) |
|  | | | | | | | | |
|  | Control Group (N = 5) | Last Post-Baseline | Normal | 1 (20.0) | 1 (20.0) | 0 |  | 2 (40.0) |
|  |  |  | Abnormal, NCS | 0 | 1 (20.0) | 1 (20.0) |  | 2 (40.0) |
|  |  |  | Abnormal, CS | 0 | 0 | 1 (20.0) |  | 1 (20.0) |
|  |  |  | Total | 1 (20.0) | 2 (40.0) | 2 (40.0) |  | 5 (100) |
|  | | | | | | | | |
|  |  | Worst Post-Baseline | Normal | 1 (20.0) | 1 (20.0) | 0 |  | 2 (40.0) |
|  |  |  | Abnormal, NCS | 0 | 1 (20.0) | 1 (20.0) |  | 2 (40.0) |
|  |  |  | Abnormal, CS | 0 | 0 | 1 (20.0) |  | 1 (20.0) |
|  |  |  | Total | 1 (20.0) | 2 (40.0) | 2 (40.0) |  | 5 (100) |

Baseline is defined as the last available assessment before the first administration of investigational drug (D-1553 or IN10018).

Last post-baseline is the last value of investigator's assessment at all post-baseline visits, including any scheduled, unscheduled, EOT/early withdraw from the study and safety follow-up.

Worst post-baseline is the value of worst investigator's assessment at all post-baseline visits, including any scheduled, unscheduled, EOT/early withdraw from the study and safety follow-up.

Percentages are based on the number of subjects of each respective group in the Safety Analysis Set.

Source Data: Listing 16.2.11.1

|  |  |  |
| --- | --- | --- |
| Program: t-eg-shift.sas | DCO: 27APR2024 | Executed: 07JUL2024 20:52 |

|  |  |
| --- | --- |
| **InxMed (Shanghai) Co., Ltd.  Protocol No. IN10018-602** |  |

**Table 14.3.8.3.3 Summary of Abnormal QTcF - Phase II part 2 - CRC (Safety Analysis Set)**

|  | Treatment Group (N = 5) n (%) | Control Group (N = 5) n (%) | Total (N = 10) n (%) |
| --- | --- | --- | --- |
| Subjects with At Least One Post-baseline Abnormal QTcF | 5 (100) | 4 (80.0) | 9 (90.0) |
|  | | | |
| QTcF |  |  |  |
| > 450 msec | 1 (20.0) | 1 (20.0) | 2 (20.0) |
| > 480 msec | 0 | 0 | 0 |
| > 500 msec | 0 | 0 | 0 |
| Change from baseline > 30 msec | 2 (40.0) | 1 (20.0) | 3 (30.0) |
| Change from baseline > 60 msec | 0 | 0 | 0 |

Baseline is defined as the last available assessment before the first administration of investigational drug (D-1553 or IN10018).

Percentages are based on the number of subjects of each respective group in the Safety Analysis Set.

Source Data: Listing 16.2.11.1

|  |  |  |
| --- | --- | --- |
| Program: t-eg-qtcf.sas | DCO: 27APR2024 | Executed: 07JUL2024 20:52 |

|  |  |
| --- | --- |
| **InxMed (Shanghai) Co., Ltd.  Protocol No. IN10018-602** |  |

**Table 14.3.9.3 Summary of Shifts from Baseline in Slip Lamp Examination According to Investigator’s Assessment - Phase II part 2 - CRC (Safety Analysis Set)**

|  | | | | | Post-baseline | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Parameter | Group | Site | Visit | Baseline | Normal | Abnormal, NCS |  | Abnormal, CS | Missing | Total |
| Outer Eye | Treatment Group (N = 5) | Left | Last Post-Baseline | Normal | 2 (40.0) | 0 |  | 0 | 2 (40.0) | 4 (80.0) |
|  |  |  |  | Abnormal, NCS | 0 | 0 |  | 0 | 0 | 0 |
|  |  |  |  | Abnormal, CS | 0 | 0 |  | 0 | 0 | 0 |
|  |  |  |  | Missing | 0 | 0 |  | 0 | 1 (20.0) | 1 (20.0) |
|  |  |  |  | Total | 2 (40.0) | 0 |  | 0 | 3 (60.0) | 5 (100) |
|  | | | | | | | | | | |
|  |  |  | Worst Post-Baseline | Normal | 2 (40.0) | 0 |  | 0 | 2 (40.0) | 4 (80.0) |
|  |  |  |  | Abnormal, NCS | 0 | 0 |  | 0 | 0 | 0 |
|  |  |  |  | Abnormal, CS | 0 | 0 |  | 0 | 0 | 0 |
|  |  |  |  | Missing | 0 | 0 |  | 0 | 1 (20.0) | 1 (20.0) |
|  |  |  |  | Total | 2 (40.0) | 0 |  | 0 | 3 (60.0) | 5 (100) |
|  | | | | | | | | | | |
|  |  | Right | Last Post-Baseline | Normal | 2 (40.0) | 0 |  | 0 | 2 (40.0) | 4 (80.0) |
|  |  |  |  | Abnormal, NCS | 0 | 0 |  | 0 | 0 | 0 |
|  |  |  |  | Abnormal, CS | 0 | 0 |  | 0 | 0 | 0 |
|  |  |  |  | Missing | 0 | 0 |  | 0 | 1 (20.0) | 1 (20.0) |
|  |  |  |  | Total | 2 (40.0) | 0 |  | 0 | 3 (60.0) | 5 (100) |
|  | | | | | | | | | | |
|  |  |  | Worst Post-Baseline | Normal | 2 (40.0) | 0 |  | 0 | 2 (40.0) | 4 (80.0) |
|  |  |  |  | Abnormal, NCS | 0 | 0 |  | 0 | 0 | 0 |
|  |  |  |  | Abnormal, CS | 0 | 0 |  | 0 | 0 | 0 |
|  |  |  |  | Missing | 0 | 0 |  | 0 | 1 (20.0) | 1 (20.0) |
|  |  |  |  | Total | 2 (40.0) | 0 |  | 0 | 3 (60.0) | 5 (100) |
|  | | | | | | | | | | |
|  | Control Group (N = 5) | Left | Last Post-Baseline | Normal | 1 (20.0) | 0 |  | 0 | 4 (80.0) | 5 (100) |
|  |  |  |  | Abnormal, NCS | 0 | 0 |  | 0 | 0 | 0 |
|  |  |  |  | Abnormal, CS | 0 | 0 |  | 0 | 0 | 0 |
|  |  |  |  | Total | 1 (20.0) | 0 |  | 0 | 4 (80.0) | 5 (100) |
|  | | | | | | | | | | |
|  |  |  | Worst Post-Baseline | Normal | 1 (20.0) | 0 |  | 0 | 4 (80.0) | 5 (100) |
|  |  |  |  | Abnormal, NCS | 0 | 0 |  | 0 | 0 | 0 |
|  |  |  |  | Abnormal, CS | 0 | 0 |  | 0 | 0 | 0 |
|  |  |  |  | Total | 1 (20.0) | 0 |  | 0 | 4 (80.0) | 5 (100) |
|  | | | | | | | | | | |
|  |  | Right | Last Post-Baseline | Normal | 1 (20.0) | 0 |  | 0 | 4 (80.0) | 5 (100) |
|  |  |  |  | Abnormal, NCS | 0 | 0 |  | 0 | 0 | 0 |
|  |  |  |  | Abnormal, CS | 0 | 0 |  | 0 | 0 | 0 |
|  |  |  |  | Total | 1 (20.0) | 0 |  | 0 | 4 (80.0) | 5 (100) |
|  | | | | | | | | | | |
|  |  |  | Worst Post-Baseline | Normal | 1 (20.0) | 0 |  | 0 | 4 (80.0) | 5 (100) |
|  |  |  |  | Abnormal, NCS | 0 | 0 |  | 0 | 0 | 0 |
|  |  |  |  | Abnormal, CS | 0 | 0 |  | 0 | 0 | 0 |
|  |  |  |  | Total | 1 (20.0) | 0 |  | 0 | 4 (80.0) | 5 (100) |
|  | | | | | | | | | | |
| Eyelid Margin | Treatment Group (N = 5) | Left | Last Post-Baseline | Normal | 2 (40.0) | 0 |  | 0 | 2 (40.0) | 4 (80.0) |
|  |  |  |  | Abnormal, NCS | 0 | 0 |  | 0 | 0 | 0 |
|  |  |  |  | Abnormal, CS | 0 | 0 |  | 0 | 0 | 0 |
|  |  |  |  | Missing | 0 | 0 |  | 0 | 1 (20.0) | 1 (20.0) |
|  |  |  |  | Total | 2 (40.0) | 0 |  | 0 | 3 (60.0) | 5 (100) |
|  | | | | | | | | | | |
|  |  |  | Worst Post-Baseline | Normal | 2 (40.0) | 0 |  | 0 | 2 (40.0) | 4 (80.0) |
|  |  |  |  | Abnormal, NCS | 0 | 0 |  | 0 | 0 | 0 |
|  |  |  |  | Abnormal, CS | 0 | 0 |  | 0 | 0 | 0 |
|  |  |  |  | Missing | 0 | 0 |  | 0 | 1 (20.0) | 1 (20.0) |
|  |  |  |  | Total | 2 (40.0) | 0 |  | 0 | 3 (60.0) | 5 (100) |
|  | | | | | | | | | | |
|  |  | Right | Last Post-Baseline | Normal | 2 (40.0) | 0 |  | 0 | 2 (40.0) | 4 (80.0) |
|  |  |  |  | Abnormal, NCS | 0 | 0 |  | 0 | 0 | 0 |
|  |  |  |  | Abnormal, CS | 0 | 0 |  | 0 | 0 | 0 |
|  |  |  |  | Missing | 0 | 0 |  | 0 | 1 (20.0) | 1 (20.0) |
|  |  |  |  | Total | 2 (40.0) | 0 |  | 0 | 3 (60.0) | 5 (100) |
|  | | | | | | | | | | |
|  |  |  | Worst Post-Baseline | Normal | 2 (40.0) | 0 |  | 0 | 2 (40.0) | 4 (80.0) |
|  |  |  |  | Abnormal, NCS | 0 | 0 |  | 0 | 0 | 0 |
|  |  |  |  | Abnormal, CS | 0 | 0 |  | 0 | 0 | 0 |
|  |  |  |  | Missing | 0 | 0 |  | 0 | 1 (20.0) | 1 (20.0) |
|  |  |  |  | Total | 2 (40.0) | 0 |  | 0 | 3 (60.0) | 5 (100) |
|  | | | | | | | | | | |
|  | Control Group (N = 5) | Left | Last Post-Baseline | Normal | 1 (20.0) | 0 |  | 0 | 4 (80.0) | 5 (100) |
|  |  |  |  | Abnormal, NCS | 0 | 0 |  | 0 | 0 | 0 |
|  |  |  |  | Abnormal, CS | 0 | 0 |  | 0 | 0 | 0 |
|  |  |  |  | Total | 1 (20.0) | 0 |  | 0 | 4 (80.0) | 5 (100) |
|  | | | | | | | | | | |
|  |  |  | Worst Post-Baseline | Normal | 1 (20.0) | 0 |  | 0 | 4 (80.0) | 5 (100) |
|  |  |  |  | Abnormal, NCS | 0 | 0 |  | 0 | 0 | 0 |
|  |  |  |  | Abnormal, CS | 0 | 0 |  | 0 | 0 | 0 |
|  |  |  |  | Total | 1 (20.0) | 0 |  | 0 | 4 (80.0) | 5 (100) |
|  | | | | | | | | | | |
|  |  | Right | Last Post-Baseline | Normal | 1 (20.0) | 0 |  | 0 | 4 (80.0) | 5 (100) |
|  |  |  |  | Abnormal, NCS | 0 | 0 |  | 0 | 0 | 0 |
|  |  |  |  | Abnormal, CS | 0 | 0 |  | 0 | 0 | 0 |
|  |  |  |  | Total | 1 (20.0) | 0 |  | 0 | 4 (80.0) | 5 (100) |
|  | | | | | | | | | | |
|  |  |  | Worst Post-Baseline | Normal | 1 (20.0) | 0 |  | 0 | 4 (80.0) | 5 (100) |
|  |  |  |  | Abnormal, NCS | 0 | 0 |  | 0 | 0 | 0 |
|  |  |  |  | Abnormal, CS | 0 | 0 |  | 0 | 0 | 0 |
|  |  |  |  | Total | 1 (20.0) | 0 |  | 0 | 4 (80.0) | 5 (100) |
|  | | | | | | | | | | |
| Bulbar Conjunctiva | Treatment Group (N = 5) | Left | Last Post-Baseline | Normal | 1 (20.0) | 1 (20.0) |  | 0 | 3 (60.0) | 5 (100) |
|  |  |  |  | Abnormal, NCS | 0 | 0 |  | 0 | 0 | 0 |
|  |  |  |  | Abnormal, CS | 0 | 0 |  | 0 | 0 | 0 |
|  |  |  |  | Total | 1 (20.0) | 1 (20.0) |  | 0 | 3 (60.0) | 5 (100) |
|  | | | | | | | | | | |
|  |  |  | Worst Post-Baseline | Normal | 1 (20.0) | 1 (20.0) |  | 0 | 3 (60.0) | 5 (100) |
|  |  |  |  | Abnormal, NCS | 0 | 0 |  | 0 | 0 | 0 |
|  |  |  |  | Abnormal, CS | 0 | 0 |  | 0 | 0 | 0 |
|  |  |  |  | Total | 1 (20.0) | 1 (20.0) |  | 0 | 3 (60.0) | 5 (100) |
|  | | | | | | | | | | |
|  |  | Right | Last Post-Baseline | Normal | 1 (20.0) | 1 (20.0) |  | 0 | 3 (60.0) | 5 (100) |
|  |  |  |  | Abnormal, NCS | 0 | 0 |  | 0 | 0 | 0 |
|  |  |  |  | Abnormal, CS | 0 | 0 |  | 0 | 0 | 0 |
|  |  |  |  | Total | 1 (20.0) | 1 (20.0) |  | 0 | 3 (60.0) | 5 (100) |
|  | | | | | | | | | | |
|  |  |  | Worst Post-Baseline | Normal | 1 (20.0) | 1 (20.0) |  | 0 | 3 (60.0) | 5 (100) |
|  |  |  |  | Abnormal, NCS | 0 | 0 |  | 0 | 0 | 0 |
|  |  |  |  | Abnormal, CS | 0 | 0 |  | 0 | 0 | 0 |
|  |  |  |  | Total | 1 (20.0) | 1 (20.0) |  | 0 | 3 (60.0) | 5 (100) |
|  | | | | | | | | | | |
|  | Control Group (N = 5) | Left | Last Post-Baseline | Normal | 0 | 0 |  | 0 | 4 (80.0) | 4 (80.0) |
|  |  |  |  | Abnormal, NCS | 1 (20.0) | 0 |  | 0 | 0 | 1 (20.0) |
|  |  |  |  | Abnormal, CS | 0 | 0 |  | 0 | 0 | 0 |
|  |  |  |  | Total | 1 (20.0) | 0 |  | 0 | 4 (80.0) | 5 (100) |
|  | | | | | | | | | | |
|  |  |  | Worst Post-Baseline | Normal | 0 | 0 |  | 0 | 4 (80.0) | 4 (80.0) |
|  |  |  |  | Abnormal, NCS | 1 (20.0) | 0 |  | 0 | 0 | 1 (20.0) |
|  |  |  |  | Abnormal, CS | 0 | 0 |  | 0 | 0 | 0 |
|  |  |  |  | Total | 1 (20.0) | 0 |  | 0 | 4 (80.0) | 5 (100) |
|  | | | | | | | | | | |
|  |  | Right | Last Post-Baseline | Normal | 1 (20.0) | 0 |  | 0 | 3 (60.0) | 4 (80.0) |
|  |  |  |  | Abnormal, NCS | 0 | 0 |  | 0 | 1 (20.0) | 1 (20.0) |
|  |  |  |  | Abnormal, CS | 0 | 0 |  | 0 | 0 | 0 |
|  |  |  |  | Total | 1 (20.0) | 0 |  | 0 | 4 (80.0) | 5 (100) |
|  | | | | | | | | | | |
|  |  |  | Worst Post-Baseline | Normal | 1 (20.0) | 0 |  | 0 | 3 (60.0) | 4 (80.0) |
|  |  |  |  | Abnormal, NCS | 0 | 0 |  | 0 | 1 (20.0) | 1 (20.0) |
|  |  |  |  | Abnormal, CS | 0 | 0 |  | 0 | 0 | 0 |
|  |  |  |  | Total | 1 (20.0) | 0 |  | 0 | 4 (80.0) | 5 (100) |
|  | | | | | | | | | | |
| Cornea | Treatment Group (N = 5) | Left | Last Post-Baseline | Normal | 2 (40.0) | 0 |  | 0 | 3 (60.0) | 5 (100) |
|  |  |  |  | Abnormal, NCS | 0 | 0 |  | 0 | 0 | 0 |
|  |  |  |  | Abnormal, CS | 0 | 0 |  | 0 | 0 | 0 |
|  |  |  |  | Total | 2 (40.0) | 0 |  | 0 | 3 (60.0) | 5 (100) |
|  | | | | | | | | | | |
|  |  |  | Worst Post-Baseline | Normal | 2 (40.0) | 0 |  | 0 | 3 (60.0) | 5 (100) |
|  |  |  |  | Abnormal, NCS | 0 | 0 |  | 0 | 0 | 0 |
|  |  |  |  | Abnormal, CS | 0 | 0 |  | 0 | 0 | 0 |
|  |  |  |  | Total | 2 (40.0) | 0 |  | 0 | 3 (60.0) | 5 (100) |
|  | | | | | | | | | | |
|  |  | Right | Last Post-Baseline | Normal | 2 (40.0) | 0 |  | 0 | 3 (60.0) | 5 (100) |
|  |  |  |  | Abnormal, NCS | 0 | 0 |  | 0 | 0 | 0 |
|  |  |  |  | Abnormal, CS | 0 | 0 |  | 0 | 0 | 0 |
|  |  |  |  | Total | 2 (40.0) | 0 |  | 0 | 3 (60.0) | 5 (100) |
|  | | | | | | | | | | |
|  |  |  | Worst Post-Baseline | Normal | 2 (40.0) | 0 |  | 0 | 3 (60.0) | 5 (100) |
|  |  |  |  | Abnormal, NCS | 0 | 0 |  | 0 | 0 | 0 |
|  |  |  |  | Abnormal, CS | 0 | 0 |  | 0 | 0 | 0 |
|  |  |  |  | Total | 2 (40.0) | 0 |  | 0 | 3 (60.0) | 5 (100) |
|  | | | | | | | | | | |
|  | Control Group (N = 5) | Left | Last Post-Baseline | Normal | 1 (20.0) | 0 |  | 0 | 4 (80.0) | 5 (100) |
|  |  |  |  | Abnormal, NCS | 0 | 0 |  | 0 | 0 | 0 |
|  |  |  |  | Abnormal, CS | 0 | 0 |  | 0 | 0 | 0 |
|  |  |  |  | Total | 1 (20.0) | 0 |  | 0 | 4 (80.0) | 5 (100) |
|  | | | | | | | | | | |
|  |  |  | Worst Post-Baseline | Normal | 1 (20.0) | 0 |  | 0 | 4 (80.0) | 5 (100) |
|  |  |  |  | Abnormal, NCS | 0 | 0 |  | 0 | 0 | 0 |
|  |  |  |  | Abnormal, CS | 0 | 0 |  | 0 | 0 | 0 |
|  |  |  |  | Total | 1 (20.0) | 0 |  | 0 | 4 (80.0) | 5 (100) |
|  | | | | | | | | | | |
|  |  | Right | Last Post-Baseline | Normal | 1 (20.0) | 0 |  | 0 | 4 (80.0) | 5 (100) |
|  |  |  |  | Abnormal, NCS | 0 | 0 |  | 0 | 0 | 0 |
|  |  |  |  | Abnormal, CS | 0 | 0 |  | 0 | 0 | 0 |
|  |  |  |  | Total | 1 (20.0) | 0 |  | 0 | 4 (80.0) | 5 (100) |
|  | | | | | | | | | | |
|  |  |  | Worst Post-Baseline | Normal | 1 (20.0) | 0 |  | 0 | 4 (80.0) | 5 (100) |
|  |  |  |  | Abnormal, NCS | 0 | 0 |  | 0 | 0 | 0 |
|  |  |  |  | Abnormal, CS | 0 | 0 |  | 0 | 0 | 0 |
|  |  |  |  | Total | 1 (20.0) | 0 |  | 0 | 4 (80.0) | 5 (100) |
|  | | | | | | | | | | |
| Anterior Chamber | Treatment Group (N = 5) | Left | Last Post-Baseline | Normal | 2 (40.0) | 0 |  | 0 | 3 (60.0) | 5 (100) |
|  |  |  |  | Abnormal, NCS | 0 | 0 |  | 0 | 0 | 0 |
|  |  |  |  | Abnormal, CS | 0 | 0 |  | 0 | 0 | 0 |
|  |  |  |  | Total | 2 (40.0) | 0 |  | 0 | 3 (60.0) | 5 (100) |
|  | | | | | | | | | | |
|  |  |  | Worst Post-Baseline | Normal | 2 (40.0) | 0 |  | 0 | 3 (60.0) | 5 (100) |
|  |  |  |  | Abnormal, NCS | 0 | 0 |  | 0 | 0 | 0 |
|  |  |  |  | Abnormal, CS | 0 | 0 |  | 0 | 0 | 0 |
|  |  |  |  | Total | 2 (40.0) | 0 |  | 0 | 3 (60.0) | 5 (100) |
|  | | | | | | | | | | |
|  |  | Right | Last Post-Baseline | Normal | 2 (40.0) | 0 |  | 0 | 3 (60.0) | 5 (100) |
|  |  |  |  | Abnormal, NCS | 0 | 0 |  | 0 | 0 | 0 |
|  |  |  |  | Abnormal, CS | 0 | 0 |  | 0 | 0 | 0 |
|  |  |  |  | Total | 2 (40.0) | 0 |  | 0 | 3 (60.0) | 5 (100) |
|  | | | | | | | | | | |
|  |  |  | Worst Post-Baseline | Normal | 2 (40.0) | 0 |  | 0 | 3 (60.0) | 5 (100) |
|  |  |  |  | Abnormal, NCS | 0 | 0 |  | 0 | 0 | 0 |
|  |  |  |  | Abnormal, CS | 0 | 0 |  | 0 | 0 | 0 |
|  |  |  |  | Total | 2 (40.0) | 0 |  | 0 | 3 (60.0) | 5 (100) |
|  | | | | | | | | | | |
|  | Control Group (N = 5) | Left | Last Post-Baseline | Normal | 1 (20.0) | 0 |  | 0 | 4 (80.0) | 5 (100) |
|  |  |  |  | Abnormal, NCS | 0 | 0 |  | 0 | 0 | 0 |
|  |  |  |  | Abnormal, CS | 0 | 0 |  | 0 | 0 | 0 |
|  |  |  |  | Total | 1 (20.0) | 0 |  | 0 | 4 (80.0) | 5 (100) |
|  | | | | | | | | | | |
|  |  |  | Worst Post-Baseline | Normal | 1 (20.0) | 0 |  | 0 | 4 (80.0) | 5 (100) |
|  |  |  |  | Abnormal, NCS | 0 | 0 |  | 0 | 0 | 0 |
|  |  |  |  | Abnormal, CS | 0 | 0 |  | 0 | 0 | 0 |
|  |  |  |  | Total | 1 (20.0) | 0 |  | 0 | 4 (80.0) | 5 (100) |
|  | | | | | | | | | | |
|  |  | Right | Last Post-Baseline | Normal | 1 (20.0) | 0 |  | 0 | 4 (80.0) | 5 (100) |
|  |  |  |  | Abnormal, NCS | 0 | 0 |  | 0 | 0 | 0 |
|  |  |  |  | Abnormal, CS | 0 | 0 |  | 0 | 0 | 0 |
|  |  |  |  | Total | 1 (20.0) | 0 |  | 0 | 4 (80.0) | 5 (100) |
|  | | | | | | | | | | |
|  |  |  | Worst Post-Baseline | Normal | 1 (20.0) | 0 |  | 0 | 4 (80.0) | 5 (100) |
|  |  |  |  | Abnormal, NCS | 0 | 0 |  | 0 | 0 | 0 |
|  |  |  |  | Abnormal, CS | 0 | 0 |  | 0 | 0 | 0 |
|  |  |  |  | Total | 1 (20.0) | 0 |  | 0 | 4 (80.0) | 5 (100) |
|  | | | | | | | | | | |
| Iris | Treatment Group (N = 5) | Left | Last Post-Baseline | Normal | 2 (40.0) | 0 |  | 0 | 3 (60.0) | 5 (100) |
|  |  |  |  | Abnormal, NCS | 0 | 0 |  | 0 | 0 | 0 |
|  |  |  |  | Abnormal, CS | 0 | 0 |  | 0 | 0 | 0 |
|  |  |  |  | Total | 2 (40.0) | 0 |  | 0 | 3 (60.0) | 5 (100) |
|  | | | | | | | | | | |
|  |  |  | Worst Post-Baseline | Normal | 2 (40.0) | 0 |  | 0 | 3 (60.0) | 5 (100) |
|  |  |  |  | Abnormal, NCS | 0 | 0 |  | 0 | 0 | 0 |
|  |  |  |  | Abnormal, CS | 0 | 0 |  | 0 | 0 | 0 |
|  |  |  |  | Total | 2 (40.0) | 0 |  | 0 | 3 (60.0) | 5 (100) |
|  | | | | | | | | | | |
|  |  | Right | Last Post-Baseline | Normal | 2 (40.0) | 0 |  | 0 | 3 (60.0) | 5 (100) |
|  |  |  |  | Abnormal, NCS | 0 | 0 |  | 0 | 0 | 0 |
|  |  |  |  | Abnormal, CS | 0 | 0 |  | 0 | 0 | 0 |
|  |  |  |  | Total | 2 (40.0) | 0 |  | 0 | 3 (60.0) | 5 (100) |
|  | | | | | | | | | | |
|  |  |  | Worst Post-Baseline | Normal | 2 (40.0) | 0 |  | 0 | 3 (60.0) | 5 (100) |
|  |  |  |  | Abnormal, NCS | 0 | 0 |  | 0 | 0 | 0 |
|  |  |  |  | Abnormal, CS | 0 | 0 |  | 0 | 0 | 0 |
|  |  |  |  | Total | 2 (40.0) | 0 |  | 0 | 3 (60.0) | 5 (100) |
|  | | | | | | | | | | |
|  | Control Group (N = 5) | Left | Last Post-Baseline | Normal | 1 (20.0) | 0 |  | 0 | 3 (60.0) | 4 (80.0) |
|  |  |  |  | Abnormal, NCS | 0 | 0 |  | 0 | 0 | 0 |
|  |  |  |  | Abnormal, CS | 0 | 0 |  | 0 | 0 | 0 |
|  |  |  |  | Missing | 0 | 0 |  | 0 | 1 (20.0) | 1 (20.0) |
|  |  |  |  | Total | 1 (20.0) | 0 |  | 0 | 4 (80.0) | 5 (100) |
|  | | | | | | | | | | |
|  |  |  | Worst Post-Baseline | Normal | 1 (20.0) | 0 |  | 0 | 3 (60.0) | 4 (80.0) |
|  |  |  |  | Abnormal, NCS | 0 | 0 |  | 0 | 0 | 0 |
|  |  |  |  | Abnormal, CS | 0 | 0 |  | 0 | 0 | 0 |
|  |  |  |  | Missing | 0 | 0 |  | 0 | 1 (20.0) | 1 (20.0) |
|  |  |  |  | Total | 1 (20.0) | 0 |  | 0 | 4 (80.0) | 5 (100) |
|  | | | | | | | | | | |
|  |  | Right | Last Post-Baseline | Normal | 1 (20.0) | 0 |  | 0 | 3 (60.0) | 4 (80.0) |
|  |  |  |  | Abnormal, NCS | 0 | 0 |  | 0 | 0 | 0 |
|  |  |  |  | Abnormal, CS | 0 | 0 |  | 0 | 0 | 0 |
|  |  |  |  | Missing | 0 | 0 |  | 0 | 1 (20.0) | 1 (20.0) |
|  |  |  |  | Total | 1 (20.0) | 0 |  | 0 | 4 (80.0) | 5 (100) |
|  | | | | | | | | | | |
|  |  |  | Worst Post-Baseline | Normal | 1 (20.0) | 0 |  | 0 | 3 (60.0) | 4 (80.0) |
|  |  |  |  | Abnormal, NCS | 0 | 0 |  | 0 | 0 | 0 |
|  |  |  |  | Abnormal, CS | 0 | 0 |  | 0 | 0 | 0 |
|  |  |  |  | Missing | 0 | 0 |  | 0 | 1 (20.0) | 1 (20.0) |
|  |  |  |  | Total | 1 (20.0) | 0 |  | 0 | 4 (80.0) | 5 (100) |
|  | | | | | | | | | | |
| Pupil | Treatment Group (N = 5) | Left | Last Post-Baseline | Normal | 2 (40.0) | 0 |  | 0 | 3 (60.0) | 5 (100) |
|  |  |  |  | Abnormal, NCS | 0 | 0 |  | 0 | 0 | 0 |
|  |  |  |  | Abnormal, CS | 0 | 0 |  | 0 | 0 | 0 |
|  |  |  |  | Total | 2 (40.0) | 0 |  | 0 | 3 (60.0) | 5 (100) |
|  | | | | | | | | | | |
|  |  |  | Worst Post-Baseline | Normal | 2 (40.0) | 0 |  | 0 | 3 (60.0) | 5 (100) |
|  |  |  |  | Abnormal, NCS | 0 | 0 |  | 0 | 0 | 0 |
|  |  |  |  | Abnormal, CS | 0 | 0 |  | 0 | 0 | 0 |
|  |  |  |  | Total | 2 (40.0) | 0 |  | 0 | 3 (60.0) | 5 (100) |
|  | | | | | | | | | | |
|  |  | Right | Last Post-Baseline | Normal | 2 (40.0) | 0 |  | 0 | 3 (60.0) | 5 (100) |
|  |  |  |  | Abnormal, NCS | 0 | 0 |  | 0 | 0 | 0 |
|  |  |  |  | Abnormal, CS | 0 | 0 |  | 0 | 0 | 0 |
|  |  |  |  | Total | 2 (40.0) | 0 |  | 0 | 3 (60.0) | 5 (100) |
|  | | | | | | | | | | |
|  |  |  | Worst Post-Baseline | Normal | 2 (40.0) | 0 |  | 0 | 3 (60.0) | 5 (100) |
|  |  |  |  | Abnormal, NCS | 0 | 0 |  | 0 | 0 | 0 |
|  |  |  |  | Abnormal, CS | 0 | 0 |  | 0 | 0 | 0 |
|  |  |  |  | Total | 2 (40.0) | 0 |  | 0 | 3 (60.0) | 5 (100) |
|  | | | | | | | | | | |
|  | Control Group (N = 5) | Left | Last Post-Baseline | Normal | 1 (20.0) | 0 |  | 0 | 4 (80.0) | 5 (100) |
|  |  |  |  | Abnormal, NCS | 0 | 0 |  | 0 | 0 | 0 |
|  |  |  |  | Abnormal, CS | 0 | 0 |  | 0 | 0 | 0 |
|  |  |  |  | Total | 1 (20.0) | 0 |  | 0 | 4 (80.0) | 5 (100) |
|  | | | | | | | | | | |
|  |  |  | Worst Post-Baseline | Normal | 1 (20.0) | 0 |  | 0 | 4 (80.0) | 5 (100) |
|  |  |  |  | Abnormal, NCS | 0 | 0 |  | 0 | 0 | 0 |
|  |  |  |  | Abnormal, CS | 0 | 0 |  | 0 | 0 | 0 |
|  |  |  |  | Total | 1 (20.0) | 0 |  | 0 | 4 (80.0) | 5 (100) |
|  | | | | | | | | | | |
|  |  | Right | Last Post-Baseline | Normal | 1 (20.0) | 0 |  | 0 | 4 (80.0) | 5 (100) |
|  |  |  |  | Abnormal, NCS | 0 | 0 |  | 0 | 0 | 0 |
|  |  |  |  | Abnormal, CS | 0 | 0 |  | 0 | 0 | 0 |
|  |  |  |  | Total | 1 (20.0) | 0 |  | 0 | 4 (80.0) | 5 (100) |
|  | | | | | | | | | | |
|  |  |  | Worst Post-Baseline | Normal | 1 (20.0) | 0 |  | 0 | 4 (80.0) | 5 (100) |
|  |  |  |  | Abnormal, NCS | 0 | 0 |  | 0 | 0 | 0 |
|  |  |  |  | Abnormal, CS | 0 | 0 |  | 0 | 0 | 0 |
|  |  |  |  | Total | 1 (20.0) | 0 |  | 0 | 4 (80.0) | 5 (100) |
|  | | | | | | | | | | |
| Lens | Treatment Group (N = 5) | Left | Last Post-Baseline | Normal | 1 (20.0) | 0 |  | 0 | 3 (60.0) | 4 (80.0) |
|  |  |  |  | Abnormal, NCS | 0 | 0 |  | 0 | 0 | 0 |
|  |  |  |  | Abnormal, CS | 0 | 0 |  | 1 (20.0) | 0 | 1 (20.0) |
|  |  |  |  | Total | 1 (20.0) | 0 |  | 1 (20.0) | 3 (60.0) | 5 (100) |
|  | | | | | | | | | | |
|  |  |  | Worst Post-Baseline | Normal | 1 (20.0) | 0 |  | 0 | 3 (60.0) | 4 (80.0) |
|  |  |  |  | Abnormal, NCS | 0 | 0 |  | 0 | 0 | 0 |
|  |  |  |  | Abnormal, CS | 0 | 0 |  | 1 (20.0) | 0 | 1 (20.0) |
|  |  |  |  | Total | 1 (20.0) | 0 |  | 1 (20.0) | 3 (60.0) | 5 (100) |
|  | | | | | | | | | | |
|  |  | Right | Last Post-Baseline | Normal | 1 (20.0) | 0 |  | 0 | 3 (60.0) | 4 (80.0) |
|  |  |  |  | Abnormal, NCS | 0 | 0 |  | 0 | 0 | 0 |
|  |  |  |  | Abnormal, CS | 0 | 0 |  | 1 (20.0) | 0 | 1 (20.0) |
|  |  |  |  | Total | 1 (20.0) | 0 |  | 1 (20.0) | 3 (60.0) | 5 (100) |
|  | | | | | | | | | | |
|  |  |  | Worst Post-Baseline | Normal | 1 (20.0) | 0 |  | 0 | 3 (60.0) | 4 (80.0) |
|  |  |  |  | Abnormal, NCS | 0 | 0 |  | 0 | 0 | 0 |
|  |  |  |  | Abnormal, CS | 0 | 0 |  | 1 (20.0) | 0 | 1 (20.0) |
|  |  |  |  | Total | 1 (20.0) | 0 |  | 1 (20.0) | 3 (60.0) | 5 (100) |
|  | | | | | | | | | | |
|  | Control Group (N = 5) | Left | Last Post-Baseline | Normal | 1 (20.0) | 0 |  | 0 | 3 (60.0) | 4 (80.0) |
|  |  |  |  | Abnormal, NCS | 0 | 0 |  | 0 | 1 (20.0) | 1 (20.0) |
|  |  |  |  | Abnormal, CS | 0 | 0 |  | 0 | 0 | 0 |
|  |  |  |  | Total | 1 (20.0) | 0 |  | 0 | 4 (80.0) | 5 (100) |
|  | | | | | | | | | | |
|  |  |  | Worst Post-Baseline | Normal | 1 (20.0) | 0 |  | 0 | 3 (60.0) | 4 (80.0) |
|  |  |  |  | Abnormal, NCS | 0 | 0 |  | 0 | 1 (20.0) | 1 (20.0) |
|  |  |  |  | Abnormal, CS | 0 | 0 |  | 0 | 0 | 0 |
|  |  |  |  | Total | 1 (20.0) | 0 |  | 0 | 4 (80.0) | 5 (100) |
|  | | | | | | | | | | |
|  |  | Right | Last Post-Baseline | Normal | 1 (20.0) | 0 |  | 0 | 3 (60.0) | 4 (80.0) |
|  |  |  |  | Abnormal, NCS | 0 | 0 |  | 0 | 1 (20.0) | 1 (20.0) |
|  |  |  |  | Abnormal, CS | 0 | 0 |  | 0 | 0 | 0 |
|  |  |  |  | Total | 1 (20.0) | 0 |  | 0 | 4 (80.0) | 5 (100) |
|  | | | | | | | | | | |
|  |  |  | Worst Post-Baseline | Normal | 1 (20.0) | 0 |  | 0 | 3 (60.0) | 4 (80.0) |
|  |  |  |  | Abnormal, NCS | 0 | 0 |  | 0 | 1 (20.0) | 1 (20.0) |
|  |  |  |  | Abnormal, CS | 0 | 0 |  | 0 | 0 | 0 |
|  |  |  |  | Total | 1 (20.0) | 0 |  | 0 | 4 (80.0) | 5 (100) |

Baseline is defined as the last available assessment before the first administration of investigational drug (D-1553 or IN10018).

Last post-baseline is the last value of investigator's assessment at all post-baseline visits, including any scheduled, unscheduled, EOT/early withdraw from the study and safety follow-up.

Worst post-baseline is the value of worst investigator's assessment at all post-baseline visits, including any scheduled, unscheduled, EOT/early withdraw from the study and safety follow-up.

Percentages are based on the number of subjects of each respective group in the Safety Analysis Set.

Source Data: Listing 16.2.12.1

|  |  |  |
| --- | --- | --- |
| Program: t-oe-shift-sle.sas | DCO: 27APR2024 | Executed: 07JUL2024 20:52 |

|  |  |
| --- | --- |
| **InxMed (Shanghai) Co., Ltd.  Protocol No. IN10018-602** |  |

**Table 14.3.10.3 Summary of Shifts from Baseline in Physical Examination According to Investigator’s Assessment - Phase II part 2 - CRC (Safety Analysis Set)**

|  | | | | Post-baseline | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Parameter | Group | Visit | Baseline | Normal | Abnormal, NCS | Abnormal, CS |  | Missing | Total |
| General condition | Treatment Group (N = 5) | Last Post-Baseline | Normal | 3 (60.0) | 0 | 0 |  | 1 (20.0) | 4 (80.0) |
|  |  |  | Abnormal, NCS | 0 | 0 | 0 |  | 0 | 0 |
|  |  |  | Abnormal, CS | 0 | 0 | 0 |  | 0 | 0 |
|  |  |  | Missing | 1 (20.0) | 0 | 0 |  | 0 | 1 (20.0) |
|  |  |  | Total | 4 (80.0) | 0 | 0 |  | 1 (20.0) | 5 (100) |
|  | | | | | | | | | |
|  |  | Worst Post-Baseline | Normal | 3 (60.0) | 0 | 0 |  | 1 (20.0) | 4 (80.0) |
|  |  |  | Abnormal, NCS | 0 | 0 | 0 |  | 0 | 0 |
|  |  |  | Abnormal, CS | 0 | 0 | 0 |  | 0 | 0 |
|  |  |  | Missing | 1 (20.0) | 0 | 0 |  | 0 | 1 (20.0) |
|  |  |  | Total | 4 (80.0) | 0 | 0 |  | 1 (20.0) | 5 (100) |
|  | | | | | | | | | |
|  | Control Group (N = 5) | Last Post-Baseline | Normal | 2 (40.0) | 0 | 0 |  | 1 (20.0) | 3 (60.0) |
|  |  |  | Abnormal, NCS | 0 | 0 | 0 |  | 0 | 0 |
|  |  |  | Abnormal, CS | 0 | 0 | 0 |  | 0 | 0 |
|  |  |  | Missing | 2 (40.0) | 0 | 0 |  | 0 | 2 (40.0) |
|  |  |  | Total | 4 (80.0) | 0 | 0 |  | 1 (20.0) | 5 (100) |
|  | | | | | | | | | |
|  |  | Worst Post-Baseline | Normal | 2 (40.0) | 0 | 0 |  | 1 (20.0) | 3 (60.0) |
|  |  |  | Abnormal, NCS | 0 | 0 | 0 |  | 0 | 0 |
|  |  |  | Abnormal, CS | 0 | 0 | 0 |  | 0 | 0 |
|  |  |  | Missing | 2 (40.0) | 0 | 0 |  | 0 | 2 (40.0) |
|  |  |  | Total | 4 (80.0) | 0 | 0 |  | 1 (20.0) | 5 (100) |
|  | | | | | | | | | |
| Head | Treatment Group (N = 5) | Last Post-Baseline | Normal | 3 (60.0) | 0 | 0 |  | 1 (20.0) | 4 (80.0) |
|  |  |  | Abnormal, NCS | 0 | 0 | 0 |  | 0 | 0 |
|  |  |  | Abnormal, CS | 0 | 0 | 0 |  | 0 | 0 |
|  |  |  | Missing | 1 (20.0) | 0 | 0 |  | 0 | 1 (20.0) |
|  |  |  | Total | 4 (80.0) | 0 | 0 |  | 1 (20.0) | 5 (100) |
|  | | | | | | | | | |
|  |  | Worst Post-Baseline | Normal | 3 (60.0) | 0 | 0 |  | 1 (20.0) | 4 (80.0) |
|  |  |  | Abnormal, NCS | 0 | 0 | 0 |  | 0 | 0 |
|  |  |  | Abnormal, CS | 0 | 0 | 0 |  | 0 | 0 |
|  |  |  | Missing | 1 (20.0) | 0 | 0 |  | 0 | 1 (20.0) |
|  |  |  | Total | 4 (80.0) | 0 | 0 |  | 1 (20.0) | 5 (100) |
|  | | | | | | | | | |
|  | Control Group (N = 5) | Last Post-Baseline | Normal | 1 (20.0) | 0 | 0 |  | 1 (20.0) | 2 (40.0) |
|  |  |  | Abnormal, NCS | 0 | 0 | 0 |  | 0 | 0 |
|  |  |  | Abnormal, CS | 0 | 0 | 1 (20.0) |  | 0 | 1 (20.0) |
|  |  |  | Missing | 2 (40.0) | 0 | 0 |  | 0 | 2 (40.0) |
|  |  |  | Total | 3 (60.0) | 0 | 1 (20.0) |  | 1 (20.0) | 5 (100) |
|  | | | | | | | | | |
|  |  | Worst Post-Baseline | Normal | 1 (20.0) | 0 | 0 |  | 1 (20.0) | 2 (40.0) |
|  |  |  | Abnormal, NCS | 0 | 0 | 0 |  | 0 | 0 |
|  |  |  | Abnormal, CS | 0 | 0 | 1 (20.0) |  | 0 | 1 (20.0) |
|  |  |  | Missing | 2 (40.0) | 0 | 0 |  | 0 | 2 (40.0) |
|  |  |  | Total | 3 (60.0) | 0 | 1 (20.0) |  | 1 (20.0) | 5 (100) |
|  | | | | | | | | | |
| Neck | Treatment Group (N = 5) | Last Post-Baseline | Normal | 3 (60.0) | 0 | 0 |  | 1 (20.0) | 4 (80.0) |
|  |  |  | Abnormal, NCS | 0 | 0 | 0 |  | 0 | 0 |
|  |  |  | Abnormal, CS | 0 | 0 | 0 |  | 0 | 0 |
|  |  |  | Missing | 1 (20.0) | 0 | 0 |  | 0 | 1 (20.0) |
|  |  |  | Total | 4 (80.0) | 0 | 0 |  | 1 (20.0) | 5 (100) |
|  | | | | | | | | | |
|  |  | Worst Post-Baseline | Normal | 3 (60.0) | 0 | 0 |  | 1 (20.0) | 4 (80.0) |
|  |  |  | Abnormal, NCS | 0 | 0 | 0 |  | 0 | 0 |
|  |  |  | Abnormal, CS | 0 | 0 | 0 |  | 0 | 0 |
|  |  |  | Missing | 1 (20.0) | 0 | 0 |  | 0 | 1 (20.0) |
|  |  |  | Total | 4 (80.0) | 0 | 0 |  | 1 (20.0) | 5 (100) |
|  | | | | | | | | | |
|  | Control Group (N = 5) | Last Post-Baseline | Normal | 2 (40.0) | 0 | 0 |  | 1 (20.0) | 3 (60.0) |
|  |  |  | Abnormal, NCS | 0 | 0 | 0 |  | 0 | 0 |
|  |  |  | Abnormal, CS | 0 | 0 | 0 |  | 0 | 0 |
|  |  |  | Missing | 2 (40.0) | 0 | 0 |  | 0 | 2 (40.0) |
|  |  |  | Total | 4 (80.0) | 0 | 0 |  | 1 (20.0) | 5 (100) |
|  | | | | | | | | | |
|  |  | Worst Post-Baseline | Normal | 2 (40.0) | 0 | 0 |  | 1 (20.0) | 3 (60.0) |
|  |  |  | Abnormal, NCS | 0 | 0 | 0 |  | 0 | 0 |
|  |  |  | Abnormal, CS | 0 | 0 | 0 |  | 0 | 0 |
|  |  |  | Missing | 2 (40.0) | 0 | 0 |  | 0 | 2 (40.0) |
|  |  |  | Total | 4 (80.0) | 0 | 0 |  | 1 (20.0) | 5 (100) |
|  | | | | | | | | | |
| Chest(includes heart and lungs) | Treatment Group (N = 5) | Last Post-Baseline | Normal | 3 (60.0) | 0 | 0 |  | 1 (20.0) | 4 (80.0) |
|  |  |  | Abnormal, NCS | 0 | 0 | 0 |  | 0 | 0 |
|  |  |  | Abnormal, CS | 0 | 0 | 0 |  | 0 | 0 |
|  |  |  | Missing | 1 (20.0) | 0 | 0 |  | 0 | 1 (20.0) |
|  |  |  | Total | 4 (80.0) | 0 | 0 |  | 1 (20.0) | 5 (100) |
|  | | | | | | | | | |
|  |  | Worst Post-Baseline | Normal | 3 (60.0) | 0 | 0 |  | 1 (20.0) | 4 (80.0) |
|  |  |  | Abnormal, NCS | 0 | 0 | 0 |  | 0 | 0 |
|  |  |  | Abnormal, CS | 0 | 0 | 0 |  | 0 | 0 |
|  |  |  | Missing | 1 (20.0) | 0 | 0 |  | 0 | 1 (20.0) |
|  |  |  | Total | 4 (80.0) | 0 | 0 |  | 1 (20.0) | 5 (100) |
|  | | | | | | | | | |
|  | Control Group (N = 5) | Last Post-Baseline | Normal | 2 (40.0) | 0 | 0 |  | 1 (20.0) | 3 (60.0) |
|  |  |  | Abnormal, NCS | 0 | 0 | 0 |  | 0 | 0 |
|  |  |  | Abnormal, CS | 0 | 0 | 0 |  | 0 | 0 |
|  |  |  | Missing | 2 (40.0) | 0 | 0 |  | 0 | 2 (40.0) |
|  |  |  | Total | 4 (80.0) | 0 | 0 |  | 1 (20.0) | 5 (100) |
|  | | | | | | | | | |
|  |  | Worst Post-Baseline | Normal | 2 (40.0) | 0 | 0 |  | 1 (20.0) | 3 (60.0) |
|  |  |  | Abnormal, NCS | 0 | 0 | 0 |  | 0 | 0 |
|  |  |  | Abnormal, CS | 0 | 0 | 0 |  | 0 | 0 |
|  |  |  | Missing | 2 (40.0) | 0 | 0 |  | 0 | 2 (40.0) |
|  |  |  | Total | 4 (80.0) | 0 | 0 |  | 1 (20.0) | 5 (100) |
|  | | | | | | | | | |
| Abdomen | Treatment Group (N = 5) | Last Post-Baseline | Normal | 3 (60.0) | 0 | 0 |  | 1 (20.0) | 4 (80.0) |
|  |  |  | Abnormal, NCS | 0 | 0 | 0 |  | 0 | 0 |
|  |  |  | Abnormal, CS | 0 | 0 | 0 |  | 0 | 0 |
|  |  |  | Missing | 0 | 1 (20.0) | 0 |  | 0 | 1 (20.0) |
|  |  |  | Total | 3 (60.0) | 1 (20.0) | 0 |  | 1 (20.0) | 5 (100) |
|  | | | | | | | | | |
|  |  | Worst Post-Baseline | Normal | 3 (60.0) | 0 | 0 |  | 1 (20.0) | 4 (80.0) |
|  |  |  | Abnormal, NCS | 0 | 0 | 0 |  | 0 | 0 |
|  |  |  | Abnormal, CS | 0 | 0 | 0 |  | 0 | 0 |
|  |  |  | Missing | 0 | 1 (20.0) | 0 |  | 0 | 1 (20.0) |
|  |  |  | Total | 3 (60.0) | 1 (20.0) | 0 |  | 1 (20.0) | 5 (100) |
|  | | | | | | | | | |
|  | Control Group (N = 5) | Last Post-Baseline | Normal | 2 (40.0) | 0 | 0 |  | 1 (20.0) | 3 (60.0) |
|  |  |  | Abnormal, NCS | 0 | 0 | 0 |  | 0 | 0 |
|  |  |  | Abnormal, CS | 0 | 0 | 0 |  | 0 | 0 |
|  |  |  | Missing | 1 (20.0) | 1 (20.0) | 0 |  | 0 | 2 (40.0) |
|  |  |  | Total | 3 (60.0) | 1 (20.0) | 0 |  | 1 (20.0) | 5 (100) |
|  | | | | | | | | | |
|  |  | Worst Post-Baseline | Normal | 2 (40.0) | 0 | 0 |  | 1 (20.0) | 3 (60.0) |
|  |  |  | Abnormal, NCS | 0 | 0 | 0 |  | 0 | 0 |
|  |  |  | Abnormal, CS | 0 | 0 | 0 |  | 0 | 0 |
|  |  |  | Missing | 1 (20.0) | 1 (20.0) | 0 |  | 0 | 2 (40.0) |
|  |  |  | Total | 3 (60.0) | 1 (20.0) | 0 |  | 1 (20.0) | 5 (100) |
|  | | | | | | | | | |
| Spine and extremities | Treatment Group (N = 5) | Last Post-Baseline | Normal | 2 (40.0) | 0 | 0 |  | 1 (20.0) | 3 (60.0) |
|  |  |  | Abnormal, NCS | 0 | 0 | 0 |  | 0 | 0 |
|  |  |  | Abnormal, CS | 0 | 0 | 1 (20.0) |  | 0 | 1 (20.0) |
|  |  |  | Missing | 1 (20.0) | 0 | 0 |  | 0 | 1 (20.0) |
|  |  |  | Total | 3 (60.0) | 0 | 1 (20.0) |  | 1 (20.0) | 5 (100) |
|  | | | | | | | | | |
|  |  | Worst Post-Baseline | Normal | 2 (40.0) | 0 | 0 |  | 1 (20.0) | 3 (60.0) |
|  |  |  | Abnormal, NCS | 0 | 0 | 0 |  | 0 | 0 |
|  |  |  | Abnormal, CS | 0 | 0 | 1 (20.0) |  | 0 | 1 (20.0) |
|  |  |  | Missing | 1 (20.0) | 0 | 0 |  | 0 | 1 (20.0) |
|  |  |  | Total | 3 (60.0) | 0 | 1 (20.0) |  | 1 (20.0) | 5 (100) |
|  | | | | | | | | | |
|  | Control Group (N = 5) | Last Post-Baseline | Normal | 2 (40.0) | 0 | 0 |  | 1 (20.0) | 3 (60.0) |
|  |  |  | Abnormal, NCS | 0 | 0 | 0 |  | 0 | 0 |
|  |  |  | Abnormal, CS | 0 | 0 | 0 |  | 0 | 0 |
|  |  |  | Missing | 1 (20.0) | 0 | 1 (20.0) |  | 0 | 2 (40.0) |
|  |  |  | Total | 3 (60.0) | 0 | 1 (20.0) |  | 1 (20.0) | 5 (100) |
|  | | | | | | | | | |
|  |  | Worst Post-Baseline | Normal | 2 (40.0) | 0 | 0 |  | 1 (20.0) | 3 (60.0) |
|  |  |  | Abnormal, NCS | 0 | 0 | 0 |  | 0 | 0 |
|  |  |  | Abnormal, CS | 0 | 0 | 0 |  | 0 | 0 |
|  |  |  | Missing | 1 (20.0) | 0 | 1 (20.0) |  | 0 | 2 (40.0) |
|  |  |  | Total | 3 (60.0) | 0 | 1 (20.0) |  | 1 (20.0) | 5 (100) |
|  | | | | | | | | | |
| Neurological system | Treatment Group (N = 5) | Last Post-Baseline | Normal | 3 (60.0) | 0 | 0 |  | 1 (20.0) | 4 (80.0) |
|  |  |  | Abnormal, NCS | 0 | 0 | 0 |  | 0 | 0 |
|  |  |  | Abnormal, CS | 0 | 0 | 0 |  | 0 | 0 |
|  |  |  | Missing | 1 (20.0) | 0 | 0 |  | 0 | 1 (20.0) |
|  |  |  | Total | 4 (80.0) | 0 | 0 |  | 1 (20.0) | 5 (100) |
|  | | | | | | | | | |
|  |  | Worst Post-Baseline | Normal | 3 (60.0) | 0 | 0 |  | 1 (20.0) | 4 (80.0) |
|  |  |  | Abnormal, NCS | 0 | 0 | 0 |  | 0 | 0 |
|  |  |  | Abnormal, CS | 0 | 0 | 0 |  | 0 | 0 |
|  |  |  | Missing | 1 (20.0) | 0 | 0 |  | 0 | 1 (20.0) |
|  |  |  | Total | 4 (80.0) | 0 | 0 |  | 1 (20.0) | 5 (100) |
|  | | | | | | | | | |
|  | Control Group (N = 5) | Last Post-Baseline | Normal | 2 (40.0) | 0 | 0 |  | 1 (20.0) | 3 (60.0) |
|  |  |  | Abnormal, NCS | 0 | 0 | 0 |  | 0 | 0 |
|  |  |  | Abnormal, CS | 0 | 0 | 0 |  | 0 | 0 |
|  |  |  | Missing | 2 (40.0) | 0 | 0 |  | 0 | 2 (40.0) |
|  |  |  | Total | 4 (80.0) | 0 | 0 |  | 1 (20.0) | 5 (100) |
|  | | | | | | | | | |
|  |  | Worst Post-Baseline | Normal | 2 (40.0) | 0 | 0 |  | 1 (20.0) | 3 (60.0) |
|  |  |  | Abnormal, NCS | 0 | 0 | 0 |  | 0 | 0 |
|  |  |  | Abnormal, CS | 0 | 0 | 0 |  | 0 | 0 |
|  |  |  | Missing | 2 (40.0) | 0 | 0 |  | 0 | 2 (40.0) |
|  |  |  | Total | 4 (80.0) | 0 | 0 |  | 1 (20.0) | 5 (100) |
|  | | | | | | | | | |
| Skin | Treatment Group (N = 5) | Last Post-Baseline | Normal | 1 (20.0) | 0 | 0 |  | 0 | 1 (20.0) |
|  |  |  | Abnormal, NCS | 0 | 2 (40.0) | 0 |  | 1 (20.0) | 3 (60.0) |
|  |  |  | Abnormal, CS | 0 | 0 | 0 |  | 0 | 0 |
|  |  |  | Missing | 1 (20.0) | 0 | 0 |  | 0 | 1 (20.0) |
|  |  |  | Total | 2 (40.0) | 2 (40.0) | 0 |  | 1 (20.0) | 5 (100) |
|  | | | | | | | | | |
|  |  | Worst Post-Baseline | Normal | 1 (20.0) | 0 | 0 |  | 0 | 1 (20.0) |
|  |  |  | Abnormal, NCS | 0 | 2 (40.0) | 0 |  | 1 (20.0) | 3 (60.0) |
|  |  |  | Abnormal, CS | 0 | 0 | 0 |  | 0 | 0 |
|  |  |  | Missing | 1 (20.0) | 0 | 0 |  | 0 | 1 (20.0) |
|  |  |  | Total | 2 (40.0) | 2 (40.0) | 0 |  | 1 (20.0) | 5 (100) |
|  | | | | | | | | | |
|  | Control Group (N = 5) | Last Post-Baseline | Normal | 1 (20.0) | 0 | 0 |  | 1 (20.0) | 2 (40.0) |
|  |  |  | Abnormal, NCS | 0 | 0 | 0 |  | 0 | 0 |
|  |  |  | Abnormal, CS | 0 | 0 | 1 (20.0) |  | 0 | 1 (20.0) |
|  |  |  | Missing | 1 (20.0) | 1 (20.0) | 0 |  | 0 | 2 (40.0) |
|  |  |  | Total | 2 (40.0) | 1 (20.0) | 1 (20.0) |  | 1 (20.0) | 5 (100) |
|  | | | | | | | | | |
|  |  | Worst Post-Baseline | Normal | 1 (20.0) | 0 | 0 |  | 1 (20.0) | 2 (40.0) |
|  |  |  | Abnormal, NCS | 0 | 0 | 0 |  | 0 | 0 |
|  |  |  | Abnormal, CS | 0 | 0 | 1 (20.0) |  | 0 | 1 (20.0) |
|  |  |  | Missing | 1 (20.0) | 1 (20.0) | 0 |  | 0 | 2 (40.0) |
|  |  |  | Total | 2 (40.0) | 1 (20.0) | 1 (20.0) |  | 1 (20.0) | 5 (100) |
|  | | | | | | | | | |
| lymph node | Treatment Group (N = 5) | Last Post-Baseline | Normal | 3 (60.0) | 0 | 0 |  | 1 (20.0) | 4 (80.0) |
|  |  |  | Abnormal, NCS | 0 | 0 | 0 |  | 0 | 0 |
|  |  |  | Abnormal, CS | 0 | 0 | 0 |  | 0 | 0 |
|  |  |  | Missing | 1 (20.0) | 0 | 0 |  | 0 | 1 (20.0) |
|  |  |  | Total | 4 (80.0) | 0 | 0 |  | 1 (20.0) | 5 (100) |
|  | | | | | | | | | |
|  |  | Worst Post-Baseline | Normal | 3 (60.0) | 0 | 0 |  | 1 (20.0) | 4 (80.0) |
|  |  |  | Abnormal, NCS | 0 | 0 | 0 |  | 0 | 0 |
|  |  |  | Abnormal, CS | 0 | 0 | 0 |  | 0 | 0 |
|  |  |  | Missing | 1 (20.0) | 0 | 0 |  | 0 | 1 (20.0) |
|  |  |  | Total | 4 (80.0) | 0 | 0 |  | 1 (20.0) | 5 (100) |
|  | | | | | | | | | |
|  | Control Group (N = 5) | Last Post-Baseline | Normal | 2 (40.0) | 0 | 0 |  | 0 | 2 (40.0) |
|  |  |  | Abnormal, NCS | 0 | 0 | 0 |  | 0 | 0 |
|  |  |  | Abnormal, CS | 0 | 0 | 0 |  | 1 (20.0) | 1 (20.0) |
|  |  |  | Missing | 2 (40.0) | 0 | 0 |  | 0 | 2 (40.0) |
|  |  |  | Total | 4 (80.0) | 0 | 0 |  | 1 (20.0) | 5 (100) |
|  | | | | | | | | | |
|  |  | Worst Post-Baseline | Normal | 2 (40.0) | 0 | 0 |  | 0 | 2 (40.0) |
|  |  |  | Abnormal, NCS | 0 | 0 | 0 |  | 0 | 0 |
|  |  |  | Abnormal, CS | 0 | 0 | 0 |  | 1 (20.0) | 1 (20.0) |
|  |  |  | Missing | 2 (40.0) | 0 | 0 |  | 0 | 2 (40.0) |
|  |  |  | Total | 4 (80.0) | 0 | 0 |  | 1 (20.0) | 5 (100) |

Baseline is defined as the last available assessment before the first administration of investigational drug (D-1553 or IN10018).

Last post-baseline is the last value of investigator's assessment at all post-baseline visits, including any scheduled, unscheduled, EOT/early withdraw from the study and safety follow-up.

Worst post-baseline is the value of worst investigator's assessment at all post-baseline visits, including any scheduled, unscheduled, EOT/early withdraw from the study and safety follow-up.

Percentages are based on the number of subjects of each respective group in the Safety Analysis Set.

Source Data: Listing 16.2.13.1

|  |  |  |
| --- | --- | --- |
| Program: t-pe-shift.sas | DCO: 27APR2024 | Executed: 07JUL2024 20:52 |

|  |  |
| --- | --- |
| **InxMed (Shanghai) Co., Ltd.  Protocol No. IN10018-602** |  |

**Table 14.3.11.1.3 Summary of Echocardiogram Parameters - Phase II part 2 - CRC (Safety Analysis Set)**

|  | | | | Observed Value | | | |  | Change from Baseline | | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Parameter | Group |  | Visit | n | Mean (STD) | Median (Q1, Q3) | Min, Max |  | n | Mean (STD) | Median (Q1, Q3) | Min, Max |
| Left Ventricular Ejection Fraction (%) | Treatment Group (N = 5) |  | Baseline | 5 | 68.80 (5.891) | 72.00 (63.00, 72.00) | 62.0, 75.0 |  |  |  |  |  |
|  |  |  | C5D1 | 2 | 70.00 (0.000) | 70.00 (70.00, 70.00) | 70.0, 70.0 |  | 2 | -3.50 (2.121) | -3.50 (-5.00, -2.00) | -5.0, -2.0 |
|  | | | | | | | | | | | | |
|  | Control Group (N = 5) |  | Baseline | 5 | 68.80 (6.301) | 67.00 (65.00, 72.00) | 62.0, 78.0 |  |  |  |  |  |
|  |  |  | C5D1 | 1 | 72.00 (NA) | 72.00 (72.00, 72.00) | 72.0, 72.0 |  | 1 | 5.00 (NA) | 5.00 (5.00, 5.00) | 5.0, 5.0 |
|  |  |  | End of Treatment | 1 | 70.00 (NA) | 70.00 (70.00, 70.00) | 70.0, 70.0 |  | 1 | -8.00 (NA) | -8.00 (-8.00, -8.00) | -8.0, -8.0 |
|  | | | | | | | | | | | | |
|  | Total (N = 10) |  | Baseline | 10 | 68.80 (5.750) | 69.50 (63.00, 72.00) | 62.0, 78.0 |  |  |  |  |  |
|  |  |  | C5D1 | 3 | 70.67 (1.155) | 70.00 (70.00, 72.00) | 70.0, 72.0 |  | 3 | -0.67 (5.132) | -2.00 (-5.00, 5.00) | -5.0, 5.0 |
|  |  |  | End of Treatment | 1 | 70.00 (NA) | 70.00 (70.00, 70.00) | 70.0, 70.0 |  | 1 | -8.00 (NA) | -8.00 (-8.00, -8.00) | -8.0, -8.0 |

NA = Not applicable.

Baseline is defined as the last available assessment before the first administration of investigational drug (D-1553 or IN10018).

Only subjects with data at both baseline and the relevant post baseline visit are included in the change from baseline summary statistics.

Source Data: Listing 16.2.14.1

|  |  |  |
| --- | --- | --- |
| Program: t-cv-chg.sas | DCO: 27APR2024 | Executed: 07JUL2024 20:52 |

|  |  |
| --- | --- |
| **InxMed (Shanghai) Co., Ltd.  Protocol No. IN10018-602** |  |

**Table 14.3.11.2.3 Summary of Shifts from Baseline in Echocardiogram According to Investigator’s Assessment - Phase II part 2 - CRC (Safety Analysis Set)**

|  | | | | Post-baseline | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Parameter | Group | Visit | Baseline | Normal | Abnormal, NCS | Abnormal, CS |  | Missing | Total |
| Interpretation | Treatment Group (N = 5) | Last Post-Baseline | Normal | 0 | 0 | 0 |  | 3 (60.0) | 3 (60.0) |
|  |  |  | Abnormal, NCS | 1 (20.0) | 1 (20.0) | 0 |  | 0 | 2 (40.0) |
|  |  |  | Abnormal, CS | 0 | 0 | 0 |  | 0 | 0 |
|  |  |  | Total | 1 (20.0) | 1 (20.0) | 0 |  | 3 (60.0) | 5 (100) |
|  | | | | | | | | | |
|  |  | Worst Post-Baseline | Normal | 0 | 0 | 0 |  | 3 (60.0) | 3 (60.0) |
|  |  |  | Abnormal, NCS | 1 (20.0) | 1 (20.0) | 0 |  | 0 | 2 (40.0) |
|  |  |  | Abnormal, CS | 0 | 0 | 0 |  | 0 | 0 |
|  |  |  | Total | 1 (20.0) | 1 (20.0) | 0 |  | 3 (60.0) | 5 (100) |
|  | | | | | | | | | |
|  | Control Group (N = 5) | Last Post-Baseline | Normal | 0 | 0 | 1 (20.0) |  | 2 (40.0) | 3 (60.0) |
|  |  |  | Abnormal, NCS | 0 | 1 (20.0) | 0 |  | 1 (20.0) | 2 (40.0) |
|  |  |  | Abnormal, CS | 0 | 0 | 0 |  | 0 | 0 |
|  |  |  | Total | 0 | 1 (20.0) | 1 (20.0) |  | 3 (60.0) | 5 (100) |
|  | | | | | | | | | |
|  |  | Worst Post-Baseline | Normal | 0 | 0 | 1 (20.0) |  | 2 (40.0) | 3 (60.0) |
|  |  |  | Abnormal, NCS | 0 | 1 (20.0) | 0 |  | 1 (20.0) | 2 (40.0) |
|  |  |  | Abnormal, CS | 0 | 0 | 0 |  | 0 | 0 |
|  |  |  | Total | 0 | 1 (20.0) | 1 (20.0) |  | 3 (60.0) | 5 (100) |

Baseline is defined as the last available assessment before the first administration of investigational drug (D-1553 or IN10018).

Last post-baseline is the last value of investigator's assessment at all post-baseline visits, including any scheduled, unscheduled, EOT/early withdraw from the study and safety follow-up.

Worst post-baseline is the value of worst investigator's assessment at all post-baseline visits, including any scheduled, unscheduled, EOT/early withdraw from the study and safety follow-up.

Percentages are based on the number of subjects of each respective group in the Safety Analysis Set.

Source Data: Listing 16.2.14.1

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| --- | --- | --- |
| Program: t-cv-shift.sas | DCO: 27APR2024 | Executed: 07JUL2024 20:54 |