**Table of Contents**

[**Table 14.1.1.2 Subject Disposition - Phase II part 1 treatment-naive locally-advanced or metastatic NSCLC (All Subjects Screened)** 7](#_Toc171427681)

[**Table 14.1.2.2 Demographics - Phase II part 1 treatment-naive locally-advanced or metastatic NSCLC (Full Analysis Set)** 8](#_Toc171427682)

[**Table 14.1.3.2 Baseline Disease Characteristics - Phase II part 1 treatment-naive locally-advanced or metastatic NSCLC (Full Analysis Set)** 10](#_Toc171427683)

[**Table 14.1.4.3 Prior Anti-cancer Therapy - Phase II part 1 treatment-naive locally-advanced or metastatic NSCLC (Safety Analysis Set)** 17](#_Toc171427684)

[**Table 14.1.4.4 Summary of Prior Systemic Anti-cancer Therapy by ATC Classification 2nd Level and Preferred Name - Phase II part 1 treatment-naive locally-advanced or metastatic NSCLC (Safety Analysis Set)** 19](#_Toc171427685)

[**Table 14.1.5.2 Summary of Medical History by SOC and PT - Phase II part 1 treatment-naive locally-advanced or metastatic NSCLC (Safety Analysis Set)** 20](#_Toc171427686)

[**Table 14.1.6.1.2 Summary of Prior Medications by ATC Classification 2nd Level and Preferred Name - Phase II part 1 treatment-naive locally-advanced or metastatic NSCLC (Safety Analysis Set)** 25](#_Toc171427687)

[**Table 14.1.6.2.2 Summary of Concomitant Medications by ATC Classification 2nd Level and Preferred Name - Phase II part 1 treatment-naive locally-advanced or metastatic NSCLC (Safety Analysis Set)** 27](#_Toc171427688)

[**Table 14.1.7.2 Summary of New Anti-cancer Therapies - Phase II part 1 treatment-naive locally-advanced or metastatic NSCLC (Safety Analysis Set)** 37](#_Toc171427689)

[**Table 14.1.8.2 Summary of Drug Exposure - Phase II part 1 treatment-naive locally-advanced or metastatic NSCLC (Safety Analysis Set)** 38](#_Toc171427690)

[**Table 14.2.1.1.2.1 Summary of Confirmed Best Overall Response based on RECIST 1.1 Criteria - Phase II part 1 Treatment naive locally-advanced or metastatic NSCLC (Safety Analysis Set)** 40](#_Toc171427691)

[**Table 14.2.1.1.2.2 Summary of Unconfirmed Best Overall Response based on RECIST 1.1 Criteria - Phase II part 1 Treatment naive locally-advanced or metastatic NSCLC (Safety Analysis Set)** 41](#_Toc171427692)

[**Table 14.2.1.2.2.1 Summary of Confirmed Best Overall Response based on RECIST 1.1 Criteria - Phase II part 1 Treatment naive locally-advanced or metastatic NSCLC (Response Evaluation Set)** 42](#_Toc171427693)

[**Table 14.2.1.2.2.2 Summary of Unconfirmed Best Overall Response based on RECIST 1.1 Criteria - Phase II part 1 Treatment naive locally-advanced or metastatic NSCLC (Response Evaluation Set)** 43](#_Toc171427694)

[**Table 14.2.1.3.1.1 Summary of Confirmed Objective Response Rate Subgroup Analysis - Phase II part 1 Treatment naive locally-advanced or metastatic NSCLC (Safety Analysis Set)** 44](#_Toc171427695)

[**Table 14.2.1.3.1.2 Summary of Unconfirmed Objective Response Rate Subgroup Analysis - Phase II part 1 Treatment naive locally-advanced or metastatic NSCLC (Safety Analysis Set)** 50](#_Toc171427696)

[**Table 14.2.1.4.1.1 Summary of Confirmed Objective Response Rate Subgroup Analysis - Phase II part 1 Treatment naive locally-advanced or metastatic NSCLC (Response Evaluation Set)** 56](#_Toc171427697)

[**Table 14.2.1.4.1.2 Summary of Unconfirmed Objective Response Rate Subgroup Analysis - Phase II part 1 Treatment naive locally-advanced or metastatic NSCLC (Response Evaluation Set)** 62](#_Toc171427698)

[**Table 14.2.2.1.2 Progression Free Survival based on RECIST 1.1 Criteria - Phase II part 1 Treatment naive locally-advanced or metastatic NSCLC (Safety Analysis Set)** 68](#_Toc171427699)

[**Table 14.2.2.2.1.1 Summary of PFS Subgroup Analysis - Phase II part 1 Treatment naive locally-advanced or metastatic NSCLC (Safety Analysis Set)** 69](#_Toc171427700)

[**Table 14.2.3.1.2.1 Duration of Response based on RECIST 1.1 Criteria (Confirmed) - Phase II part 1 Treatment naive locally-advanced or metastatic NSCLC (Response Evaluation Set)** 76](#_Toc171427701)

[**Table 14.2.3.1.2.2 Duration of Response based on RECIST 1.1 Criteria (Unconfirmed) - Phase II part 1 Treatment naive locally-advanced or metastatic NSCLC (Response Evaluation Set)** 77](#_Toc171427702)

[**Table 14.2.4.1.2 Overall Survival - Phase II part 1 Treatment naive locally-advanced or metastatic NSCLC (Safety Analysis Set)** 78](#_Toc171427703)

[**Table 14.2.4.2.1.1 Summary of OS Subgroup Analysis - Phase II part 1 Treatment naive locally-advanced or metastatic NSCLC (Safety Analysis Set)** 79](#_Toc171427704)

[**Table 14.3.1.1.2 Overview of All AEs - Phase II part 1 treatment-naive locally-advanced or metastatic NSCLC (Safety Analysis Set)** 85](#_Toc171427705)

[**Table 14.3.1.1.4 Overview of All AEs by Grouped PT - Phase II part 1 treatment-naive locally-advanced or metastatic NSCLC (Safety Analysis Set)** 87](#_Toc171427706)

[**Table 14.3.1.3.1.2 Summary of TEAEs by SOC and PT - Phase II part 1 treatment-naive locally-advanced or metastatic NSCLC (Safety Analysis Set)** 89](#_Toc171427707)

[**Table 14.3.1.3.1.4 Summary of TEAEs by Grouped SOC and Grouped PT - Phase II part 1 treatment-naive locally-advanced or metastatic NSCLC (Safety Analysis Set)** 95](#_Toc171427708)

[**Table 14.3.1.3.2.2 Summary of D-1553 Related TEAEs by SOC and PT - Phase II Part 1 treatment-naive locally-advanced or metastatic NSCLC (Safety Analysis Set)** 101](#_Toc171427709)

[**Table 14.3.1.3.2.4 Summary of D-1553 Related TEAEs by Grouped SOC and Grouped PT - Phase II part 1 treatment-naive locally-advanced or metastatic NSCLC (Safety Analysis Set)** 106](#_Toc171427710)

[**Table 14.3.1.3.2.8 Summary of IN10018 Related TEAEs by SOC and PT - Phase II Part 1 treatment-naive locally-advanced or metastatic NSCLC (Safety Analysis Set)** 111](#_Toc171427711)

[**Table 14.3.1.3.2.10 Summary of IN10018 Related TEAEs by Grouped SOC and Grouped PT - Phase II part 1 treatment-naive locally-advanced or metastatic NSCLC (Safety Analysis Set)** 116](#_Toc171427712)

[**Table 14.3.1.3.3.2 Summary of TEAEs by SOC, PT and Severity - Phase II Part 1 treatment-naive locally-advanced or metastatic NSCLC (Safety Analysis Set)** 121](#_Toc171427713)

[**Table 14.3.1.3.3.4 Summary of TEAEs by Grouped SOC and Grouped PT and Severity - Phase II part 1 treatment-naive locally-advanced or metastatic NSCLC (Safety Analysis Set)** 127](#_Toc171427714)

[**Table 14.3.1.3.4.2 Summary of D-1553 Related TEAEs by SOC, PT and Severity - Phase II Part 1 treatment-naive locally-advanced or metastatic NSCLC (Safety Analysis Set)** 133](#_Toc171427715)

[**Table 14.3.1.3.4.4 Summary of D-1553 Related TEAEs by Grouped SOC and Grouped PT and Severity - Phase II part 1 treatment-naive locally-advanced or metastatic NSCLC (Safety Analysis Set)** 138](#_Toc171427716)

[**Table 14.3.1.3.4.8 Summary of IN10018 Related TEAEs by SOC, PT and Severity - Phase II Part 1 treatment-naive locally-advanced or metastatic NSCLC (Safety Analysis Set)** 143](#_Toc171427717)

[**Table 14.3.1.3.4.10 Summary of IN10018 Related TEAEs by Grouped SOC and Grouped PT and Severity - Phase II part 1 treatment-naive locally-advanced or metastatic NSCLC (Safety Analysis Set)** 148](#_Toc171427718)

[**Table 14.3.1.4.1.2 Summary of CTCAE Grade 3/4 TEAEs by SOC and PT - Phase II part 1 treatment-naive locally-advanced or metastatic NSCLC (Safety Analysis Set)** 153](#_Toc171427719)

[**Table 14.3.1.4.1.4 Summary of CTCAE Grade 3/4 TEAEs by Grouped SOC and Grouped PT - Phase II part 1 treatment-naive locally-advanced or metastatic NSCLC (Safety Analysis Set)** 155](#_Toc171427720)

[**Table 14.3.1.4.2.2 Summary of D-1553 Related CTCAE Grade 3/4 TEAEs by SOC and PT - Phase II part 1 treatment-naive locally-advanced or metastatic NSCLC (Safety Analysis Set)** 157](#_Toc171427721)

[**Table 14.3.1.4.2.4 Summary of D-1553 Related CTCAE Grade 3/4 TEAEs by Grouped SOC and Grouped PT - Phase II part 1 treatment-naive locally-advanced or metastatic NSCLC (Safety Analysis Set)** 158](#_Toc171427722)

[**Table 14.3.1.4.2.8 Summary of IN10018 Related CTCAE Grade 3/4 TEAEs by SOC and PT - Phase II part 1 treatment-naive locally-advanced or metastatic NSCLC (Safety Analysis Set)** 159](#_Toc171427723)

[**Table 14.3.1.4.2.10 Summary of IN10018 Related CTCAE Grade 3/4 TEAEs by Grouped SOC and Grouped PT - Phase II part 1 treatment-naive locally-advanced or metastatic NSCLC (Safety Analysis Set)** 160](#_Toc171427724)

[**Table 14.3.1.5.1.2 Summary of TEAEs Leading to D-1553 Dose Reduction by SOC and PT - Phase II part 1 treatment-naive locally-advanced or metastatic NSCLC (Safety Analysis Set)** 161](#_Toc171427725)

[**Table 14.3.1.5.1.4 Summary of TEAEs Leading to D-1553 Dose Reduction by Grouped SOC and Grouped PT - Phase II part 1 treatment-naive locally-advanced or metastatic NSCLC (Safety Analysis Set)** 162](#_Toc171427726)

[**Table 14.3.1.5.1.8 Summary of TEAEs Leading to IN10018 Dose Reduction by SOC and PT - Phase II part 1 treatment-naive locally-advanced or metastatic NSCLC (Safety Analysis Set)** 163](#_Toc171427727)

[**Table 14.3.1.5.1.10 Summary of TEAEs Leading to IN10018 Dose Reduction by Grouped SOC and Grouped PT - Phase II part 1 treatment-naive locally-advanced or metastatic NSCLC (Safety Analysis Set)** 164](#_Toc171427728)

[**Table 14.3.1.5.2.2 Summary of D-1553 Related TEAEs Leading to D-1553 Dose Reduction by SOC and PT - Phase II part 1 treatment-naive locally-advanced or metastatic NSCLC (Safety Analysis Set)** 165](#_Toc171427729)

[**Table 14.3.1.5.2.4 Summary of D-1553 Related TEAEs Leading to D-1553 Dose Reduction by Grouped SOC and Grouped PT - Phase II part 1 treatment-naive locally-advanced or metastatic NSCLC (Safety Analysis Set)** 166](#_Toc171427730)

[**Table 14.3.1.5.2.8 Summary of IN10018 Related TEAEs Leading to IN10018 Dose Reduction by SOC and PT - Phase II part 1 treatment-naive locally-advanced or metastatic NSCLC (Safety Analysis Set)** 167](#_Toc171427731)

[**Table 14.3.1.5.2.10 Summary of IN10018 Related TEAEs Leading to IN10018 Dose Reduction by Grouped SOC and Grouped PT - Phase II part 1 treatment-naive locally-advanced or metastatic NSCLC (Safety Analysis Set)** 168](#_Toc171427732)

[**Table 14.3.1.6.1.2 Summary of TEAEs Leading to D-1553 Drug Interruption by SOC and PT - Phase II part 1 treatment-naive locally-advanced or metastatic NSCLC (Safety Analysis Set)** 169](#_Toc171427733)

[**Table 14.3.1.6.1.4 Summary of TEAEs Leading to D-1553 Drug Interruption by Grouped SOC and Grouped PT - Phase II part 1 treatment-naive locally-advanced or metastatic NSCLC (Safety Analysis Set)** 171](#_Toc171427734)

[**Table 14.3.1.6.1.8 Summary of TEAEs Leading to IN10018 Drug Interruption by SOC and PT - Phase II part 1 treatment-naive locally-advanced or metastatic NSCLC (Safety Analysis Set)** 173](#_Toc171427735)

[**Table 14.3.1.6.1.10 Summary of TEAEs Leading to IN10018 Drug Interruption by Grouped SOC and Grouped PT - Phase II part 1 treatment-naive locally-advanced or metastatic NSCLC (Safety Analysis Set)** 175](#_Toc171427736)

[**Table 14.3.1.6.2.2 Summary of D-1553 Related TEAEs Leading to D-1553 Drug Interruption by SOC and PT - Phase II part 1 treatment-naive locally-advanced or metastatic NSCLC (Safety Analysis Set)** 177](#_Toc171427737)

[**Table 14.3.1.6.2.4 Summary of D-1553 Related TEAEs Leading to D-1553 Drug Interruption by Grouped SOC and Grouped PT - Phase II part 1 treatment-naive locally-advanced or metastatic NSCLC (Safety Analysis Set)** 179](#_Toc171427738)

[**Table 14.3.1.6.2.8 Summary of IN10018 Related TEAEs Leading to IN10018 Drug Interruption by SOC and PT - Phase II part 1 treatment-naive locally-advanced or metastatic NSCLC (Safety Analysis Set)** 181](#_Toc171427739)

[**Table 14.3.1.6.2.10 Summary of IN10018 Related TEAEs Leading to IN10018 Drug Interruption by Grouped SOC and Grouped PT - Phase II part 1 treatment-naive locally-advanced or metastatic NSCLC (Safety Analysis Set)** 183](#_Toc171427740)

[**Table 14.3.1.7.1.2 Summary of TEAEs Leading to D-1553 Drug Withdrawn by SOC and PT - Phase II part 1 treatment-naive locally-advanced or metastatic NSCLC (Safety Analysis Set)** 185](#_Toc171427741)

[**Table 14.3.1.7.1.4 Summary of TEAEs Leading to D-1553 Drug Withdrawn by Grouped SOC and Grouped PT - Phase II part 1 treatment-naive locally-advanced or metastatic NSCLC (Safety Analysis Set)** 186](#_Toc171427742)

[**Table 14.3.1.7.1.8 Summary of TEAEs Leading to IN10018 Drug Withdrawn by SOC and PT - Phase II part 1 treatment-naive locally-advanced or metastatic NSCLC (Safety Analysis Set)** 187](#_Toc171427743)

[**Table 14.3.1.7.1.10 Summary of TEAEs Leading to IN10018 Drug Withdrawn by Grouped SOC and Grouped PT - Phase II part 1 treatment-naive locally-advanced or metastatic NSCLC (Safety Analysis Set)** 188](#_Toc171427744)

[**Table 14.3.1.7.2.2 Summary of D-1553 Related TEAEs Leading to D-1553 Drug Withdrawn by SOC and PT - Phase II part 1 treatment-naive locally-advanced or metastatic NSCLC (Safety Analysis Set)** 189](#_Toc171427745)

[**Table 14.3.1.7.2.4 Summary of D-1553 Related TEAEs Leading to D-1553 Drug Withdrawn by Grouped SOC and Grouped PT - Phase II part 1 treatment-naive locally-advanced or metastatic NSCLC (Safety Analysis Set)** 190](#_Toc171427746)

[**Table 14.3.1.7.2.8 Summary of IN10018 Related TEAEs Leading to IN10018 Drug Withdrawn by SOC and PT - Phase II part 1 treatment-naive locally-advanced or metastatic NSCLC (Safety Analysis Set)** 191](#_Toc171427747)

[**Table 14.3.1.7.2.10 Summary of IN10018 Related TEAEs Leading to IN10018 Drug Withdrawn by Grouped SOC and Grouped PT - Phase II part 1 treatment-naive locally-advanced or metastatic NSCLC (Safety Analysis Set)** 192](#_Toc171427748)

[**Table 14.3.1.8.1.2 Summary of AESI by SOC and PT - Phase II part 1 treatment-naive locally-advanced or metastatic NSCLC (Safety Analysis Set)** 193](#_Toc171427749)

[**Table 14.3.1.8.1.4 Summary of AESI by Grouped SOC and Grouped PT - Phase II part 1 treatment-naive locally-advanced or metastatic NSCLC (Safety Analysis Set)** 194](#_Toc171427750)

[**Table 14.3.1.8.2.2 Summary of AESI with CTCAE Grade 3/4 by SOC and PT - Phase II part 1 treatment-naive locally-advanced or metastatic NSCLC (Safety Analysis Set)** 195](#_Toc171427751)

[**Table 14.3.1.8.2.4 Summary of AESI with CTCAE Grade 3/4 by Grouped SOC and Grouped PT - Phase II part 1 treatment-naive locally-advanced or metastatic NSCLC (Safety Analysis Set)** 196](#_Toc171427752)

[**Table 14.3.1.8.3.2 Summary of D-1553 Related AESI by SOC and PT - Phase II part 1 treatment-naive locally-advanced or metastatic NSCLC (Safety Analysis Set)** 197](#_Toc171427753)

[**Table 14.3.1.8.3.4 Summary of D-1553 Related AESI by Grouped SOC and Grouped PT - Phase II part 1 treatment-naive locally-advanced or metastatic NSCLC (Safety Analysis Set)** 198](#_Toc171427754)

[**Table 14.3.1.8.4.2 Summary of IN10018 Related AESI by SOC and PT - Phase II part 1 treatment-naive locally-advanced or metastatic NSCLC (Safety Analysis Set)** 199](#_Toc171427755)

[**Table 14.3.1.8.4.4 Summary of IN10018 Related AESI by Grouped SOC and Grouped PT - Phase II part 1 treatment-naive locally-advanced or metastatic NSCLC (Safety Analysis Set)** 200](#_Toc171427756)

[**Table 14.3.1.9.1.2 Summary of SAEs by SOC and PT - Phase II part 1 treatment-naive locally-advanced or metastatic NSCLC (Safety Analysis Set)** 201](#_Toc171427757)

[**Table 14.3.1.9.2.2 Summary of D-1553 Related SAEs by SOC and PT - Phase II part 1 treatment-naive locally-advanced or metastatic NSCLC (Safety Analysis Set)** 203](#_Toc171427758)

[**Table 14.3.1.9.2.5 Summary of IN10018 Related SAEs by SOC and PT - Phase II part 1 treatment-naive locally-advanced or metastatic NSCLC (Safety Analysis Set)** 204](#_Toc171427759)

[**Table 14.3.1.10.1.2 Summary of TEAEs Leading to Death by SOC and PT - Phase II part 1 treatment-naive locally-advanced or metastatic NSCLC (Safety Analysis Set)** 205](#_Toc171427760)

[**Table 14.3.1.10.2.2 Summary of D-1553 Related TEAEs Leading to Death by SOC and PT - Phase II part 1 treatment-naive locally-advanced or metastatic NSCLC (Safety Analysis Set)** 206](#_Toc171427761)

[**Table 14.3.1.10.2.5 Summary of IN10018 Related TEAEs Leading to Death by SOC and PT - Phase II part 1 treatment-naive locally-advanced or metastatic NSCLC (Safety Analysis Set)** 207](#_Toc171427762)

[**Table 14.3.1.11.2 Summary of Deaths - Phase II part 1 treatment-naive locally-advanced or metastatic NSCLC (Safety Analysis Set)** 208](#_Toc171427763)

[**Table 14.3.1.12.1.2 Summary of Abnormal Liver Function by PT and Severity - Phase II part 1 treatment-naive locally-advanced or metastatic NSCLC (Safety Analysis Set)** 209](#_Toc171427764)

[**Table 14.3.1.12.2.2 Incidence and Prevalence of Abnormal Liver Function over Time - Phase II part 1 treatment-naive locally-advanced or metastatic NSCLC (Safety Analysis Set)** 211](#_Toc171427765)

[**Table 14.3.1.13.1.2 Summary of Proteinuria by Grouped PT and Severity - Phase II part 1 treatment-naive locally-advanced or metastatic NSCLC (Safety Analysis Set)** 214](#_Toc171427766)

[**Table 14.3.1.13.2.2 Incidence and Prevalence of Proteinuria over Time - Phase II part 1 treatment-naive locally-advanced or metastatic NSCLC (Safety Analysis Set)** 215](#_Toc171427767)

[**Table 14.3.5.1.1.2 Summary of Hematology Results - Phase II part 1 treatment-naive locally-advanced or metastatic NSCLC (Safety Analysis Set)** 218](#_Toc171427768)

[**Table 14.3.5.1.2.2 Summary of Chemistry Results - Phase II part 1 treatment-naive locally-advanced or metastatic NSCLC (Safety Analysis Set)** 225](#_Toc171427769)

[**Table 14.3.5.1.3.2 Summary of Urinalysis Results - Phase II part 1 treatment-naive locally-advanced or metastatic NSCLC (Safety Analysis Set)** 245](#_Toc171427770)

[**Table 14.3.5.1.4.2 Summary of Coagulation Function Results - Phase II part 1 treatment-naive locally-advanced or metastatic NSCLC (Safety Analysis Set)** 250](#_Toc171427771)

[**Table 14.3.5.2.2 Shift Table for Laboratory Test from Baseline to Last/Worst Post-baseline CTCAE Grade - Phase II part 1 treatment-naive locally-advanced or metastatic NSCLC (Safety Analysis Set)** 253](#_Toc171427772)

[**Table 14.3.5.3.1.2 Summary of Shifts from Baseline in Hematology According to Investigator’s Assessment - Phase II part 1 treatment-naive locally-advanced or metastatic NSCLC (Safety Analysis Set)** 268](#_Toc171427773)

[**Table 14.3.5.3.2.2 Summary of Shifts from Baseline in Chemistry According to Investigator’s Assessment - Phase II part 1 treatment-naive locally-advanced or metastatic NSCLC (Safety Analysis Set)** 271](#_Toc171427774)

[**Table 14.3.5.3.3.2 Summary of Shifts from Baseline in Urinalysis According to Investigator’s Assessment - Phase II part 1 treatment-naive locally-advanced or metastatic NSCLC (Safety Analysis Set)** 279](#_Toc171427775)

[**Table 14.3.5.3.4.2 Summary of Shifts from Baseline in Coagulation Function According to Investigator’s Assessment - Phase II part 1 treatment-naive locally-advanced or metastatic NSCLC (Safety Analysis Set)** 283](#_Toc171427776)

[**Table 14.3.5.4.2 Summary of Subjects with At Least One Level Increase in CTCAE Grade by Abnormality - Phase II part 1 treatment-naive locally-advanced or metastatic NSCLC (Safety Analysis Set)** 285](#_Toc171427777)

[**Table 14.3.5.5.2 Summary of Subjects with At least One Abnormal Chemistry Result Related to Liver Function Abnormality - Phase II part 1 treatment-naive locally-advanced or metastatic NSCLC (Safety Analysis Set)** 287](#_Toc171427778)

[**Table 14.3.5.5.5 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 1 treatment-naive locally-advanced or metastatic NSCLC (Safety Analysis Set)** 289](#_Toc171427779)

[**Table 14.3.5.5.8 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 1 treatment-naive locally-advanced or metastatic NSCLC (Safety Analysis Set)** 291](#_Toc171427780)

[**Table 14.3.6.2 Summary of Vital Sign Results - Phase II part 1 treatment-naive locally-advanced or metastatic NSCLC (Safety Analysis Set)** 293](#_Toc171427781)

[**Table 14.3.7.2 Summary of Shifts from Baseline to Last/Worst Post-baseline in ECOG Assessment - Phase II part 1 treatment-naive locally-advanced or metastatic NSCLC (Safety Analysis Set)** 304](#_Toc171427782)

[**Table 14.3.8.1.2 Summary of 12-Lead ECG Parameters - Phase II part 1 treatment-naive locally-advanced or metastatic NSCLC (Safety Analysis Set)** 305](#_Toc171427783)

[**Table 14.3.8.2.2 Summary of Shifts from Baseline in 12-Lead ECG According to Investigator’s Assessment - Phase II part 1 treatment-naive locally-advanced or metastatic NSCLC (Safety Analysis Set)** 310](#_Toc171427784)

[**Table 14.3.8.3.2 Summary of Abnormal QTcF - Phase II part 1 treatment-naive locally-advanced or metastatic NSCLC (Safety Analysis Set)** 311](#_Toc171427785)

[**Table 14.3.9.2 Summary of Shifts from Baseline in Slip Lamp Examination According to Investigator’s Assessment - Phase II part 1 treatment-naive locally-advanced or metastatic NSCLC (Safety Analysis Set)** 312](#_Toc171427786)

[**Table 14.3.10.2 Summary of Shifts from Baseline in Physical Examination According to Investigator’s Assessment - Phase II part 1 treatment-naive locally-advanced or metastatic NSCLC (Safety Analysis Set)** 318](#_Toc171427787)

[**Table 14.3.11.1.2 Summary of Echocardiogram Parameters - Phase II part 1 treatment-naive locally-advanced or metastatic NSCLC (Safety Analysis Set)** 321](#_Toc171427788)

[**Table 14.3.11.2.2 Summary of Shifts from Baseline in Echocardiogram According to Investigator’s Assessment - Phase II part 1 treatment-naive locally-advanced or metastatic NSCLC (Safety Analysis Set)** 322](#_Toc171427789)

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

**Table 14.1.1.2 Subject Disposition - Phase II part 1 treatment-naive locally-advanced or metastatic NSCLC (All Subjects Screened)**

|  | Treatment-naive locally-advanced or metastatic NSCLC n (%) |
| --- | --- |
| Enrolled | 33 |
|  | |
| Subject Who Received at Least One Dose of Study Intervention | 33 (100) |
|  | |
| Treatment Discontinuation | 9 (27.3) |
| Disease Progression defined by RECIST 1.1 | 5 (15.2) |
| Death | 1 (3.0) |
| Other | 3 (9.1) |
|  | |
| Study completion/withdrawal | 3 (9.1) |
| Death | 3 (9.1) |
|  | |
| Full Analysis Set (FAS) | 33 (100) |
| Safety Analysis Set (SAS) | 33 (100) |
| Response Evaluation Set (RES) | 31 (93.9) |

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

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 |

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

**Table 14.1.2.2 Demographics - Phase II part 1 treatment-naive locally-advanced or metastatic NSCLC (Full Analysis Set)**

|  | Treatment-naive locally-advanced or metastatic NSCLC (N = 33) |
| --- | --- |
| Age (years) |  |
| n | 33 |
| Mean (STD) | 66.5 (7.27) |
| Median (Q1, Q3) | 65.0 (60.0, 72.0) |
| Min, Max | 58, 83 |
|  | |
| Sex, n (%) |  |
| Male | 31 (93.9) |
| Female | 2 (6.1) |
|  | |
| Ethnicity, n (%) |  |
| Ethnic Han | 33 (100) |
| Other | 0 |
|  | |
| Race, n (%) |  |
| American Indian or Alaska Native | 0 |
| Asian | 33 (100) |
| Black or African American | 0 |
| Native Hawaiians or Other Pacific Islanders | 0 |
| White | 0 |
| Other | 0 |
|  | |
| Height (cm) |  |
| n | 33 |
| Mean (STD) | 167.00 (6.342) |
| Median (Q1, Q3) | 168.00 (165.00, 170.00) |
| Min, Max | 146.5, 178.0 |
|  | |
| Weight at Baseline (kg) |  |
| n | 33 |
| Mean (STD) | 61.54 (9.434) |
| Median (Q1, Q3) | 60.10 (55.00, 68.00) |
| Min, Max | 40.5, 78.8 |
|  | |
| BMI at Baseline (kg/m2) |  |
| n | 33 |
| Mean (STD) | 22.056 (3.1450) |
| Median (Q1, Q3) | 21.469 (20.114, 23.384) |
| Min, Max | 15.06, 29.48 |

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 14.1.3.2 Baseline Disease Characteristics - Phase II part 1 treatment-naive locally-advanced or metastatic NSCLC (Full Analysis Set)**

|  | Treatment-naive locally-advanced or metastatic NSCLC (N = 33) |
| --- | --- |
| Clinical Diagnosis, n (%) |  |
| Non-small cell lung cancer | 33 (100) |
| Other | 0 |
|  | |
| Time from Initial Clinical Diagnosis to ICF (months) |  |
| n | 33 |
| Mean (STD) | 4.11 (6.856) |
| Median (Q1, Q3) | 0.92 (0.69, 1.94) |
| Min, Max | 0.5, 26.3 |
|  | |
| Histological Type, n (%) |  |
| Adenocarcinoma | 32 (97.0) |
| Squamous Carcinoma | 0 |
| Neuroendocrine Carcinoma | 0 |
| Large Cell Carcinoma | 0 |
| Adenosquamous Carcinoma | 1 (3.0) |
| Sarcomatoid Carcinoma | 0 |
| Unclassified cancer | 0 |
| Other | 0 |
|  | |
| Histological Grade, n (%) |  |
| Highly differentiated | 0 |
| Moderately differentiated | 1 (3.0) |
| Poorly differentiated | 11 (33.3) |
| Undifferentiated | 0 |
| Not Evaluate | 1 (3.0) |
| Unknown | 19 (57.6) |
| Other | 1 (3.0) |
|  | |
| Clinical Stage at Initial Diagnosis, n (%) |  |
| Stage I | 0 |
| Stage IA | 1 (3.0) |
| Stage IB | 1 (3.0) |
| Stage IIA | 0 |
| Stage IIB | 2 (6.1) |
| Stage IIC | 0 |
| Stage IIIA | 1 (3.0) |
| Stage IIIB | 6 (18.2) |
| Stage IIIC | 1 (3.0) |
| Stage IVA | 10 (30.3) |
| Stage IVB | 7 (21.2) |
| Stage IVC | 0 |
| Not Evaluate | 0 |
| Unknown | 4 (12.1) |
| Other | 0 |
|  | |
| T Staging at Initial Diagnosis, n (%) |  |
| Tx | 0 |
| T0 | 0 |
| Tis | 0 |
| T1a | 0 |
| T1b | 2 (6.1) |
| T1c | 2 (6.1) |
| T2a | 5 (15.2) |
| T2b | 2 (6.1) |
| T3 | 8 (24.2) |
| T4 | 7 (21.2) |
| T4a | 0 |
| T4b | 0 |
| Not Evaluate | 0 |
| Unknown | 4 (12.1) |
| Other | 3 (9.1) |
|  | |
| N Staging at Initial Diagnosis, n (%) |  |
| Nx | 1 (3.0) |
| N0 | 4 (12.1) |
| N1 | 1 (3.0) |
| N2 | 11 (33.3) |
| N3 | 12 (36.4) |
| Not Evaluate | 0 |
| Unknown | 4 (12.1) |
| Other | 0 |
|  | |
| M Staging at Initial Diagnosis, n (%) |  |
| Mx | 1 (3.0) |
| M0 | 13 (39.4) |
| M1a | 8 (24.2) |
| M1b | 1 (3.0) |
| M1c | 6 (18.2) |
| Not Evaluate | 0 |
| Unknown | 4 (12.1) |
| Other | 0 |
|  | |
| Clinical Stage at Study Entry, n (%) |  |
| Stage I | 0 |
| Stage IA | 0 |
| Stage IB | 0 |
| Stage IIA | 0 |
| Stage IIB | 0 |
| Stage IIC | 0 |
| Stage IIIA | 0 |
| Stage IIIB | 4 (12.1) |
| Stage IIIC | 2 (6.1) |
| Stage IVA | 14 (42.4) |
| Stage IVB | 13 (39.4) |
| Stage IVC | 0 |
| Not Evaluate | 0 |
| Unknown | 0 |
| Other | 0 |
|  | |
| T Staging at Study Entry, n (%) |  |
| Tx | 1 (3.0) |
| T0 | 1 (3.0) |
| Tis | 0 |
| T1a | 0 |
| T1b | 0 |
| T1c | 0 |
| T2a | 5 (15.2) |
| T2b | 3 (9.1) |
| T3 | 11 (33.3) |
| T4 | 11 (33.3) |
| T4a | 0 |
| T4b | 0 |
| Not Evaluate | 0 |
| Unknown | 0 |
| Other | 1 (3.0) |
|  | |
| N Staging at Study Entry, n (%) |  |
| Nx | 2 (6.1) |
| N0 | 4 (12.1) |
| N1 | 0 |
| N2 | 11 (33.3) |
| N3 | 16 (48.5) |
| Not Evaluate | 0 |
| Unknown | 0 |
| Other | 0 |
|  | |
| M Staging at Study Entry, n (%) |  |
| Mx | 0 |
| M0 | 6 (18.2) |
| M1a | 11 (33.3) |
| M1b | 3 (9.1) |
| M1c | 13 (39.4) |
| Not Evaluate | 0 |
| Unknown | 0 |
| Other | 0 |
|  | |
| Metastases, n (%) |  |
| Yes | 27 (81.8) |
| No | 6 (18.2) |
|  | |
| Sites of Metastases at study entry, n (%) |  |
| Lymph Node | 6 (18.2) |
| Bone | 11 (33.3) |
| Adrenal | 6 (18.2) |
| Brain | 2 (6.1) |
| Liver | 5 (15.2) |
| Lung | 15 (45.5) |
| Peritoneum | 0 |
| Mediastinum | 0 |
| Head and neck | 1 (3.0) |
| Pericardium | 1 (3.0) |
| Pleura | 9 (27.3) |
| Spleen | 0 |
| Pancreas | 0 |
| Kidney | 3 (9.1) |
| Uterus and accessories | 0 |
| Intestines | 0 |
| Skin | 0 |
| Other | 8 (24.2) |
|  | |
| Number of metastatic organs at study entry, n (%) |  |
| One | 10 (30.3) |
| Two | 3 (9.1) |
| Three | 6 (18.2) |
| Four | 7 (21.2) |
| Five | 1 (3.0) |
| Six | 0 |
| More | 0 |
|  | |
| Smoking History, n (%) |  |
| Never | 3 (9.1) |
| Former | 26 (78.8) |
| Current | 4 (12.1) |
|  | |
| Number of cigarettes per day (cigarettes/day) |  |
| n | 28 |
| Mean (STD) | 22.5 (13.76) |
| Median (Q1, Q3) | 20.0 (10.0, 30.0) |
| Min, Max | 4, 60 |
|  | |
| Total years of smoking (years) |  |
| n | 30 |
| Mean (STD) | 38.4 (10.41) |
| Median (Q1, Q3) | 40.0 (30.0, 50.0) |
| Min, Max | 18, 60 |
|  | |
| Years since smoking cessation (Years) |  |
| n | 26 |
| Mean (STD) | 2.07 (5.661) |
| Median (Q1, Q3) | 0.13 (0.03, 1.13) |
| Min, Max | 0.0, 22.4 |
|  | |
| Baseline ECOG Performance, n (%) |  |
| 0 | 3 (9.1) |
| 1 | 30 (90.9) |
|  | |
| Baseline PD-L1 |  |
| Yes | 17 (51.5) |
| <1%\* | 6 (35.3) |
| 1-49%\* | 6 (35.3) |
| ≥50%\* | 5 (29.4) |
| No | 16 (48.5) |
|  | |
| Baseline TMB |  |
| Yes | 1 (3.0) |
| <10mut/Mb# | 1 (100) |
| ≥10mut/Mb# | 0 |
| No | 32 (97.0) |
|  | |
| KRAS G12C Mutation, n (%) |  |
| Negative | 0 |
| Positive | 33 (100) |
| Not Done | 0 |
| Other | 0 |
|  | |
| KRAS G12C Mutation Ratio (%) |  |
| n | 28 |
| Mean (STD) | 31.374 (20.8702) |
| Median (Q1, Q3) | 25.440 (17.880, 38.425) |
| Min, Max | 5.13, 92.51 |
|  | |
| STK11 Mutation, n (%) |  |
| Negative | 5 (15.2) |
| Positive | 2 (6.1) |
| Not Done | 26 (78.8) |
| Other | 0 |
|  | |
| Sum of the Diameters across Target Lesions at Baseline (mm) |  |
| n | 33 |
| Mean (STD) | 79.994 (34.8224) |
| Median (Q1, Q3) | 74.400 (62.960, 95.870) |
| Min, Max | 14.60, 194.00 |
|  | |
| Non-Target Lesions Existed, n (%) |  |
| Yes | 32 (97.0) |
| No | 1 (3.0) |

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 16.2.4.2.2.1, 16.2.4.2.2.2

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

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

**Table 14.1.4.3 Prior Anti-cancer Therapy - Phase II part 1 treatment-naive locally-advanced or metastatic NSCLC (Safety Analysis Set)**

|  | Treatment-naive locally-advanced or metastatic NSCLC (N = 33) n (%) |
| --- | --- |
| Subjects with at least one Prior Anti-cancer Therapy | 9 (27.3) |
|  | |
| Systemic | 3 (9.1) |
| Treatment line\* |  |
| Neoadjuvant | 0 |
| Adjuvant | 1 (33.3) |
| First-line treatment | 0 |
| First-line maintain | 0 |
| Second-line treatment | 0 |
| Second-line maintain | 0 |
| Third-line treatment | 0 |
| Third-line maintain | 0 |
| >Third-line treatment | 0 |
| Other | 2 (66.7) |
|  | |
| Maximum Treatment line\* |  |
| Neoadjuvant | 0 |
| Adjuvant | 1 (33.3) |
| First-line treatment | 0 |
| First-line maintain | 0 |
| Second-line treatment | 0 |
| Second-line maintain | 0 |
| Third-line treatment | 0 |
| Third-line maintain | 0 |
| >Third-line treatment | 0 |
|  | |
| Treatment Type\* |  |
| Chemotherapy | 1 (33.3) |
| Immunotherapy | 0 |
| Targeted therapy | 0 |
| Endocrine therapy | 0 |
| Chinese herbal therapy | 2 (66.7) |
| Other | 0 |
|  | |
| Radiotherapy | 1 (3.0) |
|  | |
| Surgery | 5 (15.2) |
|  | |
| Other | 2 (6.1) |

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

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

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

**Table 14.1.4.4 Summary of Prior Systemic Anti-cancer Therapy by ATC Classification 2nd Level and Preferred Name - Phase II part 1 treatment-naive locally-advanced or metastatic NSCLC (Safety Analysis Set)**

| ATC Classification 2nd Level  Preferred Name | Treatment-naive locally-advanced or metastatic NSCLC (N = 33) n (%) |
| --- | --- |
| Subjects with at least one Prior Systemic Anti-cancer Therapy | 3 (9.1) |
|  | |
| ANTINEOPLASTIC AGENTS | 3 (9.1) |
| ANTINEOPLASTIC AGENTS | 1 (3.0) |
| CARBOPLATIN | 1 (3.0) |
| GLYCYRRHIZA SPP. ROOT;PANAX GINSENG ROOT;TAXUS WALLICHIANA | 1 (3.0) |
| PEMETREXED | 1 (3.0) |

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

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| 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 14.1.5.2 Summary of Medical History by SOC and PT - Phase II part 1 treatment-naive locally-advanced or metastatic NSCLC (Safety Analysis Set)**

| System Organ Class  Preferred Term | Treatment-naive locally-advanced or metastatic NSCLC  (N = 33) n (%) |
| --- | --- |
| Subjects with at least one Medical History | 31 (93.9) |
|  | |
| Metabolism and nutrition disorders | 15 (45.5) |
| Hyperlipidaemia | 6 (18.2) |
| Decreased appetite | 3 (9.1) |
| Hyperglycaemia | 2 (6.1) |
| Hypoproteinaemia | 2 (6.1) |
| Diabetes mellitus | 1 (3.0) |
| Hypercholesterolaemia | 1 (3.0) |
| Hypertriglyceridaemia | 1 (3.0) |
| Hyperuricaemia | 1 (3.0) |
| Hypoalbuminaemia | 1 (3.0) |
| Hypocalcaemia | 1 (3.0) |
| Hypokalaemia | 1 (3.0) |
| Hyponatraemia | 1 (3.0) |
| Malnutrition | 1 (3.0) |
| Type 2 diabetes mellitus | 1 (3.0) |
|  | |
| Respiratory, thoracic and mediastinal disorders | 15 (45.5) |
| Cough | 8 (24.2) |
| Productive cough | 6 (18.2) |
| Dyspnoea | 5 (15.2) |
| Emphysema | 4 (12.1) |
| Bronchitis chronic | 2 (6.1) |
| Haemoptysis | 2 (6.1) |
| Chronic obstructive pulmonary disease | 1 (3.0) |
| Cystic lung disease | 1 (3.0) |
| Pulmonary mass | 1 (3.0) |
|  | |
| Investigations | 13 (39.4) |
| C-reactive protein increased | 2 (6.1) |
| Electrocardiogram PR prolongation | 2 (6.1) |
| Fibrin D dimer increased | 2 (6.1) |
| Blood alkaline phosphatase increased | 1 (3.0) |
| Blood bilirubin increased | 1 (3.0) |
| Blood cholesterol increased | 1 (3.0) |
| Blood creatinine decreased | 1 (3.0) |
| Bone density abnormal | 1 (3.0) |
| Electrocardiogram Q wave abnormal | 1 (3.0) |
| Electrocardiogram ST-T change | 1 (3.0) |
| Gamma-glutamyltransferase increased | 1 (3.0) |
| Lymphocyte count decreased | 1 (3.0) |
| Neutrophil count decreased | 1 (3.0) |
| White blood cell count decreased | 1 (3.0) |
|  | |
| Eye disorders | 12 (36.4) |
| Cataract | 7 (21.2) |
| Refraction disorder | 6 (18.2) |
| Corneal opacity | 2 (6.1) |
| Meibomian gland dysfunction | 1 (3.0) |
| Pterygium | 1 (3.0) |
| Visual impairment | 1 (3.0) |
| Vitreous floaters | 1 (3.0) |
| Xerophthalmia | 1 (3.0) |
|  | |
| Cardiac disorders | 11 (33.3) |
| Atrioventricular block first degree | 2 (6.1) |
| Bundle branch block right | 2 (6.1) |
| Coronary artery disease | 2 (6.1) |
| Sinus tachycardia | 2 (6.1) |
| Aortic valve incompetence | 1 (3.0) |
| Cardiac dysfunction | 1 (3.0) |
| Cardiac valve disease | 1 (3.0) |
| Degenerative aortic valve disease | 1 (3.0) |
| Degenerative mitral valve disease | 1 (3.0) |
| Sinus arrhythmia | 1 (3.0) |
| Supraventricular extrasystoles | 1 (3.0) |
| Ventricular extrasystoles | 1 (3.0) |
|  | |
| Vascular disorders | 11 (33.3) |
| Hypertension | 10 (30.3) |
| Superior vena cava syndrome | 1 (3.0) |
| Thrombosis | 1 (3.0) |
|  | |
| Renal and urinary disorders | 10 (30.3) |
| Proteinuria | 3 (9.1) |
| Nephrolithiasis | 2 (6.1) |
| Renal cyst | 2 (6.1) |
| Albuminuria | 1 (3.0) |
| Calculus urinary | 1 (3.0) |
| Micturition urgency | 1 (3.0) |
| Pollakiuria | 1 (3.0) |
|  | |
| General disorders and administration site conditions | 7 (21.2) |
| Chest discomfort | 6 (18.2) |
| Chest pain | 2 (6.1) |
| Asthenia | 1 (3.0) |
| Fatigue | 1 (3.0) |
| Pain | 1 (3.0) |
| Pyrexia | 1 (3.0) |
|  | |
| Blood and lymphatic system disorders | 6 (18.2) |
| Anaemia | 6 (18.2) |
|  | |
| Nervous system disorders | 6 (18.2) |
| Cerebral infarction | 2 (6.1) |
| Carotid arteriosclerosis | 1 (3.0) |
| Cerebral atrophy | 1 (3.0) |
| Headache | 1 (3.0) |
| Hypoaesthesia | 1 (3.0) |
| Paraesthesia | 1 (3.0) |
|  | |
| Infections and infestations | 5 (15.2) |
| Pneumonia | 1 (3.0) |
| Sinusitis | 1 (3.0) |
| Tuberculosis | 1 (3.0) |
| Urinary tract infection | 1 (3.0) |
| Viral hepatitis carrier | 1 (3.0) |
|  | |
| Gastrointestinal disorders | 4 (12.1) |
| Abdominal pain upper | 2 (6.1) |
| Chronic gastritis | 1 (3.0) |
| Constipation | 1 (3.0) |
| Gastric ulcer | 1 (3.0) |
| Intestinal obstruction | 1 (3.0) |
|  | |
| Musculoskeletal and connective tissue disorders | 4 (12.1) |
| Pain in extremity | 2 (6.1) |
| Arthralgia | 1 (3.0) |
| Back pain | 1 (3.0) |
| Intervertebral disc protrusion | 1 (3.0) |
| Muscular weakness | 1 (3.0) |
| Neck pain | 1 (3.0) |
| Scoliosis | 1 (3.0) |
|  | |
| Psychiatric disorders | 4 (12.1) |
| Insomnia | 4 (12.1) |
| Agitation | 1 (3.0) |
|  | |
| Hepatobiliary disorders | 3 (9.1) |
| Cholecystitis | 1 (3.0) |
| Cholelithiasis | 1 (3.0) |
| Hepatic cyst | 1 (3.0) |
| Hepatic function abnormal | 1 (3.0) |
|  | |
| Skin and subcutaneous tissue disorders | 3 (9.1) |
| Pruritus | 3 (9.1) |
| Rash | 1 (3.0) |
| Rash pruritic | 1 (3.0) |
|  | |
| Injury, poisoning and procedural complications | 2 (6.1) |
| Foreign body in eye | 1 (3.0) |
| Pneumoconiosis | 1 (3.0) |
| Silicosis | 1 (3.0) |
|  | |
| Surgical and medical procedures | 2 (6.1) |
| Duodenal operation | 1 (3.0) |
| Intraocular lens implant | 1 (3.0) |
|  | |
| Congenital, familial and genetic disorders | 1 (3.0) |
| Clinodactyly | 1 (3.0) |
|  | |
| Endocrine disorders | 1 (3.0) |
| Hyperplasia adrenal | 1 (3.0) |
|  | |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 1 (3.0) |
| Cancer pain | 1 (3.0) |
|  | |
| Reproductive system and breast disorders | 1 (3.0) |
| Benign prostatic hyperplasia | 1 (3.0) |

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

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| 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 14.1.6.1.2 Summary of Prior Medications by ATC Classification 2nd Level and Preferred Name - Phase II part 1 treatment-naive locally-advanced or metastatic NSCLC (Safety Analysis Set)**

| ATC Classification 2nd Level  Preferred Name | Treatment-naive locally-advanced or metastatic NSCLC (N = 33) n (%) |
| --- | --- |
| Subjects with at Least One Prior Medications | 11 (33.3) |
|  | |
| CALCIUM CHANNEL BLOCKERS | 3 (9.1) |
| NIFEDIPINE | 2 (6.1) |
| AMLODIPINE BESILATE | 1 (3.0) |
|  | |
| UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE | 3 (9.1) |
| TRADITIONAL MEDICINE | 3 (9.1) |
|  | |
| ANTIBACTERIALS FOR SYSTEMIC USE | 2 (6.1) |
| AMOXICILLIN | 1 (3.0) |
| LEVOFLOXACIN | 1 (3.0) |
| LEVOFLOXACIN HYDROCHLORIDE | 1 (3.0) |
| PIPERACILLIN SODIUM;TAZOBACTAM SODIUM | 1 (3.0) |
|  | |
| AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM | 1 (3.0) |
| VALSARTAN | 1 (3.0) |
|  | |
| ANALGESICS | 1 (3.0) |
| MORPHINE HYDROCHLORIDE | 1 (3.0) |
|  | |
| ANTIPRURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. | 1 (3.0) |
| DIPHENHYDRAMINE HYDROCHLORIDE | 1 (3.0) |
|  | |
| APPETITE STIMULANTS | 1 (3.0) |
| MEGESTROL ACETATE | 1 (3.0) |
|  | |
| BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS | 1 (3.0) |
| SODIUM CHLORIDE | 1 (3.0) |
|  | |
| CORTICOSTEROIDS FOR SYSTEMIC USE | 1 (3.0) |
| METHYLPREDNISOLONE | 1 (3.0) |
|  | |
| DRUGS FOR ACID RELATED DISORDERS | 1 (3.0) |
| OMEPRAZOLE | 1 (3.0) |
| TRIPOTASSIUM DICITRATOBISMUTHATE | 1 (3.0) |
|  | |
| DRUGS FOR TREATMENT OF BONE DISEASES | 1 (3.0) |
| DENOSUMAB | 1 (3.0) |
|  | |
| TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN | 1 (3.0) |
| LOXOPROFEN SODIUM | 1 (3.0) |

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

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| 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 14.1.6.2.2 Summary of Concomitant Medications by ATC Classification 2nd Level and Preferred Name - Phase II part 1 treatment-naive locally-advanced or metastatic NSCLC (Safety Analysis Set)**

| ATC Classification 2nd Level  Preferred Name | Treatment-naive locally-advanced or metastatic NSCLC (N = 33) n (%) |
| --- | --- |
| Subjects with at least one Concomitant Medications | 33 (100) |
|  | |
| ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS | 14 (42.4) |
| CELECOXIB | 5 (15.2) |
| IBUPROFEN | 5 (15.2) |
| CALCIUM CARBONATE;CHONDROITIN SULFATE;GLUCOSAMINE HYDROCHLORIDE | 1 (3.0) |
| DICLOFENAC | 1 (3.0) |
| ETORICOXIB | 1 (3.0) |
| GLUCOSAMINE HYDROCHLORIDE | 1 (3.0) |
| INDOMETACIN | 1 (3.0) |
| RABBIT VACCINIA EXTRACT | 1 (3.0) |
|  | |
| ANTIBACTERIALS FOR SYSTEMIC USE | 13 (39.4) |
| CEFIXIME | 2 (6.1) |
| CEFOPERAZONE SODIUM;SULBACTAM SODIUM | 2 (6.1) |
| PIPERACILLIN SODIUM;TAZOBACTAM SODIUM | 2 (6.1) |
| AMOXICILLIN | 1 (3.0) |
| BIAPENEM | 1 (3.0) |
| CEFDINIR | 1 (3.0) |
| CEFTAZIDIME | 1 (3.0) |
| CEFTIZOXIME SODIUM | 1 (3.0) |
| CEFUROXIME AXETIL | 1 (3.0) |
| CEFUROXIME SODIUM | 1 (3.0) |
| CLINDAMYCIN HYDROCHLORIDE | 1 (3.0) |
| COLISTIMETHATE SODIUM | 1 (3.0) |
| FOSFOMYCIN CALCIUM | 1 (3.0) |
| LEVOFLOXACIN | 1 (3.0) |
| METRONIDAZOLE | 1 (3.0) |
| MINOCYCLINE HYDROCHLORIDE | 1 (3.0) |
| POLYMYXIN B SULFATE | 1 (3.0) |
| TIGECYCLINE | 1 (3.0) |
|  | |
| ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATORY/ANTIINFECTIVE AGENTS | 12 (36.4) |
| MONTMORILLONITE | 8 (24.2) |
| DIOSMECTITE | 3 (9.1) |
| BERBERINE HYDROCHLORIDE | 2 (6.1) |
| LOPERAMIDE HYDROCHLORIDE | 2 (6.1) |
| BACILLUS CEREUS;BIFIDOBACTERIUM INFANTIS;ENTEROCOCCUS FAECALIS;LACTOBACILLUS ACIDOPHILUS | 1 (3.0) |
| BACILLUS LICHENFORMIS | 1 (3.0) |
| BIFIDOBACTERIUM LONGUM;ENTEROCOCCUS FAECALIS;LACTOBACILLUS ACIDOPHILUS | 1 (3.0) |
| GLUCOSE;POTASSIUM CHLORIDE;SODIUM BICARBONATE;SODIUM CHLORIDE | 1 (3.0) |
| LACTOBACILLUS NOS | 1 (3.0) |
| LOPERAMIDE | 1 (3.0) |
|  | |
| AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM | 10 (30.3) |
| IRBESARTAN | 3 (9.1) |
| HYDROCHLOROTHIAZIDE;IRBESARTAN | 2 (6.1) |
| HYDROCHLOROTHIAZIDE;VALSARTAN | 2 (6.1) |
| BENAZEPRIL HYDROCHLORIDE | 1 (3.0) |
| CANDESARTAN CILEXETIL | 1 (3.0) |
| SACUBITRIL;VALSARTAN | 1 (3.0) |
| TELMISARTAN | 1 (3.0) |
| VALSARTAN | 1 (3.0) |
|  | |
| DIURETICS | 10 (30.3) |
| SPIRONOLACTONE | 5 (15.2) |
| FUROSEMIDE | 4 (12.1) |
| HYDROCHLOROTHIAZIDE | 3 (9.1) |
| INDAPAMIDE | 2 (6.1) |
| BUMETANIDE | 1 (3.0) |
|  | |
| VITAMINS | 9 (27.3) |
| ASCORBIC ACID | 5 (15.2) |
| PYRIDOXINE HYDROCHLORIDE | 2 (6.1) |
| MULTIVITAMINS WITH MINERALS [UMBRELLA TERM] | 1 (3.0) |
| PYRIDOXINE | 1 (3.0) |
| RIBOFLAVIN | 1 (3.0) |
| THIAMINE | 1 (3.0) |
| THIAMINE HYDROCHLORIDE | 1 (3.0) |
| TOCOPHEROL | 1 (3.0) |
| VITAMIN B NOS | 1 (3.0) |
| VITAMIN D NOS | 1 (3.0) |
| VITAMINS NOS | 1 (3.0) |
|  | |
| COUGH AND COLD PREPARATIONS | 8 (24.2) |
| AMBROXOL HYDROCHLORIDE | 4 (12.1) |
| ACETYLCYSTEINE | 3 (9.1) |
| BROMHEXINE HYDROCHLORIDE | 2 (6.1) |
| BROMHEXINE | 1 (3.0) |
| CARBOCISTEINE | 1 (3.0) |
| CHRYSANTHEMUM X MORIFOLIUM FLOWER;FORSYTHIA SUSPENSA FRUIT;GLYCYRRHIZA SPP. ROOT WITH RHIZOME;HOUTTUYNIA CORDATA HERB;MENTHA CANADENSIS HERB;MORUS ALBA LEAF;PERILLA FRUTESCENS LEAF;PHRAGMITES COMMUNISRHIZOME;PLATYCODON GRANDIFLORUS ROOT;PRUNUS SPP. SEED;SCHIZONEPETA TENUIFOLIA HERB | 1 (3.0) |
| CHYMOTRYPSIN | 1 (3.0) |
| CINEOLE;DIPENTEN;PINENE | 1 (3.0) |
| DEXTROMETHORPHAN HYDROBROMIDE | 1 (3.0) |
| HERBAL EXPECTORANTS AND EMOLLIENTS | 1 (3.0) |
|  | |
| ANTITHROMBOTIC AGENTS | 7 (21.2) |
| RIVAROXABAN | 4 (12.1) |
| ACETYLSALICYLIC ACID | 3 (9.1) |
| CLOPIDOGREL | 1 (3.0) |
|  | |
| DRUGS FOR ACID RELATED DISORDERS | 7 (21.2) |
| OMEPRAZOLE | 3 (9.1) |
| RABEPRAZOLE SODIUM | 2 (6.1) |
| RANITIDINE HYDROCHLORIDE | 1 (3.0) |
| TEPRENONE | 1 (3.0) |
| TRIPOTASSIUM DICITRATOBISMUTHATE | 1 (3.0) |
|  | |
| OTHER NERVOUS SYSTEM DRUGS | 7 (21.2) |
| MECOBALAMIN | 7 (21.2) |
|  | |
| ANALGESICS | 6 (18.2) |
| OXYCODONE HYDROCHLORIDE | 2 (6.1) |
| AMANTADINE HYDROCHLORIDE;CAFFEINE;CHLORPHENAMINE MALEATE;COW BEZOAR;PARACETAMOL | 1 (3.0) |
| AMINOPHENAZONE;CAFFEINE | 1 (3.0) |
| DIHYDROCODEINE BITARTRATE;PARACETAMOL | 1 (3.0) |
| GABAPENTIN | 1 (3.0) |
| HYDROCODONE BITARTRATE;PARACETAMOL | 1 (3.0) |
| MORPHINE HYDROCHLORIDE | 1 (3.0) |
| PARACETAMOL | 1 (3.0) |
| PARACETAMOL;TRAMADOL HYDROCHLORIDE | 1 (3.0) |
|  | |
| BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS | 6 (18.2) |
| ALBUMIN HUMAN | 3 (9.1) |
| POTASSIUM CHLORIDE | 3 (9.1) |
| GLUCOSE | 2 (6.1) |
| GLUCOSE;SODIUM CHLORIDE | 2 (6.1) |
| MANNITOL | 2 (6.1) |
| GLYCINE MAX SEED OIL;LECITHIN | 1 (3.0) |
| INVERT SUGAR | 1 (3.0) |
| SODIUM CHLORIDE | 1 (3.0) |
|  | |
| ALL OTHER THERAPEUTIC PRODUCTS | 5 (15.2) |
| GLUTATHIONE | 4 (12.1) |
| AMIFOSTINE | 1 (3.0) |
|  | |
| BILE AND LIVER THERAPY | 5 (15.2) |
| DL-METHIONINE;GLYCINE;GLYCYRRHIZIC ACID, AMMONIUM SALT | 2 (6.1) |
| POLYENE PHOSPHATIDYLCHOLINE | 2 (6.1) |
| URSODEOXYCHOLIC ACID | 2 (6.1) |
| BICYCLOL | 1 (3.0) |
| BIFENDATE | 1 (3.0) |
| CYSTEINE HYDROCHLORIDE;GLYCINE;GLYCYRRHIZIC ACID, AMMONIUM SALT | 1 (3.0) |
| DIAMMONIUM GLYCYRRHIZINATE | 1 (3.0) |
| MAGNESIUM ISOGLYCYRRHIZINATE | 1 (3.0) |
| SILIBININ | 1 (3.0) |
| TIOPRONIN | 1 (3.0) |
|  | |
| DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES | 5 (15.2) |
| BUDESONIDE | 4 (12.1) |
| DOXOFYLLINE | 3 (9.1) |
| IPRATROPIUM BROMIDE | 2 (6.1) |
| AMINOPHYLLINE | 1 (3.0) |
| AMINOPHYLLINE;CHLORPHENAMINE MALEATE;METHOXYPHENAMINE HYDROCHLORIDE;NOSCAPINE | 1 (3.0) |
| MONTELUKAST | 1 (3.0) |
| TERBUTALINE SULFATE | 1 (3.0) |
|  | |
| LIPID MODIFYING AGENTS | 5 (15.2) |
| ATORVASTATIN CALCIUM | 3 (9.1) |
| ATORVASTATIN | 2 (6.1) |
|  | |
| MINERAL SUPPLEMENTS | 5 (15.2) |
| CALCIUM CARBONATE;COLECALCIFEROL | 2 (6.1) |
| POTASSIUM CHLORIDE | 2 (6.1) |
| CALCIUM | 1 (3.0) |
| CALCIUM CARBONATE;COPPER;MAGNESIUM OXIDE;MANGANESE;MEDICAGO SATIVA;ZINC | 1 (3.0) |
|  | |
| CORTICOSTEROIDS FOR SYSTEMIC USE | 4 (12.1) |
| DEXAMETHASONE SODIUM PHOSPHATE | 2 (6.1) |
| METHYLPREDNISOLONE SODIUM SUCCINATE | 2 (6.1) |
| BETAMETHASONE SODIUM PHOSPHATE | 1 (3.0) |
| DEXAMETHASONE | 1 (3.0) |
| METHYLPREDNISOLONE | 1 (3.0) |
|  | |
| UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE | 4 (12.1) |
| ANGELICA DAHURICA ROOT;ATRACTYLODES SPP. RHIZOME;BUPLEURUM SPP. ROOT;CAMELLIA SINENSIS LEAF;CITRUS AURANTIUM PERICARP;CITRUS SPP. UNRIPE FRUIT;CRATAEGUS PINNATIFIDA FRUIT;FORSYTHIA SUSPENSAFRUIT;GLYCYRRHIZA SPP. ROOT WITH RHIZOME;HANSENIA FORBESII ROOT WITH RHIZOME;HORDEUM VULGARE MALT;LIGUSTICUM CHUANXIONG RHIZOME;MAGNOLIA OFFICINALIS BARK;MASSA MEDICA FERMENTUM;PERILLA FRUTESCENSLEAF;PEUCEDANUM PRAERUPTORUM ROOT;PLATYCODON GRANDIFLORUS ROOT;POGOSTEMON CABLIN ESSENTIAL OIL;SAPOSHNIKOVIA DIVARICATA ROOT | 1 (3.0) |
| ARDISIA CRISPA LEAF;ARDISIA CRISPA ROOT;CICADA SLOUGH;MENTHOL;SOPHORA TONKINENSIS ROOT WITH RHIZOME | 1 (3.0) |
| ARNICA MONTANA;RHUS RADICANS | 1 (3.0) |
| PERIPLANETA AMERICANA | 1 (3.0) |
| SMILAX SPP. TUBER;SOPHORA FLAVESCENS ROOT | 1 (3.0) |
|  | |
| ANTIANEMIC PREPARATIONS | 3 (9.1) |
| ANGELICA SINENSIS;ASTRAGALUS SPP.;ATRACTYLODES MACROCEPHALA;FERROUS SULFATE;FOLIC ACID;YEAST DRIED | 1 (3.0) |
| ASTRAGALUS MONGHOLICUS ROOT;BLOOD, PIG;ZIZIPHUS JUJUBA FRUIT | 1 (3.0) |
| CYANOCOBALAMIN | 1 (3.0) |
| EPOETIN BETA | 1 (3.0) |
|  | |
| ANTIVIRALS FOR SYSTEMIC USE | 3 (9.1) |
| CALCIUM SULFATE DIHYDRATE;DRYOPTERIS CRASSIRHIZOMA RHIZOME;EPHEDRA SPP. HERB;FORSYTHIA SUSPENSA;GLYCYRRHIZA SPP. ROOT WITH RHIZOME;HOUTTUYNIA CORDATA HERB;ISATIS TINCTORIA ROOT;LONICERA JAPONICAFLOWER;MENTHOL;POGOSTEMON CABLIN HERB;PRUNUS SPP. SEED;RHEUM SPP. ROOT WITH RHIZOME;RHODIOLA CRENULATA ROOT WITH RHIZOME | 1 (3.0) |
| NIRMATRELVIR | 1 (3.0) |
| NIRMATRELVIR;RITONAVIR | 1 (3.0) |
| RITONAVIR | 1 (3.0) |
|  | |
| BETA BLOCKING AGENTS | 3 (9.1) |
| METOPROLOL TARTRATE | 2 (6.1) |
| LANDIOLOL HYDROCHLORIDE | 1 (3.0) |
| METOPROLOL SUCCINATE | 1 (3.0) |
|  | |
| DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS | 3 (9.1) |
| ANISODAMINE HYDROBROMIDE | 1 (3.0) |
| DOMPERIDONE | 1 (3.0) |
| MOSAPRIDE CITRATE | 1 (3.0) |
|  | |
| DRUGS USED IN DIABETES | 3 (9.1) |
| DAPAGLIFLOZIN | 1 (3.0) |
| INSULIN | 1 (3.0) |
| ISOPHANE INSULIN | 1 (3.0) |
|  | |
| ENDOCRINE THERAPY | 3 (9.1) |
| TOREMIFENE CITRATE | 2 (6.1) |
| TOREMIFENE | 1 (3.0) |
|  | |
| UROLOGICALS | 3 (9.1) |
| ATRACTYLODES LANCEA RHIZOME;CUSCUTA SPP. SEED;IMPERATA CYLINDRICA RHIZOME;LONICERA JAPONICA FLOWER BUD;LYCIUM BARBARUM FRUIT;PANAX GINSENG ROOT;POLYGONATUM SPP. RHIZOME;PORIA COCOSSCLEROTIUM;STEPHANIA TETRANDRA ROOT;TARAXACUM SPP. WHOLE PLANT | 1 (3.0) |
| CINNAMOMUM CASSIA TWIG;PAEONIA LACTIFLORA ROOT;PAEONIA X SUFFRUTICOSA ROOT BARK;PORIA COCOS SCLEROTIUM;PRUNUS SPP. SEED | 1 (3.0) |
| SODIUM BICARBONATE | 1 (3.0) |
|  | |
| ANTIBIOTICS AND CHEMOTHERAPEUTICS FOR DERMATOLOGICAL USE | 2 (6.1) |
| FUSIDIC ACID | 1 (3.0) |
| MUPIROCIN | 1 (3.0) |
|  | |
| ANTIHISTAMINES FOR SYSTEMIC USE | 2 (6.1) |
| CETIRIZINE | 1 (3.0) |
| CHLORPHENAMINE MALEATE | 1 (3.0) |
|  | |
| ANTIPRURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. | 2 (6.1) |
| CETIRIZINE | 1 (3.0) |
| LORATADINE | 1 (3.0) |
|  | |
| CARDIAC THERAPY | 2 (6.1) |
| AUCKLANDIA COSTUS ROOT;CRATAEGUS PINNATIFIDA FRUIT;PANAX NOTOGINSENG ROOT;PUERARIA LOBATA ROOT;SALVIA MILTIORRHIZA ROOT | 1 (3.0) |
| CARTHAMUS TINCTORIUS FLOWER;SALVIA MILTIORRHIZA ROOT | 1 (3.0) |
| METARAMINOL TARTRATE | 1 (3.0) |
| NOREPINEPHRINE BITARTRATE | 1 (3.0) |
|  | |
| DIGESTIVES, INCL. ENZYMES | 2 (6.1) |
| ALPHA-AMYLASE SWINE PANCREAS;AMYLASE;CELLULASE;PANCRELIPASE;PAPAIN;PEPSIN;TRYPSIN;URSODEOXYCHOLIC ACID | 2 (6.1) |
|  | |
| DRUGS FOR TREATMENT OF BONE DISEASES | 2 (6.1) |
| DENOSUMAB | 1 (3.0) |
| ZOLEDRONIC ACID | 1 (3.0) |
|  | |
| OTHER RESPIRATORY SYSTEM PRODUCTS | 2 (6.1) |
| AMBROXOL HYDROCHLORIDE | 1 (3.0) |
| NIKETHAMIDE | 1 (3.0) |
|  | |
| PSYCHOLEPTICS | 2 (6.1) |
| ESZOPICLONE | 1 (3.0) |
| ZOLPIDEM TARTRATE | 1 (3.0) |
|  | |
| TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN | 2 (6.1) |
| DICLOFENAC DIETHYLAMINE | 2 (6.1) |
|  | |
| ANESTHETICS | 1 (3.0) |
| LIDOCAINE HYDROCHLORIDE | 1 (3.0) |
|  | |
| ANTIEMETICS AND ANTINAUSEANTS | 1 (3.0) |
| METOCLOPRAMIDE | 1 (3.0) |
|  | |
| ANTIGOUT PREPARATIONS | 1 (3.0) |
| FEBUXOSTAT | 1 (3.0) |
|  | |
| ANTIHEMORRHAGICS | 1 (3.0) |
| CARBAZOCHROME SODIUM SULFONATE | 1 (3.0) |
|  | |
| ANTIMYCOTICS FOR SYSTEMIC USE | 1 (3.0) |
| VORICONAZOLE | 1 (3.0) |
|  | |
| ANTINEOPLASTIC AGENTS | 1 (3.0) |
| BETA ELEMENE;DELTA ELEMENE;GAMMA ELEMENE | 1 (3.0) |
| BLEOMYCIN HYDROCHLORIDE | 1 (3.0) |
|  | |
| APPETITE STIMULANTS | 1 (3.0) |
| MEGESTROL ACETATE | 1 (3.0) |
|  | |
| CALCIUM CHANNEL BLOCKERS | 1 (3.0) |
| BENIDIPINE HYDROCHLORIDE | 1 (3.0) |
|  | |
| CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS | 1 (3.0) |
| HALOMETASONE | 1 (3.0) |
|  | |
| DRUGS FOR CONSTIPATION | 1 (3.0) |
| GLYCEROL | 1 (3.0) |
| LACTULOSE | 1 (3.0) |
|  | |
| IMMUNOSTIMULANTS | 1 (3.0) |
| NUCLEOTIDES NOS;POLYPEPTIDE | 1 (3.0) |
|  | |
| OPHTHALMOLOGICALS | 1 (3.0) |
| ABALONE SHELL;AKEBIA SPP. STEM;ALISMA ORIENTALE TUBER;ANTELOPE HORN;ARECA CATECHU SEED;CHRYSANTHEMUM X MORIFOLIUM FLOWER;COPTIS SPP. RHIZOME;CORNUS OFFICINALIS FRUIT;CUSCUTA SPP. SEED;DENDROBIUM SPP.STEM;DIOSCOREA OPPOSITIFOLIA RHIZOME;EQUISETUM HYEMALE HERB;ERIOCAULON BUERGERIANUM INFLORESCENCE;LIGUSTRUM LUCIDUM RIPE FRUIT;LYCIUM BARBARUM FRUIT;PAEONIA X SUFFRUTICOSA ROOT BARK;PANAX GINSENG ROOTWITH RHIZOME;PLANTAGO SPP. SEED;PORIA COCOS SCLEROTIUM;PRUNELLA VULGARIS SPIKE;REHMANNIA GLUTINOSA ROOT TUBER;SENNA SPP. SEED;TRIBULUS TERRESTRIS FRUIT | 1 (3.0) |
| HYALURONATE SODIUM | 1 (3.0) |
|  | |
| Uncoded | 5 (15.2) |
| ~FUROSEMIDE TABLETS | 1 (3.0) |
| ~IBANDRONIC ACID | 1 (3.0) |
| ~LOPERAMIDE HYDROCHLORIDE CAPSULES | 1 (3.0) |
| ~NETUPITANT AND PALONOSETRON HYDROCHLORIDE CAPSULES | 1 (3.0) |
| ~POTASSIUM CHLORIDE GRANULES | 1 (3.0) |
| ~QING LV SAI QIN PIAN | 1 (3.0) |
| ~SPIRONOLACTONE TABLETS | 1 (3.0) |

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 |

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

**Table 14.1.7.2 Summary of New Anti-cancer Therapies - Phase II part 1 treatment-naive locally-advanced or metastatic NSCLC (Safety Analysis Set)**

|  | Treatment-naive locally-advanced or metastatic NSCLC (N = 33) n (%) |
| --- | --- |
| Subjects with at least one New Anti-cancer Therapy | 3 (9.1) |
|  | |
| Systemic | 3 (9.1) |
| Treatment Type\* |  |
| Chemotherapy | 3 (100) |
| Immunotherapy | 1 (33.3) |
| Targeted therapy | 1 (33.3) |
| Endocrine therapy | 0 |
| Chinese herbal therapy | 0 |
| Other | 0 |
|  | |
| Radiotherapy | 0 |
|  | |
| Surgery | 0 |
|  | |
| Other | 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 |

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

**Table 14.1.8.2 Summary of Drug Exposure - Phase II part 1 treatment-naive locally-advanced or metastatic NSCLC (Safety Analysis Set)**

|  | Treatment-naive locally-advanced or metastatic NSCLC | |
| --- | --- | --- |
|  | D-1553 (N = 33) | IN10018 (N = 33) |
| Total Duration of treatment (days) |  |  |
| n | 33 | 33 |
| Mean (STD) | 159.9 (81.53) | 159.0 (81.90) |
| Median (Q1, Q3) | 146.0 (127.0, 173.0) | 145.0 (124.0, 173.0) |
| Min, Max | 12, 368 | 12, 368 |
|  | | |
| Actual Cumulative Dose (mg) |  |  |
| n | 33 | 33 |
| Mean (STD) | 184618.2 (95291.20) | 13850.8 (6181.26) |
| Median (Q1, Q3) | 175200.0 (145800.0, 204000.0) | 13000.0 (11400.0, 16600.0) |
| Min, Max | 14400, 440400 | 1200, 28400 |
|  | | |
| Actual Dose Intensity (mg/day) |  |  |
| n | 33 | 33 |
| Mean (STD) | 1156.7303 (99.8388) | 90.4746 (15.2504) |
| Median (Q1, Q3) | 1195.3846 (1176.3158, 1200.0000) | 100.0000 (85.4839, 100.0000) |
| Min, Max | 811.2554, 1200.0000 | 49.1228, 100.0000 |
|  | | |
| Relative Dose Intensity (%) |  |  |
| n | 33 | 33 |
| Mean (STD) | 96.39 (8.320) | 90.47 (15.250) |
| Median (Q1, Q3) | 99.62 (98.03, 100.00) | 100.00 (85.48, 100.00) |
| Min, Max | 67.6, 100.0 | 49.1, 100.0 |
|  | | |
| Dose Adjustments, n (%) |  |  |
| Yes | 21 (63.6) | 22 (66.7) |
| No | 12 (36.4) | 11 (33.3) |
|  | | |
| Subjects with Dose Adjustments, n (%) |  |  |
| Adverse Event | 12 (36.4) | 19 (57.6) |
| Disease Progression | 5 (15.2) | 5 (15.2) |
| Other | 15 (45.5) | 12 (36.4) |

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 |

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

**Table 14.2.1.1.2.1 Summary of Confirmed Best Overall Response based on RECIST 1.1 Criteria - Phase II part 1 Treatment naive locally-advanced or metastatic NSCLC (Safety Analysis Set)**

|  | Treatment-naive locally-advanced or metastatic NSCLC (N = 33) n (%) |
| --- | --- |
| Best Overall Response (BOR) |  |
| Complete Response (CR) | 0 |
| Partial Response (PR) | 25 (75.8) |
| Stable Disease (SD) | 5 (15.2) |
| Progressive Disease (PD) | 1 (3.0) |
| Not Evaluable (NE) | 1 (3.0) |
| Not Applicable (NA) | 1 (3.0) |
|  | |
| Objective Response Rate (ORR) | 25 (75.8) |
| 90% CI | 60.5, 87.3 |
| 95% CI | 57.7, 88.9 |
|  | |
| Disease Control Rate (DCR) | 30 (90.9) |
| 95% CI | 75.7, 98.1 |

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 Safety Analysis 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 14.2.1.1.2.2 Summary of Unconfirmed Best Overall Response based on RECIST 1.1 Criteria - Phase II part 1 Treatment naive locally-advanced or metastatic NSCLC (Safety Analysis Set)**

|  | Treatment-naive locally-advanced or metastatic NSCLC (N = 33) n (%) |
| --- | --- |
| Best Overall Response (BOR) |  |
| Complete Response (CR) | 0 |
| Partial Response (PR) | 27 (81.8) |
| Stable Disease (SD) | 3 (9.1) |
| Progressive Disease (PD) | 1 (3.0) |
| Not Evaluable (NE) | 1 (3.0) |
| Not Applicable (NA) | 1 (3.0) |
|  | |
| Objective Response Rate (ORR) | 27 (81.8) |
| 90% CI | 67.2, 91.8 |
| 95% CI | 64.5, 93.0 |
|  | |
| Disease Control Rate (DCR) | 30 (90.9) |
| 95% CI | 75.7, 98.1 |

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 Safety Analysis 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 14.2.1.2.2.1 Summary of Confirmed Best Overall Response based on RECIST 1.1 Criteria - Phase II part 1 Treatment naive locally-advanced or metastatic NSCLC (Response Evaluation Set)**

|  | Treatment-naive locally-advanced or metastatic NSCLC (N = 31) n (%) |
| --- | --- |
| Best Overall Response (BOR) |  |
| Complete Response (CR) | 0 |
| Partial Response (PR) | 25 (80.6) |
| Stable Disease (SD) | 5 (16.1) |
| Progressive Disease (PD) | 1 (3.2) |
| Not Evaluable (NE) | 0 |
|  | |
| Objective Response Rate (ORR) | 25 (80.6) |
| 90% CI | 65.3, 91.2 |
| 95% CI | 62.5, 92.5 |
|  | |
| Disease Control Rate (DCR) | 30 (96.8) |
| 95% CI | 83.3, 99.9 |

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 14.2.1.2.2.2 Summary of Unconfirmed Best Overall Response based on RECIST 1.1 Criteria - Phase II part 1 Treatment naive locally-advanced or metastatic NSCLC (Response Evaluation Set)**

|  | Treatment-naive locally-advanced or metastatic NSCLC (N = 31) n (%) |
| --- | --- |
| Best Overall Response (BOR) |  |
| Complete Response (CR) | 0 |
| Partial Response (PR) | 27 (87.1) |
| Stable Disease (SD) | 3 (9.7) |
| Progressive Disease (PD) | 1 (3.2) |
| Not Evaluable (NE) | 0 |
|  | |
| Objective Response Rate (ORR) | 27 (87.1) |
| 90% CI | 72.9, 95.5 |
| 95% CI | 70.2, 96.4 |
|  | |
| Disease Control Rate (DCR) | 30 (96.8) |
| 95% CI | 83.3, 99.9 |

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 14.2.1.3.1.1 Summary of Confirmed Objective Response Rate Subgroup Analysis - Phase II part 1 Treatment naive locally-advanced or metastatic NSCLC (Safety Analysis Set)**

| Subgroup |  | | Treatment-naive locally-advanced or metastatic NSCLC |
| --- | --- | --- | --- |
| Age | <65 years | N | 16 |
|  |  | Confirmed ORR, n (%) | 13 (81.3) |
|  |  | 95% CI | 54.4, 96.0 |
|  | | | |
|  | >=65 years | N | 17 |
|  |  | Confirmed ORR, n (%) | 12 (70.6) |
|  |  | 95% CI | 44.0, 89.7 |
|  | | | |
| Sex | Male | N | 31 |
|  |  | Confirmed ORR, n (%) | 24 (77.4) |
|  |  | 95% CI | 58.9, 90.4 |
|  | | | |
|  | Female | N | 2 |
|  |  | Confirmed ORR, n (%) | 1 (50.0) |
|  | | | |
| Baseline ECOG status | 0 | N | 3 |
|  |  | Confirmed ORR, n (%) | 3 (100) |
|  |  | 95% CI | 29.2, 100 |
|  | | | |
|  | 1 | N | 30 |
|  |  | Confirmed ORR, n (%) | 22 (73.3) |
|  |  | 95% CI | 54.1, 87.7 |
|  | | | |
| Differentiation | Well or moderate differentiated | N | 1 |
|  |  | Confirmed ORR, n (%) | 1 (100) |
|  | | | |
|  | Poorly or undifferentiated | N | 11 |
|  |  | Confirmed ORR, n (%) | 10 (90.9) |
|  |  | 95% CI | 58.7, 99.8 |
|  | | | |
| Number of metastatic organs | <=3 | N | 19 |
|  |  | Confirmed ORR, n (%) | 12 (63.2) |
|  |  | 95% CI | 38.4, 83.7 |
|  | | | |
|  | >3 | N | 8 |
|  |  | Confirmed ORR, n (%) | 8 (100) |
|  |  | 95% CI | 63.1, 100 |
|  | | | |
| Brain metastasis | Yes | N | 2 |
|  |  | Confirmed ORR, n (%) | 2 (100) |
|  | | | |
|  | No | N | 31 |
|  |  | Confirmed ORR, n (%) | 23 (74.2) |
|  |  | 95% CI | 55.4, 88.1 |
|  | | | |
| Liver metastasis | Yes | N | 5 |
|  |  | Confirmed ORR, n (%) | 3 (60.0) |
|  |  | 95% CI | 14.7, 94.7 |
|  | | | |
|  | No | N | 28 |
|  |  | Confirmed ORR, n (%) | 22 (78.6) |
|  |  | 95% CI | 59.0, 91.7 |
|  | | | |
| Bone metastasis | Yes | N | 11 |
|  |  | Confirmed ORR, n (%) | 8 (72.7) |
|  |  | 95% CI | 39.0, 94.0 |
|  | | | |
|  | No | N | 22 |
|  |  | Confirmed ORR, n (%) | 17 (77.3) |
|  |  | 95% CI | 54.6, 92.2 |
|  | | | |
| Smoking history | Never | N | 3 |
|  |  | Confirmed ORR, n (%) | 2 (66.7) |
|  |  | 95% CI | 9.4, 99.2 |
|  | | | |
|  | Former | N | 26 |
|  |  | Confirmed ORR, n (%) | 20 (76.9) |
|  |  | 95% CI | 56.4, 91.0 |
|  | | | |
|  | Current | N | 4 |
|  |  | Confirmed ORR, n (%) | 3 (75.0) |
|  |  | 95% CI | 19.4, 99.4 |
|  | | | |
| TNM staging | IIIB/C | N | 6 |
|  |  | Confirmed ORR, n (%) | 5 (83.3) |
|  |  | 95% CI | 35.9, 99.6 |
|  | | | |
|  | IVA | N | 14 |
|  |  | Confirmed ORR, n (%) | 11 (78.6) |
|  |  | 95% CI | 49.2, 95.3 |
|  | | | |
|  | IVB | N | 13 |
|  |  | Confirmed ORR, n (%) | 9 (69.2) |
|  |  | 95% CI | 38.6, 90.9 |
|  | | | |
| TP53 | Altered | N | 1 |
|  |  | Confirmed ORR, n (%) | 0 |
|  | | | |
|  | Wild-type | N | 32 |
|  |  | Confirmed ORR, n (%) | 25 (78.1) |
|  |  | 95% CI | 60.0, 90.7 |
|  | | | |
| STK11 | Wild-type | N | 33 |
|  |  | Confirmed ORR, n (%) | 25 (75.8) |
|  |  | 95% CI | 57.7, 88.9 |
|  | | | |
| KEAP1 | Wild-type | N | 33 |
|  |  | Confirmed ORR, n (%) | 25 (75.8) |
|  |  | 95% CI | 57.7, 88.9 |
|  | | | |
| EGFR | Wild-type | N | 33 |
|  |  | Confirmed ORR, n (%) | 25 (75.8) |
|  |  | 95% CI | 57.7, 88.9 |
|  | | | |
| BRAF | Wild-type | N | 33 |
|  |  | Confirmed ORR, n (%) | 25 (75.8) |
|  |  | 95% CI | 57.7, 88.9 |
|  | | | |
| ALK | Wild-type | N | 33 |
|  |  | Confirmed ORR, n (%) | 25 (75.8) |
|  |  | 95% CI | 57.7, 88.9 |
|  | | | |
| MET | Wild-type | N | 33 |
|  |  | Confirmed ORR, n (%) | 25 (75.8) |
|  |  | 95% CI | 57.7, 88.9 |
|  | | | |
| RET | Wild-type | N | 33 |
|  |  | Confirmed ORR, n (%) | 25 (75.8) |
|  |  | 95% CI | 57.7, 88.9 |
|  | | | |
| ROS1 | Wild-type | N | 33 |
|  |  | Confirmed ORR, n (%) | 25 (75.8) |
|  |  | 95% CI | 57.7, 88.9 |
|  | | | |
| ERBB2 | Altered | N | 1 |
|  |  | Confirmed ORR, n (%) | 0 |
|  | | | |
|  | Wild-type | N | 32 |
|  |  | Confirmed ORR, n (%) | 25 (78.1) |
|  |  | 95% CI | 60.0, 90.7 |
|  | | | |
| NTRK1 | Wild-type | N | 33 |
|  |  | Confirmed ORR, n (%) | 25 (75.8) |
|  |  | 95% CI | 57.7, 88.9 |
|  | | | |
| NTRK2 | Wild-type | N | 33 |
|  |  | Confirmed ORR, n (%) | 25 (75.8) |
|  |  | 95% CI | 57.7, 88.9 |
|  | | | |
| NTRK3 | Altered | N | 1 |
|  |  | Confirmed ORR, n (%) | 0 |
|  | | | |
|  | Wild-type | N | 32 |
|  |  | Confirmed ORR, n (%) | 25 (78.1) |
|  |  | 95% CI | 60.0, 90.7 |
|  | | | |
| KRAS(other than G12C) | Altered | N | 1 |
|  |  | Confirmed ORR, n (%) | 0 |
|  | | | |
|  | Wild-type | N | 32 |
|  |  | Confirmed ORR, n (%) | 25 (78.1) |
|  |  | 95% CI | 60.0, 90.7 |
|  | | | |
| NRAS | Wild-type | N | 33 |
|  |  | Confirmed ORR, n (%) | 25 (75.8) |
|  |  | 95% CI | 57.7, 88.9 |
|  | | | |
| HRAS | Wild-type | N | 33 |
|  |  | Confirmed ORR, n (%) | 25 (75.8) |
|  |  | 95% CI | 57.7, 88.9 |
|  | | | |
| PIK3CA | Wild-type | N | 33 |
|  |  | Confirmed ORR, n (%) | 25 (75.8) |
|  |  | 95% CI | 57.7, 88.9 |
|  | | | |
| PIK3R1 | Wild-type | N | 33 |
|  |  | Confirmed ORR, n (%) | 25 (75.8) |
|  |  | 95% CI | 57.7, 88.9 |
|  | | | |
| MAP2K1 | Wild-type | N | 33 |
|  |  | Confirmed ORR, n (%) | 25 (75.8) |
|  |  | 95% CI | 57.7, 88.9 |
|  | | | |
| RAF1 | Wild-type | N | 33 |
|  |  | Confirmed ORR, n (%) | 25 (75.8) |
|  |  | 95% CI | 57.7, 88.9 |
|  | | | |
| FGFR3 | Wild-type | N | 33 |
|  |  | Confirmed ORR, n (%) | 25 (75.8) |
|  |  | 95% CI | 57.7, 88.9 |
|  | | | |
| NF1 | Wild-type | N | 33 |
|  |  | Confirmed ORR, n (%) | 25 (75.8) |
|  |  | 95% CI | 57.7, 88.9 |
|  | | | |
| PTEN | Wild-type | N | 33 |
|  |  | Confirmed ORR, n (%) | 25 (75.8) |
|  |  | 95% CI | 57.7, 88.9 |

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 Safety Analysis 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-part1.sas | DCO: 27APR2024 | Executed: 09JUL2024 11:30 |

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

**Table 14.2.1.3.1.2 Summary of Unconfirmed Objective Response Rate Subgroup Analysis - Phase II part 1 Treatment naive locally-advanced or metastatic NSCLC (Safety Analysis Set)**

| Subgroup |  | | Treatment-naive locally-advanced or metastatic NSCLC |
| --- | --- | --- | --- |
| Age | <65 years | N | 16 |
|  |  | Unconfirmed ORR, n (%) | 14 (87.5) |
|  |  | 95% CI | 61.7, 98.4 |
|  | | | |
|  | >=65 years | N | 17 |
|  |  | Unconfirmed ORR, n (%) | 13 (76.5) |
|  |  | 95% CI | 50.1, 93.2 |
|  | | | |
| Sex | Male | N | 31 |
|  |  | Unconfirmed ORR, n (%) | 26 (83.9) |
|  |  | 95% CI | 66.3, 94.5 |
|  | | | |
|  | Female | N | 2 |
|  |  | Unconfirmed ORR, n (%) | 1 (50.0) |
|  | | | |
| Baseline ECOG status | 0 | N | 3 |
|  |  | Unconfirmed ORR, n (%) | 3 (100) |
|  |  | 95% CI | 29.2, 100 |
|  | | | |
|  | 1 | N | 30 |
|  |  | Unconfirmed ORR, n (%) | 24 (80.0) |
|  |  | 95% CI | 61.4, 92.3 |
|  | | | |
| Differentiation | Well or moderate differentiated | N | 1 |
|  |  | Unconfirmed ORR, n (%) | 1 (100) |
|  | | | |
|  | Poorly or undifferentiated | N | 11 |
|  |  | Unconfirmed ORR, n (%) | 10 (90.9) |
|  |  | 95% CI | 58.7, 99.8 |
|  | | | |
| Number of metastatic organs | <=3 | N | 19 |
|  |  | Unconfirmed ORR, n (%) | 14 (73.7) |
|  |  | 95% CI | 48.8, 90.9 |
|  | | | |
|  | >3 | N | 8 |
|  |  | Unconfirmed ORR, n (%) | 8 (100) |
|  |  | 95% CI | 63.1, 100 |
|  | | | |
| Brain metastasis | Yes | N | 2 |
|  |  | Unconfirmed ORR, n (%) | 2 (100) |
|  | | | |
|  | No | N | 31 |
|  |  | Unconfirmed ORR, n (%) | 25 (80.6) |
|  |  | 95% CI | 62.5, 92.5 |
|  | | | |
| Liver metastasis | Yes | N | 5 |
|  |  | Unconfirmed ORR, n (%) | 4 (80.0) |
|  |  | 95% CI | 28.4, 99.5 |
|  | | | |
|  | No | N | 28 |
|  |  | Unconfirmed ORR, n (%) | 23 (82.1) |
|  |  | 95% CI | 63.1, 93.9 |
|  | | | |
| Bone metastasis | Yes | N | 11 |
|  |  | Unconfirmed ORR, n (%) | 9 (81.8) |
|  |  | 95% CI | 48.2, 97.7 |
|  | | | |
|  | No | N | 22 |
|  |  | Unconfirmed ORR, n (%) | 18 (81.8) |
|  |  | 95% CI | 59.7, 94.8 |
|  | | | |
| Smoking history | Never | N | 3 |
|  |  | Unconfirmed ORR, n (%) | 2 (66.7) |
|  |  | 95% CI | 9.4, 99.2 |
|  | | | |
|  | Former | N | 26 |
|  |  | Unconfirmed ORR, n (%) | 22 (84.6) |
|  |  | 95% CI | 65.1, 95.6 |
|  | | | |
|  | Current | N | 4 |
|  |  | Unconfirmed ORR, n (%) | 3 (75.0) |
|  |  | 95% CI | 19.4, 99.4 |
|  | | | |
| TNM staging | IIIB/C | N | 6 |
|  |  | Unconfirmed ORR, n (%) | 5 (83.3) |
|  |  | 95% CI | 35.9, 99.6 |
|  | | | |
|  | IVA | N | 14 |
|  |  | Unconfirmed ORR, n (%) | 12 (85.7) |
|  |  | 95% CI | 57.2, 98.2 |
|  | | | |
|  | IVB | N | 13 |
|  |  | Unconfirmed ORR, n (%) | 10 (76.9) |
|  |  | 95% CI | 46.2, 95.0 |
|  | | | |
| TP53 | Altered | N | 1 |
|  |  | Unconfirmed ORR, n (%) | 0 |
|  | | | |
|  | Wild-type | N | 32 |
|  |  | Unconfirmed ORR, n (%) | 27 (84.4) |
|  |  | 95% CI | 67.2, 94.7 |
|  | | | |
| STK11 | Wild-type | N | 33 |
|  |  | Unconfirmed ORR, n (%) | 27 (81.8) |
|  |  | 95% CI | 64.5, 93.0 |
|  | | | |
| KEAP1 | Wild-type | N | 33 |
|  |  | Unconfirmed ORR, n (%) | 27 (81.8) |
|  |  | 95% CI | 64.5, 93.0 |
|  | | | |
| EGFR | Wild-type | N | 33 |
|  |  | Unconfirmed ORR, n (%) | 27 (81.8) |
|  |  | 95% CI | 64.5, 93.0 |
|  | | | |
| BRAF | Wild-type | N | 33 |
|  |  | Unconfirmed ORR, n (%) | 27 (81.8) |
|  |  | 95% CI | 64.5, 93.0 |
|  | | | |
| ALK | Wild-type | N | 33 |
|  |  | Unconfirmed ORR, n (%) | 27 (81.8) |
|  |  | 95% CI | 64.5, 93.0 |
|  | | | |
| MET | Wild-type | N | 33 |
|  |  | Unconfirmed ORR, n (%) | 27 (81.8) |
|  |  | 95% CI | 64.5, 93.0 |
|  | | | |
| RET | Wild-type | N | 33 |
|  |  | Unconfirmed ORR, n (%) | 27 (81.8) |
|  |  | 95% CI | 64.5, 93.0 |
|  | | | |
| ROS1 | Wild-type | N | 33 |
|  |  | Unconfirmed ORR, n (%) | 27 (81.8) |
|  |  | 95% CI | 64.5, 93.0 |
|  | | | |
| ERBB2 | Altered | N | 1 |
|  |  | Unconfirmed ORR, n (%) | 0 |
|  | | | |
|  | Wild-type | N | 32 |
|  |  | Unconfirmed ORR, n (%) | 27 (84.4) |
|  |  | 95% CI | 67.2, 94.7 |
|  | | | |
| NTRK1 | Wild-type | N | 33 |
|  |  | Unconfirmed ORR, n (%) | 27 (81.8) |
|  |  | 95% CI | 64.5, 93.0 |
|  | | | |
| NTRK2 | Wild-type | N | 33 |
|  |  | Unconfirmed ORR, n (%) | 27 (81.8) |
|  |  | 95% CI | 64.5, 93.0 |
|  | | | |
| NTRK3 | Altered | N | 1 |
|  |  | Unconfirmed ORR, n (%) | 0 |
|  | | | |
|  | Wild-type | N | 32 |
|  |  | Unconfirmed ORR, n (%) | 27 (84.4) |
|  |  | 95% CI | 67.2, 94.7 |
|  | | | |
| KRAS(other than G12C) | Altered | N | 1 |
|  |  | Unconfirmed ORR, n (%) | 0 |
|  | | | |
|  | Wild-type | N | 32 |
|  |  | Unconfirmed ORR, n (%) | 27 (84.4) |
|  |  | 95% CI | 67.2, 94.7 |
|  | | | |
| NRAS | Wild-type | N | 33 |
|  |  | Unconfirmed ORR, n (%) | 27 (81.8) |
|  |  | 95% CI | 64.5, 93.0 |
|  | | | |
| HRAS | Wild-type | N | 33 |
|  |  | Unconfirmed ORR, n (%) | 27 (81.8) |
|  |  | 95% CI | 64.5, 93.0 |
|  | | | |
| PIK3CA | Wild-type | N | 33 |
|  |  | Unconfirmed ORR, n (%) | 27 (81.8) |
|  |  | 95% CI | 64.5, 93.0 |
|  | | | |
| PIK3R1 | Wild-type | N | 33 |
|  |  | Unconfirmed ORR, n (%) | 27 (81.8) |
|  |  | 95% CI | 64.5, 93.0 |
|  | | | |
| MAP2K1 | Wild-type | N | 33 |
|  |  | Unconfirmed ORR, n (%) | 27 (81.8) |
|  |  | 95% CI | 64.5, 93.0 |
|  | | | |
| RAF1 | Wild-type | N | 33 |
|  |  | Unconfirmed ORR, n (%) | 27 (81.8) |
|  |  | 95% CI | 64.5, 93.0 |
|  | | | |
| FGFR3 | Wild-type | N | 33 |
|  |  | Unconfirmed ORR, n (%) | 27 (81.8) |
|  |  | 95% CI | 64.5, 93.0 |
|  | | | |
| NF1 | Wild-type | N | 33 |
|  |  | Unconfirmed ORR, n (%) | 27 (81.8) |
|  |  | 95% CI | 64.5, 93.0 |
|  | | | |
| PTEN | Wild-type | N | 33 |
|  |  | Unconfirmed ORR, n (%) | 27 (81.8) |
|  |  | 95% CI | 64.5, 93.0 |

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 Safety Analysis 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-part1.sas | DCO: 27APR2024 | Executed: 09JUL2024 11:30 |

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

**Table 14.2.1.4.1.1 Summary of Confirmed Objective Response Rate Subgroup Analysis - Phase II part 1 Treatment naive locally-advanced or metastatic NSCLC (Response Evaluation Set)**

| Subgroup |  | | Treatment-naive locally-advanced or metastatic NSCLC |
| --- | --- | --- | --- |
| Age | <65 years | N | 16 |
|  |  | Confirmed ORR, n (%) | 13 (81.3) |
|  |  | 95% CI | 54.4, 96.0 |
|  | | | |
|  | >=65 years | N | 15 |
|  |  | Confirmed ORR, n (%) | 12 (80.0) |
|  |  | 95% CI | 51.9, 95.7 |
|  | | | |
| Sex | Male | N | 29 |
|  |  | Confirmed ORR, n (%) | 24 (82.8) |
|  |  | 95% CI | 64.2, 94.2 |
|  | | | |
|  | Female | N | 2 |
|  |  | Confirmed ORR, n (%) | 1 (50.0) |
|  | | | |
| Baseline ECOG status | 0 | N | 3 |
|  |  | Confirmed ORR, n (%) | 3 (100) |
|  |  | 95% CI | 29.2, 100 |
|  | | | |
|  | 1 | N | 28 |
|  |  | Confirmed ORR, n (%) | 22 (78.6) |
|  |  | 95% CI | 59.0, 91.7 |
|  | | | |
| Differentiation | Well or moderate differentiated | N | 1 |
|  |  | Confirmed ORR, n (%) | 1 (100) |
|  | | | |
|  | Poorly or undifferentiated | N | 11 |
|  |  | Confirmed ORR, n (%) | 10 (90.9) |
|  |  | 95% CI | 58.7, 99.8 |
|  | | | |
| Number of metastatic organs | <=3 | N | 17 |
|  |  | Confirmed ORR, n (%) | 12 (70.6) |
|  |  | 95% CI | 44.0, 89.7 |
|  | | | |
|  | >3 | N | 8 |
|  |  | Confirmed ORR, n (%) | 8 (100) |
|  |  | 95% CI | 63.1, 100 |
|  | | | |
| Brain metastasis | Yes | N | 2 |
|  |  | Confirmed ORR, n (%) | 2 (100) |
|  | | | |
|  | No | N | 29 |
|  |  | Confirmed ORR, n (%) | 23 (79.3) |
|  |  | 95% CI | 60.3, 92.0 |
|  | | | |
| Liver metastasis | Yes | N | 4 |
|  |  | Confirmed ORR, n (%) | 3 (75.0) |
|  |  | 95% CI | 19.4, 99.4 |
|  | | | |
|  | No | N | 27 |
|  |  | Confirmed ORR, n (%) | 22 (81.5) |
|  |  | 95% CI | 61.9, 93.7 |
|  | | | |
| Bone metastasis | Yes | N | 10 |
|  |  | Confirmed ORR, n (%) | 8 (80.0) |
|  |  | 95% CI | 44.4, 97.5 |
|  | | | |
|  | No | N | 21 |
|  |  | Confirmed ORR, n (%) | 17 (81.0) |
|  |  | 95% CI | 58.1, 94.6 |
|  | | | |
| Smoking history | Never | N | 3 |
|  |  | Confirmed ORR, n (%) | 2 (66.7) |
|  |  | 95% CI | 9.4, 99.2 |
|  | | | |
|  | Former | N | 24 |
|  |  | Confirmed ORR, n (%) | 20 (83.3) |
|  |  | 95% CI | 62.6, 95.3 |
|  | | | |
|  | Current | N | 4 |
|  |  | Confirmed ORR, n (%) | 3 (75.0) |
|  |  | 95% CI | 19.4, 99.4 |
|  | | | |
| TNM staging | IIIB/C | N | 6 |
|  |  | Confirmed ORR, n (%) | 5 (83.3) |
|  |  | 95% CI | 35.9, 99.6 |
|  | | | |
|  | IVA | N | 14 |
|  |  | Confirmed ORR, n (%) | 11 (78.6) |
|  |  | 95% CI | 49.2, 95.3 |
|  | | | |
|  | IVB | N | 11 |
|  |  | Confirmed ORR, n (%) | 9 (81.8) |
|  |  | 95% CI | 48.2, 97.7 |
|  | | | |
| TP53 | Altered | N | 1 |
|  |  | Confirmed ORR, n (%) | 0 |
|  | | | |
|  | Wild-type | N | 30 |
|  |  | Confirmed ORR, n (%) | 25 (83.3) |
|  |  | 95% CI | 65.3, 94.4 |
|  | | | |
| STK11 | Wild-type | N | 31 |
|  |  | Confirmed ORR, n (%) | 25 (80.6) |
|  |  | 95% CI | 62.5, 92.5 |
|  | | | |
| KEAP1 | Wild-type | N | 31 |
|  |  | Confirmed ORR, n (%) | 25 (80.6) |
|  |  | 95% CI | 62.5, 92.5 |
|  | | | |
| EGFR | Wild-type | N | 31 |
|  |  | Confirmed ORR, n (%) | 25 (80.6) |
|  |  | 95% CI | 62.5, 92.5 |
|  | | | |
| BRAF | Wild-type | N | 31 |
|  |  | Confirmed ORR, n (%) | 25 (80.6) |
|  |  | 95% CI | 62.5, 92.5 |
|  | | | |
| ALK | Wild-type | N | 31 |
|  |  | Confirmed ORR, n (%) | 25 (80.6) |
|  |  | 95% CI | 62.5, 92.5 |
|  | | | |
| MET | Wild-type | N | 31 |
|  |  | Confirmed ORR, n (%) | 25 (80.6) |
|  |  | 95% CI | 62.5, 92.5 |
|  | | | |
| RET | Wild-type | N | 31 |
|  |  | Confirmed ORR, n (%) | 25 (80.6) |
|  |  | 95% CI | 62.5, 92.5 |
|  | | | |
| ROS1 | Wild-type | N | 31 |
|  |  | Confirmed ORR, n (%) | 25 (80.6) |
|  |  | 95% CI | 62.5, 92.5 |
|  | | | |
| ERBB2 | Altered | N | 1 |
|  |  | Confirmed ORR, n (%) | 0 |
|  | | | |
|  | Wild-type | N | 30 |
|  |  | Confirmed ORR, n (%) | 25 (83.3) |
|  |  | 95% CI | 65.3, 94.4 |
|  | | | |
| NTRK1 | Wild-type | N | 31 |
|  |  | Confirmed ORR, n (%) | 25 (80.6) |
|  |  | 95% CI | 62.5, 92.5 |
|  | | | |
| NTRK2 | Wild-type | N | 31 |
|  |  | Confirmed ORR, n (%) | 25 (80.6) |
|  |  | 95% CI | 62.5, 92.5 |
|  | | | |
| NTRK3 | Altered | N | 1 |
|  |  | Confirmed ORR, n (%) | 0 |
|  | | | |
|  | Wild-type | N | 30 |
|  |  | Confirmed ORR, n (%) | 25 (83.3) |
|  |  | 95% CI | 65.3, 94.4 |
|  | | | |
| KRAS(other than G12C) | Altered | N | 1 |
|  |  | Confirmed ORR, n (%) | 0 |
|  | | | |
|  | Wild-type | N | 30 |
|  |  | Confirmed ORR, n (%) | 25 (83.3) |
|  |  | 95% CI | 65.3, 94.4 |
|  | | | |
| NRAS | Wild-type | N | 31 |
|  |  | Confirmed ORR, n (%) | 25 (80.6) |
|  |  | 95% CI | 62.5, 92.5 |
|  | | | |
| HRAS | Wild-type | N | 31 |
|  |  | Confirmed ORR, n (%) | 25 (80.6) |
|  |  | 95% CI | 62.5, 92.5 |
|  | | | |
| PIK3CA | Wild-type | N | 31 |
|  |  | Confirmed ORR, n (%) | 25 (80.6) |
|  |  | 95% CI | 62.5, 92.5 |
|  | | | |
| PIK3R1 | Wild-type | N | 31 |
|  |  | Confirmed ORR, n (%) | 25 (80.6) |
|  |  | 95% CI | 62.5, 92.5 |
|  | | | |
| MAP2K1 | Wild-type | N | 31 |
|  |  | Confirmed ORR, n (%) | 25 (80.6) |
|  |  | 95% CI | 62.5, 92.5 |
|  | | | |
| RAF1 | Wild-type | N | 31 |
|  |  | Confirmed ORR, n (%) | 25 (80.6) |
|  |  | 95% CI | 62.5, 92.5 |
|  | | | |
| FGFR3 | Wild-type | N | 31 |
|  |  | Confirmed ORR, n (%) | 25 (80.6) |
|  |  | 95% CI | 62.5, 92.5 |
|  | | | |
| NF1 | Wild-type | N | 31 |
|  |  | Confirmed ORR, n (%) | 25 (80.6) |
|  |  | 95% CI | 62.5, 92.5 |
|  | | | |
| PTEN | Wild-type | N | 31 |
|  |  | Confirmed ORR, n (%) | 25 (80.6) |
|  |  | 95% CI | 62.5, 92.5 |

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-part1.sas | DCO: 27APR2024 | Executed: 09JUL2024 11:30 |

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

**Table 14.2.1.4.1.2 Summary of Unconfirmed Objective Response Rate Subgroup Analysis - Phase II part 1 Treatment naive locally-advanced or metastatic NSCLC (Response Evaluation Set)**

| Subgroup |  | | Treatment-naive locally-advanced or metastatic NSCLC |
| --- | --- | --- | --- |
| Age | <65 years | N | 16 |
|  |  | Unconfirmed ORR, n (%) | 14 (87.5) |
|  |  | 95% CI | 61.7, 98.4 |
|  | | | |
|  | >=65 years | N | 15 |
|  |  | Unconfirmed ORR, n (%) | 13 (86.7) |
|  |  | 95% CI | 59.5, 98.3 |
|  | | | |
| Sex | Male | N | 29 |
|  |  | Unconfirmed ORR, n (%) | 26 (89.7) |
|  |  | 95% CI | 72.6, 97.8 |
|  | | | |
|  | Female | N | 2 |
|  |  | Unconfirmed ORR, n (%) | 1 (50.0) |
|  | | | |
| Baseline ECOG status | 0 | N | 3 |
|  |  | Unconfirmed ORR, n (%) | 3 (100) |
|  |  | 95% CI | 29.2, 100 |
|  | | | |
|  | 1 | N | 28 |
|  |  | Unconfirmed ORR, n (%) | 24 (85.7) |
|  |  | 95% CI | 67.3, 96.0 |
|  | | | |
| Differentiation | Well or moderate differentiated | N | 1 |
|  |  | Unconfirmed ORR, n (%) | 1 (100) |
|  | | | |
|  | Poorly or undifferentiated | N | 11 |
|  |  | Unconfirmed ORR, n (%) | 10 (90.9) |
|  |  | 95% CI | 58.7, 99.8 |
|  | | | |
| Number of metastatic organs | <=3 | N | 17 |
|  |  | Unconfirmed ORR, n (%) | 14 (82.4) |
|  |  | 95% CI | 56.6, 96.2 |
|  | | | |
|  | >3 | N | 8 |
|  |  | Unconfirmed ORR, n (%) | 8 (100) |
|  |  | 95% CI | 63.1, 100 |
|  | | | |
| Brain metastasis | Yes | N | 2 |
|  |  | Unconfirmed ORR, n (%) | 2 (100) |
|  | | | |
|  | No | N | 29 |
|  |  | Unconfirmed ORR, n (%) | 25 (86.2) |
|  |  | 95% CI | 68.3, 96.1 |
|  | | | |
| Liver metastasis | Yes | N | 4 |
|  |  | Unconfirmed ORR, n (%) | 4 (100) |
|  |  | 95% CI | 39.8, 100 |
|  | | | |
|  | No | N | 27 |
|  |  | Unconfirmed ORR, n (%) | 23 (85.2) |
|  |  | 95% CI | 66.3, 95.8 |
|  | | | |
| Bone metastasis | Yes | N | 10 |
|  |  | Unconfirmed ORR, n (%) | 9 (90.0) |
|  |  | 95% CI | 55.5, 99.7 |
|  | | | |
|  | No | N | 21 |
|  |  | Unconfirmed ORR, n (%) | 18 (85.7) |
|  |  | 95% CI | 63.7, 97.0 |
|  | | | |
| Smoking history | Never | N | 3 |
|  |  | Unconfirmed ORR, n (%) | 2 (66.7) |
|  |  | 95% CI | 9.4, 99.2 |
|  | | | |
|  | Former | N | 24 |
|  |  | Unconfirmed ORR, n (%) | 22 (91.7) |
|  |  | 95% CI | 73.0, 99.0 |
|  | | | |
|  | Current | N | 4 |
|  |  | Unconfirmed ORR, n (%) | 3 (75.0) |
|  |  | 95% CI | 19.4, 99.4 |
|  | | | |
| TNM staging | IIIB/C | N | 6 |
|  |  | Unconfirmed ORR, n (%) | 5 (83.3) |
|  |  | 95% CI | 35.9, 99.6 |
|  | | | |
|  | IVA | N | 14 |
|  |  | Unconfirmed ORR, n (%) | 12 (85.7) |
|  |  | 95% CI | 57.2, 98.2 |
|  | | | |
|  | IVB | N | 11 |
|  |  | Unconfirmed ORR, n (%) | 10 (90.9) |
|  |  | 95% CI | 58.7, 99.8 |
|  | | | |
| TP53 | Altered | N | 1 |
|  |  | Unconfirmed ORR, n (%) | 0 |
|  | | | |
|  | Wild-type | N | 30 |
|  |  | Unconfirmed ORR, n (%) | 27 (90.0) |
|  |  | 95% CI | 73.5, 97.9 |
|  | | | |
| STK11 | Wild-type | N | 31 |
|  |  | Unconfirmed ORR, n (%) | 27 (87.1) |
|  |  | 95% CI | 70.2, 96.4 |
|  | | | |
| KEAP1 | Wild-type | N | 31 |
|  |  | Unconfirmed ORR, n (%) | 27 (87.1) |
|  |  | 95% CI | 70.2, 96.4 |
|  | | | |
| EGFR | Wild-type | N | 31 |
|  |  | Unconfirmed ORR, n (%) | 27 (87.1) |
|  |  | 95% CI | 70.2, 96.4 |
|  | | | |
| BRAF | Wild-type | N | 31 |
|  |  | Unconfirmed ORR, n (%) | 27 (87.1) |
|  |  | 95% CI | 70.2, 96.4 |
|  | | | |
| ALK | Wild-type | N | 31 |
|  |  | Unconfirmed ORR, n (%) | 27 (87.1) |
|  |  | 95% CI | 70.2, 96.4 |
|  | | | |
| MET | Wild-type | N | 31 |
|  |  | Unconfirmed ORR, n (%) | 27 (87.1) |
|  |  | 95% CI | 70.2, 96.4 |
|  | | | |
| RET | Wild-type | N | 31 |
|  |  | Unconfirmed ORR, n (%) | 27 (87.1) |
|  |  | 95% CI | 70.2, 96.4 |
|  | | | |
| ROS1 | Wild-type | N | 31 |
|  |  | Unconfirmed ORR, n (%) | 27 (87.1) |
|  |  | 95% CI | 70.2, 96.4 |
|  | | | |
| ERBB2 | Altered | N | 1 |
|  |  | Unconfirmed ORR, n (%) | 0 |
|  | | | |
|  | Wild-type | N | 30 |
|  |  | Unconfirmed ORR, n (%) | 27 (90.0) |
|  |  | 95% CI | 73.5, 97.9 |
|  | | | |
| NTRK1 | Wild-type | N | 31 |
|  |  | Unconfirmed ORR, n (%) | 27 (87.1) |
|  |  | 95% CI | 70.2, 96.4 |
|  | | | |
| NTRK2 | Wild-type | N | 31 |
|  |  | Unconfirmed ORR, n (%) | 27 (87.1) |
|  |  | 95% CI | 70.2, 96.4 |
|  | | | |
| NTRK3 | Altered | N | 1 |
|  |  | Unconfirmed ORR, n (%) | 0 |
|  | | | |
|  | Wild-type | N | 30 |
|  |  | Unconfirmed ORR, n (%) | 27 (90.0) |
|  |  | 95% CI | 73.5, 97.9 |
|  | | | |
| KRAS(other than G12C) | Altered | N | 1 |
|  |  | Unconfirmed ORR, n (%) | 0 |
|  | | | |
|  | Wild-type | N | 30 |
|  |  | Unconfirmed ORR, n (%) | 27 (90.0) |
|  |  | 95% CI | 73.5, 97.9 |
|  | | | |
| NRAS | Wild-type | N | 31 |
|  |  | Unconfirmed ORR, n (%) | 27 (87.1) |
|  |  | 95% CI | 70.2, 96.4 |
|  | | | |
| HRAS | Wild-type | N | 31 |
|  |  | Unconfirmed ORR, n (%) | 27 (87.1) |
|  |  | 95% CI | 70.2, 96.4 |
|  | | | |
| PIK3CA | Wild-type | N | 31 |
|  |  | Unconfirmed ORR, n (%) | 27 (87.1) |
|  |  | 95% CI | 70.2, 96.4 |
|  | | | |
| PIK3R1 | Wild-type | N | 31 |
|  |  | Unconfirmed ORR, n (%) | 27 (87.1) |
|  |  | 95% CI | 70.2, 96.4 |
|  | | | |
| MAP2K1 | Wild-type | N | 31 |
|  |  | Unconfirmed ORR, n (%) | 27 (87.1) |
|  |  | 95% CI | 70.2, 96.4 |
|  | | | |
| RAF1 | Wild-type | N | 31 |
|  |  | Unconfirmed ORR, n (%) | 27 (87.1) |
|  |  | 95% CI | 70.2, 96.4 |
|  | | | |
| FGFR3 | Wild-type | N | 31 |
|  |  | Unconfirmed ORR, n (%) | 27 (87.1) |
|  |  | 95% CI | 70.2, 96.4 |
|  | | | |
| NF1 | Wild-type | N | 31 |
|  |  | Unconfirmed ORR, n (%) | 27 (87.1) |
|  |  | 95% CI | 70.2, 96.4 |
|  | | | |
| PTEN | Wild-type | N | 31 |
|  |  | Unconfirmed ORR, n (%) | 27 (87.1) |
|  |  | 95% CI | 70.2, 96.4 |

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-part1.sas | DCO: 27APR2024 | Executed: 09JUL2024 11:30 |

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

**Table 14.2.2.1.2 Progression Free Survival based on RECIST 1.1 Criteria - Phase II part 1 Treatment naive locally-advanced or metastatic NSCLC (Safety Analysis Set)**

|  | Treatment-naive locally-advanced or metastatic NSCLC (N = 33) |
| --- | --- |
| Progressive Disease or Death, n (%) | 8 (24.2) |
| Censored, n (%) | 25 (75.8) |
|  | |
| Progression Free Survival (months) |  |
| Minimum | 0.03+ |
| 25th Percentile (95% CI) | 4.27 (2.73, NE) |
| Median (95% CI) | NE (4.27, NE) |
| 75th Percentile (95% CI) | NE (NE, NE) |
| Maximum | 11.73+ |
|  | |
| Probability (%) of Being Progression-free at Least: |  |
| 3 months (95% CI) | 90.5 (73.4, 96.8) |
| 6 months (95% CI) | 69.7 (47.5, 83.9) |
| 9 months (95% CI) | 69.7 (47.5, 83.9) |
| 12 months (95% CI) | NE (NE, NE) |

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

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 16.2.6.4.1

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

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

**Table 14.2.2.2.1.1 Summary of PFS Subgroup Analysis - Phase II part 1 Treatment naive locally-advanced or metastatic NSCLC (Safety Analysis Set)**

| Subgroup |  | | Treatment-naive locally-advanced or metastatic NSCLC |
| --- | --- | --- | --- |
| Age | <65 years | N | 16 |
|  |  | Progressive Diease or Death, n (%) | 4 (25.0) |
|  |  | Censored, n (%) | 12 (75.0) |
|  | | | |
|  | >=65 years | N | 17 |
|  |  | Progressive Diease or Death, n (%) | 4 (23.5) |
|  |  | Censored, n (%) | 13 (76.5) |
|  | | | |
| Sex | Male | N | 31 |
|  |  | Progressive Diease or Death, n (%) | 8 (25.8) |
|  |  | Censored, n (%) | 23 (74.2) |
|  |  | mPFS (months) (95% CI) | NE (4.27, NE) |
|  | | | |
|  | Female | N | 2 |
|  |  | Progressive Diease or Death, n (%) | 0 |
|  |  | Censored, n (%) | 2 (100) |
|  | | | |
| Baseline ECOG status | 0 | N | 3 |
|  |  | Progressive Diease or Death, n (%) | 1 (33.3) |
|  |  | Censored, n (%) | 2 (66.7) |
|  | | | |
|  | 1 | N | 30 |
|  |  | Progressive Diease or Death, n (%) | 7 (23.3) |
|  |  | Censored, n (%) | 23 (76.7) |
|  |  | mPFS (months) (95% CI) | NE (4.27, NE) |
|  | | | |
| Differentiation | Well or moderate differentiated | N | 1 |
|  |  | Progressive Diease or Death, n (%) | 0 |
|  |  | Censored, n (%) | 1 (100) |
|  | | | |
|  | Poorly or undifferentiated | N | 11 |
|  |  | Progressive Diease or Death, n (%) | 3 (27.3) |
|  |  | Censored, n (%) | 8 (72.7) |
|  | | | |
| Number of metastatic organs | <=3 | N | 19 |
|  |  | Progressive Diease or Death, n (%) | 5 (26.3) |
|  |  | Censored, n (%) | 14 (73.7) |
|  |  | mPFS (months) (95% CI) | NE (3.06, NE) |
|  | | | |
|  | >3 | N | 8 |
|  |  | Progressive Diease or Death, n (%) | 2 (25.0) |
|  |  | Censored, n (%) | 6 (75.0) |
|  | | | |
| Brain metastasis | Yes | N | 2 |
|  |  | Progressive Diease or Death, n (%) | 0 |
|  |  | Censored, n (%) | 2 (100) |
|  | | | |
|  | No | N | 31 |
|  |  | Progressive Diease or Death, n (%) | 8 (25.8) |
|  |  | Censored, n (%) | 23 (74.2) |
|  |  | mPFS (months) (95% CI) | NE (4.27, NE) |
|  | | | |
| Liver metastasis | Yes | N | 5 |
|  |  | Progressive Diease or Death, n (%) | 3 (60.0) |
|  |  | Censored, n (%) | 2 (40.0) |
|  | | | |
|  | No | N | 28 |
|  |  | Progressive Diease or Death, n (%) | 5 (17.9) |
|  |  | Censored, n (%) | 23 (82.1) |
|  |  | mPFS (months) (95% CI) | NE (4.27, NE) |
|  | | | |
| Bone metastasis | Yes | N | 11 |
|  |  | Progressive Diease or Death, n (%) | 5 (45.5) |
|  |  | Censored, n (%) | 6 (54.5) |
|  |  | mPFS (months) (95% CI) | 4.27 (2.73, NE) |
|  | | | |
|  | No | N | 22 |
|  |  | Progressive Diease or Death, n (%) | 3 (13.6) |
|  |  | Censored, n (%) | 19 (86.4) |
|  | | | |
| Smoking history | Never | N | 3 |
|  |  | Progressive Diease or Death, n (%) | 1 (33.3) |
|  |  | Censored, n (%) | 2 (66.7) |
|  | | | |
|  | Former | N | 26 |
|  |  | Progressive Diease or Death, n (%) | 7 (26.9) |
|  |  | Censored, n (%) | 19 (73.1) |
|  |  | mPFS (months) (95% CI) | NE (4.17, NE) |
|  | | | |
|  | Current | N | 4 |
|  |  | Progressive Diease or Death, n (%) | 0 |
|  |  | Censored, n (%) | 4 (100) |
|  | | | |
| TNM staging | IIIB/C | N | 6 |
|  |  | Progressive Diease or Death, n (%) | 1 (16.7) |
|  |  | Censored, n (%) | 5 (83.3) |
|  | | | |
|  | IVA | N | 14 |
|  |  | Progressive Diease or Death, n (%) | 3 (21.4) |
|  |  | Censored, n (%) | 11 (78.6) |
|  | | | |
|  | IVB | N | 13 |
|  |  | Progressive Diease or Death, n (%) | 4 (30.8) |
|  |  | Censored, n (%) | 9 (69.2) |
|  | | | |
| TP53 | Altered | N | 1 |
|  |  | Progressive Diease or Death, n (%) | 1 (100) |
|  |  | Censored, n (%) | 0 |
|  | | | |
|  | Wild-type | N | 32 |
|  |  | Progressive Diease or Death, n (%) | 7 (21.9) |
|  |  | Censored, n (%) | 25 (78.1) |
|  |  | mPFS (months) (95% CI) | NE (4.27, NE) |
|  | | | |
| STK11 | Wild-type | N | 33 |
|  |  | Progressive Diease or Death, n (%) | 8 (24.2) |
|  |  | Censored, n (%) | 25 (75.8) |
|  |  | mPFS (months) (95% CI) | NE (4.27, NE) |
|  | | | |
| KEAP1 | Wild-type | N | 33 |
|  |  | Progressive Diease or Death, n (%) | 8 (24.2) |
|  |  | Censored, n (%) | 25 (75.8) |
|  |  | mPFS (months) (95% CI) | NE (4.27, NE) |
|  | | | |
| EGFR | Wild-type | N | 33 |
|  |  | Progressive Diease or Death, n (%) | 8 (24.2) |
|  |  | Censored, n (%) | 25 (75.8) |
|  |  | mPFS (months) (95% CI) | NE (4.27, NE) |
|  | | | |
| BRAF | Wild-type | N | 33 |
|  |  | Progressive Diease or Death, n (%) | 8 (24.2) |
|  |  | Censored, n (%) | 25 (75.8) |
|  |  | mPFS (months) (95% CI) | NE (4.27, NE) |
|  | | | |
| ALK | Wild-type | N | 33 |
|  |  | Progressive Diease or Death, n (%) | 8 (24.2) |
|  |  | Censored, n (%) | 25 (75.8) |
|  |  | mPFS (months) (95% CI) | NE (4.27, NE) |
|  | | | |
| MET | Wild-type | N | 33 |
|  |  | Progressive Diease or Death, n (%) | 8 (24.2) |
|  |  | Censored, n (%) | 25 (75.8) |
|  |  | mPFS (months) (95% CI) | NE (4.27, NE) |
|  | | | |
| RET | Wild-type | N | 33 |
|  |  | Progressive Diease or Death, n (%) | 8 (24.2) |
|  |  | Censored, n (%) | 25 (75.8) |
|  |  | mPFS (months) (95% CI) | NE (4.27, NE) |
|  | | | |
| ROS1 | Wild-type | N | 33 |
|  |  | Progressive Diease or Death, n (%) | 8 (24.2) |
|  |  | Censored, n (%) | 25 (75.8) |
|  |  | mPFS (months) (95% CI) | NE (4.27, NE) |
|  | | | |
| ERBB2 | Altered | N | 1 |
|  |  | Progressive Diease or Death, n (%) | 1 (100) |
|  |  | Censored, n (%) | 0 |
|  | | | |
|  | Wild-type | N | 32 |
|  |  | Progressive Diease or Death, n (%) | 7 (21.9) |
|  |  | Censored, n (%) | 25 (78.1) |
|  |  | mPFS (months) (95% CI) | NE (4.27, NE) |
|  | | | |
| NTRK1 | Wild-type | N | 33 |
|  |  | Progressive Diease or Death, n (%) | 8 (24.2) |
|  |  | Censored, n (%) | 25 (75.8) |
|  |  | mPFS (months) (95% CI) | NE (4.27, NE) |
|  | | | |
| NTRK2 | Wild-type | N | 33 |
|  |  | Progressive Diease or Death, n (%) | 8 (24.2) |
|  |  | Censored, n (%) | 25 (75.8) |
|  |  | mPFS (months) (95% CI) | NE (4.27, NE) |
|  | | | |
| NTRK3 | Altered | N | 1 |
|  |  | Progressive Diease or Death, n (%) | 1 (100) |
|  |  | Censored, n (%) | 0 |
|  | | | |
|  | Wild-type | N | 32 |
|  |  | Progressive Diease or Death, n (%) | 7 (21.9) |
|  |  | Censored, n (%) | 25 (78.1) |
|  |  | mPFS (months) (95% CI) | NE (4.27, NE) |
|  | | | |
| KRAS(other than G12C) | Altered | N | 1 |
|  |  | Progressive Diease or Death, n (%) | 1 (100) |
|  |  | Censored, n (%) | 0 |
|  | | | |
|  | Wild-type | N | 32 |
|  |  | Progressive Diease or Death, n (%) | 7 (21.9) |
|  |  | Censored, n (%) | 25 (78.1) |
|  |  | mPFS (months) (95% CI) | NE (4.27, NE) |
|  | | | |
| NRAS | Wild-type | N | 33 |
|  |  | Progressive Diease or Death, n (%) | 8 (24.2) |
|  |  | Censored, n (%) | 25 (75.8) |
|  |  | mPFS (months) (95% CI) | NE (4.27, NE) |
|  | | | |
| HRAS | Wild-type | N | 33 |
|  |  | Progressive Diease or Death, n (%) | 8 (24.2) |
|  |  | Censored, n (%) | 25 (75.8) |
|  |  | mPFS (months) (95% CI) | NE (4.27, NE) |
|  | | | |
| PIK3CA | Wild-type | N | 33 |
|  |  | Progressive Diease or Death, n (%) | 8 (24.2) |
|  |  | Censored, n (%) | 25 (75.8) |
|  |  | mPFS (months) (95% CI) | NE (4.27, NE) |
|  | | | |
| PIK3R1 | Wild-type | N | 33 |
|  |  | Progressive Diease or Death, n (%) | 8 (24.2) |
|  |  | Censored, n (%) | 25 (75.8) |
|  |  | mPFS (months) (95% CI) | NE (4.27, NE) |
|  | | | |
| MAP2K1 | Wild-type | N | 33 |
|  |  | Progressive Diease or Death, n (%) | 8 (24.2) |
|  |  | Censored, n (%) | 25 (75.8) |
|  |  | mPFS (months) (95% CI) | NE (4.27, NE) |
|  | | | |
| RAF1 | Wild-type | N | 33 |
|  |  | Progressive Diease or Death, n (%) | 8 (24.2) |
|  |  | Censored, n (%) | 25 (75.8) |
|  |  | mPFS (months) (95% CI) | NE (4.27, NE) |
|  | | | |
| FGFR3 | Wild-type | N | 33 |
|  |  | Progressive Diease or Death, n (%) | 8 (24.2) |
|  |  | Censored, n (%) | 25 (75.8) |
|  |  | mPFS (months) (95% CI) | NE (4.27, NE) |
|  | | | |
| NF1 | Wild-type | N | 33 |
|  |  | Progressive Diease or Death, n (%) | 8 (24.2) |
|  |  | Censored, n (%) | 25 (75.8) |
|  |  | mPFS (months) (95% CI) | NE (4.27, NE) |
|  | | | |
| PTEN | Wild-type | N | 33 |
|  |  | Progressive Diease or Death, n (%) | 8 (24.2) |
|  |  | Censored, n (%) | 25 (75.8) |
|  |  | mPFS (months) (95% CI) | NE (4.27, NE) |

mPFS: Median Progression Free Survival.

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

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

Source Data: Listing 16.2.6.4.1

|  |  |  |
| --- | --- | --- |
| Program: t-pfs-subgrp-part1.sas | DCO: 27APR2024 | Executed: 07JUL2024 20:36 |

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

**Table 14.2.3.1.2.1 Duration of Response based on RECIST 1.1 Criteria (Confirmed) - Phase II part 1 Treatment naive locally-advanced or metastatic NSCLC (Response Evaluation Set)**

|  | Treatment-naive locally-advanced or metastatic NSCLC (N = 31) |
| --- | --- |
| Subjects with CR/PR, n (%) [1] | 25 (80.6) |
| Progressive Disease or Death, n (%) [2] | 5 (20.0) |
| Censored, n (%) [2] | 20 (80.0) |
|  | |
| Duration of Response (months) |  |
| Minimum | 0.99+ |
| 25th Percentile (95% CI) | 2.89 (1.54, NE) |
| Median (95% CI) | NE (2.89, NE) |
| 75th Percentile (95% CI) | NE (NE, NE) |
| Maximum | 10.32+ |
|  | |
| Probability (%) of Being Event-free at Least: |  |
| 3 months (95% CI) | 72.4 (45.4, 87.6) |
| 6 months (95% CI) | 72.4 (45.4, 87.6) |
| 9 months (95% CI) | 72.4 (45.4, 87.6) |
| 12 months (95% CI) | NE (NE, NE) |

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

[2] Percentages are based on the number of subjects with CR/PR of each respective group in the Response Evaluation Set.

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 16.2.6.3.1

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

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

**Table 14.2.3.1.2.2 Duration of Response based on RECIST 1.1 Criteria (Unconfirmed) - Phase II part 1 Treatment naive locally-advanced or metastatic NSCLC (Response Evaluation Set)**

|  | Treatment-naive locally-advanced or metastatic NSCLC (N = 31) |
| --- | --- |
| Subjects with CR/PR, n (%) [1] | 27 (87.1) |
| Progressive Disease or Death, n (%) [2] | 6 (22.2) |
| Censored, n (%) [2] | 21 (77.8) |
|  | |
| Duration of Response (months) |  |
| Minimum | 0.03+ |
| 25th Percentile (95% CI) | 2.86 (1.41, NE) |
| Median (95% CI) | NE (2.86, NE) |
| 75th Percentile (95% CI) | NE (NE, NE) |
| Maximum | 10.32+ |
|  | |
| Probability (%) of Being Event-free at Least: |  |
| 3 months (95% CI) | 69.1 (43.2, 85.0) |
| 6 months (95% CI) | 69.1 (43.2, 85.0) |
| 9 months (95% CI) | 69.1 (43.2, 85.0) |
| 12 months (95% CI) | NE (NE, NE) |

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

[2] Percentages are based on the number of subjects with CR/PR of each respective group in the Response Evaluation Set.

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 16.2.6.3.1

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

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

**Table 14.2.4.1.2 Overall Survival - Phase II part 1 Treatment naive locally-advanced or metastatic NSCLC (Safety Analysis Set)**

|  | Treatment-naive locally-advanced or metastatic NSCLC (N = 33) |
| --- | --- |
| Death, n (%) | 3 (9.1) |
| Censored, n (%) | 30 (90.9) |
|  | |
| Overall Survival (months) |  |
| Minimum | 1.05 |
| 25th Percentile (95% CI) | NE (3.84, NE) |
| Median (95% CI) | NE (NE, NE) |
| 75th Percentile (95% CI) | NE (NE, NE) |
| Maximum | 12.09+ |
|  | |
| Probability (%) of Survival at Least: |  |
| 3 months (95% CI) | 97.0 (80.4, 99.6) |
| 6 months (95% CI) | 90.7 (73.8, 96.9) |
| 9 months (95% CI) | 90.7 (73.8, 96.9) |
| 12 months (95% CI) | 90.7 (73.8, 96.9) |
| 15 months (95% CI) | NE (NE, NE) |

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

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 16.2.6.5.1

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

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

**Table 14.2.4.2.1.1 Summary of OS Subgroup Analysis - Phase II part 1 Treatment naive locally-advanced or metastatic NSCLC (Safety Analysis Set)**

| Subgroup |  | | Treatment-naive locally-advanced or metastatic NSCLC |
| --- | --- | --- | --- |
| Age | <65 years | N | 16 |
|  |  | Death, n (%) | 1 (6.3) |
|  |  | Censored, n (%) | 15 (93.8) |
|  | | | |
|  | >=65 years | N | 17 |
|  |  | Death, n (%) | 2 (11.8) |
|  |  | Censored, n (%) | 15 (88.2) |
|  | | | |
| Sex | Male | N | 31 |
|  |  | Death, n (%) | 3 (9.7) |
|  |  | Censored, n (%) | 28 (90.3) |
|  | | | |
|  | Female | N | 2 |
|  |  | Death, n (%) | 0 |
|  |  | Censored, n (%) | 2 (100) |
|  | | | |
| Baseline ECOG status | 0 | N | 3 |
|  |  | Death, n (%) | 0 |
|  |  | Censored, n (%) | 3 (100) |
|  | | | |
|  | 1 | N | 30 |
|  |  | Death, n (%) | 3 (10.0) |
|  |  | Censored, n (%) | 27 (90.0) |
|  | | | |
| Differentiation | Well or moderate differentiated | N | 1 |
|  |  | Death, n (%) | 0 |
|  |  | Censored, n (%) | 1 (100) |
|  | | | |
|  | Poorly or undifferentiated | N | 11 |
|  |  | Death, n (%) | 0 |
|  |  | Censored, n (%) | 11 (100) |
|  | | | |
| Number of metastatic organs | <=3 | N | 19 |
|  |  | Death, n (%) | 3 (15.8) |
|  |  | Censored, n (%) | 16 (84.2) |
|  | | | |
|  | >3 | N | 8 |
|  |  | Death, n (%) | 0 |
|  |  | Censored, n (%) | 8 (100) |
|  | | | |
| Brain metastasis | Yes | N | 2 |
|  |  | Death, n (%) | 0 |
|  |  | Censored, n (%) | 2 (100) |
|  | | | |
|  | No | N | 31 |
|  |  | Death, n (%) | 3 (9.7) |
|  |  | Censored, n (%) | 28 (90.3) |
|  | | | |
| Liver metastasis | Yes | N | 5 |
|  |  | Death, n (%) | 1 (20.0) |
|  |  | Censored, n (%) | 4 (80.0) |
|  | | | |
|  | No | N | 28 |
|  |  | Death, n (%) | 2 (7.1) |
|  |  | Censored, n (%) | 26 (92.9) |
|  | | | |
| Bone metastasis | Yes | N | 11 |
|  |  | Death, n (%) | 1 (9.1) |
|  |  | Censored, n (%) | 10 (90.9) |
|  | | | |
|  | No | N | 22 |
|  |  | Death, n (%) | 2 (9.1) |
|  |  | Censored, n (%) | 20 (90.9) |
|  | | | |
| Smoking history | Never | N | 3 |
|  |  | Death, n (%) | 0 |
|  |  | Censored, n (%) | 3 (100) |
|  | | | |
|  | Former | N | 26 |
|  |  | Death, n (%) | 3 (11.5) |
|  |  | Censored, n (%) | 23 (88.5) |
|  | | | |
|  | Current | N | 4 |
|  |  | Death, n (%) | 0 |
|  |  | Censored, n (%) | 4 (100) |
|  | | | |
| TNM staging | IIIB/C | N | 6 |
|  |  | Death, n (%) | 0 |
|  |  | Censored, n (%) | 6 (100) |
|  | | | |
|  | IVA | N | 14 |
|  |  | Death, n (%) | 2 (14.3) |
|  |  | Censored, n (%) | 12 (85.7) |
|  | | | |
|  | IVB | N | 13 |
|  |  | Death, n (%) | 1 (7.7) |
|  |  | Censored, n (%) | 12 (92.3) |
|  | | | |
| TP53 | Altered | N | 1 |
|  |  | Death, n (%) | 1 (100) |
|  |  | Censored, n (%) | 0 |
|  | | | |
|  | Wild-type | N | 32 |
|  |  | Death, n (%) | 2 (6.3) |
|  |  | Censored, n (%) | 30 (93.8) |
|  | | | |
| STK11 | Wild-type | N | 33 |
|  |  | Death, n (%) | 3 (9.1) |
|  |  | Censored, n (%) | 30 (90.9) |
|  | | | |
| KEAP1 | Wild-type | N | 33 |
|  |  | Death, n (%) | 3 (9.1) |
|  |  | Censored, n (%) | 30 (90.9) |
|  | | | |
| EGFR | Wild-type | N | 33 |
|  |  | Death, n (%) | 3 (9.1) |
|  |  | Censored, n (%) | 30 (90.9) |
|  | | | |
| BRAF | Wild-type | N | 33 |
|  |  | Death, n (%) | 3 (9.1) |
|  |  | Censored, n (%) | 30 (90.9) |
|  | | | |
| ALK | Wild-type | N | 33 |
|  |  | Death, n (%) | 3 (9.1) |
|  |  | Censored, n (%) | 30 (90.9) |
|  | | | |
| MET | Wild-type | N | 33 |
|  |  | Death, n (%) | 3 (9.1) |
|  |  | Censored, n (%) | 30 (90.9) |
|  | | | |
| RET | Wild-type | N | 33 |
|  |  | Death, n (%) | 3 (9.1) |
|  |  | Censored, n (%) | 30 (90.9) |
|  | | | |
| ROS1 | Wild-type | N | 33 |
|  |  | Death, n (%) | 3 (9.1) |
|  |  | Censored, n (%) | 30 (90.9) |
|  | | | |
| ERBB2 | Altered | N | 1 |
|  |  | Death, n (%) | 1 (100) |
|  |  | Censored, n (%) | 0 |
|  | | | |
|  | Wild-type | N | 32 |
|  |  | Death, n (%) | 2 (6.3) |
|  |  | Censored, n (%) | 30 (93.8) |
|  | | | |
| NTRK1 | Wild-type | N | 33 |
|  |  | Death, n (%) | 3 (9.1) |
|  |  | Censored, n (%) | 30 (90.9) |
|  | | | |
| NTRK2 | Wild-type | N | 33 |
|  |  | Death, n (%) | 3 (9.1) |
|  |  | Censored, n (%) | 30 (90.9) |
|  | | | |
| NTRK3 | Altered | N | 1 |
|  |  | Death, n (%) | 1 (100) |
|  |  | Censored, n (%) | 0 |
|  | | | |
|  | Wild-type | N | 32 |
|  |  | Death, n (%) | 2 (6.3) |
|  |  | Censored, n (%) | 30 (93.8) |
|  | | | |
| KRAS(other than G12C) | Altered | N | 1 |
|  |  | Death, n (%) | 1 (100) |
|  |  | Censored, n (%) | 0 |
|  | | | |
|  | Wild-type | N | 32 |
|  |  | Death, n (%) | 2 (6.3) |
|  |  | Censored, n (%) | 30 (93.8) |
|  | | | |
| NRAS | Wild-type | N | 33 |
|  |  | Death, n (%) | 3 (9.1) |
|  |  | Censored, n (%) | 30 (90.9) |
|  | | | |
| HRAS | Wild-type | N | 33 |
|  |  | Death, n (%) | 3 (9.1) |
|  |  | Censored, n (%) | 30 (90.9) |
|  | | | |
| PIK3CA | Wild-type | N | 33 |
|  |  | Death, n (%) | 3 (9.1) |
|  |  | Censored, n (%) | 30 (90.9) |
|  | | | |
| PIK3R1 | Wild-type | N | 33 |
|  |  | Death, n (%) | 3 (9.1) |
|  |  | Censored, n (%) | 30 (90.9) |
|  | | | |
| MAP2K1 | Wild-type | N | 33 |
|  |  | Death, n (%) | 3 (9.1) |
|  |  | Censored, n (%) | 30 (90.9) |
|  | | | |
| RAF1 | Wild-type | N | 33 |
|  |  | Death, n (%) | 3 (9.1) |
|  |  | Censored, n (%) | 30 (90.9) |
|  | | | |
| FGFR3 | Wild-type | N | 33 |
|  |  | Death, n (%) | 3 (9.1) |
|  |  | Censored, n (%) | 30 (90.9) |
|  | | | |
| NF1 | Wild-type | N | 33 |
|  |  | Death, n (%) | 3 (9.1) |
|  |  | Censored, n (%) | 30 (90.9) |
|  | | | |
| PTEN | Wild-type | N | 33 |
|  |  | Death, n (%) | 3 (9.1) |
|  |  | Censored, n (%) | 30 (90.9) |

mOS: Median Overall Survival

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

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

Source Data: Listing 16.2.6.5.1

|  |  |  |
| --- | --- | --- |
| Program: t-pfs-subgrp-part1.sas | DCO: 27APR2024 | Executed: 07JUL2024 20:36 |

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

**Table 14.3.1.1.2 Overview of All AEs - Phase II part 1 treatment-naive locally-advanced or metastatic NSCLC (Safety Analysis Set)**

|  | Treatment-naive locally- advanced or metastatic  NSCLC (N = 33) n (%) |
| --- | --- |
| All AEs | 33 (100) |
|  | |
| All TEAEs | 33 (100) |
| Related to D-1553 | 32 (97.0) |
| Related to IN10018 | 33 (100) |
|  | |
| CTCAE Grade 3/4 TEAEs | 9 (27.3) |
| Related to D-1553 | 6 (18.2) |
| Related to IN10018 | 6 (18.2) |
|  | |
| TEAEs Leading to D-1553 Dose Reduction | 1 (3.0) |
| Related to D-1553 | 1 (3.0) |
|  | |
| TEAEs Leading to IN10018 Dose Reduction | 5 (15.2) |
| Related to IN10018 | 5 (15.2) |
|  | |
| TEAEs Leading to D-1553 Drug Interruption | 11 (33.3) |
| Related to D-1553 | 7 (21.2) |
|  | |
| TEAEs Leading to IN10018 Drug Interruption | 17 (51.5) |
| Related to IN10018 | 15 (45.5) |
|  | |
| TEAEs Leading to D-1553 Drug Withdrawn | 0 |
| Related to D-1553 | 0 |
|  | |
| TEAEs Leading to IN10018 Drug Withdrawn | 0 |
| Related to IN10018 | 0 |
|  | |
| TEAEs of Special Interest (AESI) | 4 (12.1) |
| Abnormal liver function | 0 |
| Related to D-1553 | 0 |
| Related to IN10018 | 0 |
| Proteinuria | 4 (12.1) |
| Related to D-1553 | 4 (12.1) |
| Related to IN10018 | 4 (12.1) |
|  | |
| CTCAE Grade 3/4 AESI | 1 (3.0) |
| CTCAE Grade 3/4 Abnormal liver function | 0 |
| CTCAE Grade 3 Proteinuria | 1 (3.0) |
|  | |
| Treatment-emergent SAEs | 7 (21.2) |
| Related to D-1553 | 4 (12.1) |
| Related to IN10018 | 4 (12.1) |
| SAEs Leading to Death | 2 (6.1) |
| SAEs Leading to Life Threatening | 1 (3.0) |
| SAEs Leading to Congenital Anomaly or Birth Defect | 0 |
| SAEs Leading to Disability or Permanent Damage | 0 |
| SAEs Leading to Hospitalization (Initial or Prolonged) | 7 (21.2) |
| SAEs leading to Other Important Medical Events | 0 |
|  | |
| TEAEs Leading to Death | 2 (6.1) |
| Related to D-1553 | 0 |
| Related to IN10018 | 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 14.3.1.1.4 Overview of All AEs by Grouped PT - Phase II part 1 treatment-naive locally-advanced or metastatic NSCLC (Safety Analysis Set)**

|  | Treatment-naive locally- advanced or metastatic  NSCLC (N = 33) n (%) |
| --- | --- |
| All AEs | 33 (100) |
|  | |
| All TEAEs | 33 (100) |
| Related to D-1553 | 32 (97.0) |
| Related to IN10018 | 33 (100) |
|  | |
| CTCAE Grade 3/4 TEAEs | 9 (27.3) |
| Related to D-1553 | 6 (18.2) |
| Related to IN10018 | 6 (18.2) |
|  | |
| TEAEs Leading to D-1553 Dose Reduction | 1 (3.0) |
| Related to D-1553 | 1 (3.0) |
|  | |
| TEAEs Leading to IN10018 Dose Reduction | 5 (15.2) |
| Related to IN10018 | 5 (15.2) |
|  | |
| TEAEs Leading to D-1553 Drug Interruption | 11 (33.3) |
| Related to D-1553 | 7 (21.2) |
|  | |
| TEAEs Leading to IN10018 Drug Interruption | 17 (51.5) |
| Related to IN10018 | 15 (45.5) |
|  | |
| TEAEs Leading to D-1553 Drug Withdrawn | 0 |
| Related to D-1553 | 0 |
|  | |
| TEAEs Leading to IN10018 Drug Withdrawn | 0 |
| Related to IN10018 | 0 |
|  | |
| TEAEs of Special Interest (AESI) | 4 (12.1) |
| Abnormal liver function | 0 |
| Related to D-1553 | 0 |
| Related to IN10018 | 0 |
| Proteinuria | 4 (12.1) |
| Related to D-1553 | 4 (12.1) |
| Related to IN10018 | 4 (12.1) |
|  | |
| CTCAE Grade 3/4 AESI | 1 (3.0) |
| CTCAE Grade 3/4 Abnormal liver function | 0 |
| CTCAE Grade 3 Proteinuria | 1 (3.0) |
|  | |
| Treatment-emergent SAEs | 7 (21.2) |
| Related to D-1553 | 4 (12.1) |
| Related to IN10018 | 4 (12.1) |
| SAEs Leading to Death | 2 (6.1) |
| SAEs Leading to Life Threatening | 1 (3.0) |
| SAEs Leading to Congenital Anomaly or Birth Defect | 0 |
| SAEs Leading to Disability or Permanent Damage | 0 |
| SAEs Leading to Hospitalization (Initial or Prolonged) | 7 (21.2) |
| SAEs leading to Other Important Medical Events | 0 |
|  | |
| TEAEs Leading to Death | 2 (6.1) |
| Related to D-1553 | 0 |
| Related to IN10018 | 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 14.3.1.3.1.2 Summary of TEAEs by SOC and PT - Phase II part 1 treatment-naive locally-advanced or metastatic NSCLC (Safety Analysis Set)**

| System Organ Class  Preferred Term | Treatment-naive locally-advanced or metastatic NSCLC (N = 33) n (%) |
| --- | --- |
| All TEAEs | 33 (100) |
|  | |
| General disorders and administration site conditions | 25 (75.8) |
| Oedema peripheral | 13 (39.4) |
| Fatigue | 8 (24.2) |
| Peripheral swelling | 6 (18.2) |
| Pyrexia | 4 (12.1) |
| Face oedema | 3 (9.1) |
| Malaise | 3 (9.1) |
| Asthenia | 2 (6.1) |
| Chest discomfort | 2 (6.1) |
| Induration | 2 (6.1) |
| Pain | 2 (6.1) |
| Chest pain | 1 (3.0) |
| Discomfort | 1 (3.0) |
| Influenza like illness | 1 (3.0) |
| Nodule | 1 (3.0) |
| Non-pitting oedema | 1 (3.0) |
| Swelling face | 1 (3.0) |
|  | |
| Metabolism and nutrition disorders | 25 (75.8) |
| Hypertriglyceridaemia | 11 (33.3) |
| Hypoalbuminaemia | 9 (27.3) |
| Decreased appetite | 8 (24.2) |
| Hyponatraemia | 5 (15.2) |
| Hypoproteinaemia | 5 (15.2) |
| Hyperlipidaemia | 4 (12.1) |
| Hypocalcaemia | 3 (9.1) |
| Hypercholesterolaemia | 2 (6.1) |
| Hypokalaemia | 2 (6.1) |
| Hyperglycaemia | 1 (3.0) |
| Hypochloraemia | 1 (3.0) |
|  | |
| Investigations | 24 (72.7) |
| Alanine aminotransferase increased | 9 (27.3) |
| Aspartate aminotransferase increased | 8 (24.2) |
| Gamma-glutamyltransferase increased | 7 (21.2) |
| Fibrin D dimer increased | 6 (18.2) |
| Urinary occult blood positive | 4 (12.1) |
| Weight decreased | 4 (12.1) |
| Blood bilirubin increased | 3 (9.1) |
| C-reactive protein increased | 3 (9.1) |
| Electrocardiogram PR prolongation | 3 (9.1) |
| Bilirubin conjugated increased | 2 (6.1) |
| Blood alkaline phosphatase increased | 2 (6.1) |
| Total bile acids increased | 2 (6.1) |
| Blood bilirubin unconjugated increased | 1 (3.0) |
| Blood cholesterol increased | 1 (3.0) |
| Blood creatine phosphokinase decreased | 1 (3.0) |
| Blood creatine phosphokinase increased | 1 (3.0) |
| Blood creatinine increased | 1 (3.0) |
| Blood pressure increased | 1 (3.0) |
| Cystatin C increased | 1 (3.0) |
| Electrocardiogram QT prolonged | 1 (3.0) |
| Electrocardiogram ST segment depression | 1 (3.0) |
| Glucose urine present | 1 (3.0) |
| Lipoprotein increased | 1 (3.0) |
| Lymphocyte count decreased | 1 (3.0) |
| Neutrophil count increased | 1 (3.0) |
| Oxygen saturation decreased | 1 (3.0) |
| Protein urine present | 1 (3.0) |
| Weight increased | 1 (3.0) |
| White blood cell count increased | 1 (3.0) |
|  | |
| Gastrointestinal disorders | 22 (66.7) |
| Diarrhoea | 19 (57.6) |
| Nausea | 5 (15.2) |
| Abdominal discomfort | 2 (6.1) |
| Abdominal distension | 2 (6.1) |
| Abdominal pain | 2 (6.1) |
| Vomiting | 2 (6.1) |
| Abdominal pain upper | 1 (3.0) |
| Chronic gastritis | 1 (3.0) |
| Enteritis | 1 (3.0) |
| Gingival swelling | 1 (3.0) |
| Stomatitis | 1 (3.0) |
|  | |
| Renal and urinary disorders | 22 (66.7) |
| Proteinuria | 20 (60.6) |
| Haematuria | 7 (21.2) |
| Albuminuria | 1 (3.0) |
|  | |
| Musculoskeletal and connective tissue disorders | 15 (45.5) |
| Arthralgia | 5 (15.2) |
| Musculoskeletal stiffness | 4 (12.1) |
| Pain in extremity | 3 (9.1) |
| Back pain | 2 (6.1) |
| Myalgia | 2 (6.1) |
| Neck pain | 2 (6.1) |
| Arthritis | 1 (3.0) |
| Bone pain | 1 (3.0) |
| Joint range of motion decreased | 1 (3.0) |
| Joint swelling | 1 (3.0) |
| Limb discomfort | 1 (3.0) |
| Osteoarthritis | 1 (3.0) |
|  | |
| Nervous system disorders | 15 (45.5) |
| Hypoaesthesia | 9 (27.3) |
| Dizziness | 2 (6.1) |
| Motor dysfunction | 2 (6.1) |
| Paraesthesia | 2 (6.1) |
| Anaesthesia | 1 (3.0) |
| Haemorrhage intracranial | 1 (3.0) |
| Headache | 1 (3.0) |
| Neuropathy peripheral | 1 (3.0) |
|  | |
| Blood and lymphatic system disorders | 14 (42.4) |
| Anaemia | 13 (39.4) |
| Bone marrow oedema | 1 (3.0) |
|  | |
| Skin and subcutaneous tissue disorders | 13 (39.4) |
| Pruritus | 7 (21.2) |
| Rash | 4 (12.1) |
| Pain of skin | 2 (6.1) |
| Dermal cyst | 1 (3.0) |
| Drug eruption | 1 (3.0) |
| Erythema | 1 (3.0) |
| Skin mass | 1 (3.0) |
|  | |
| Cardiac disorders | 11 (33.3) |
| Sinus bradycardia | 4 (12.1) |
| Supraventricular extrasystoles | 3 (9.1) |
| Arrhythmia | 2 (6.1) |
| Atrioventricular block first degree | 2 (6.1) |
| Atrioventricular block second degree | 1 (3.0) |
| Cardiac septal hypertrophy | 1 (3.0) |
| Cardiac valve disease | 1 (3.0) |
| Left atrial enlargement | 1 (3.0) |
| Sinus tachycardia | 1 (3.0) |
| Supraventricular tachycardia | 1 (3.0) |
| Ventricular extrasystoles | 1 (3.0) |
|  | |
| Infections and infestations | 11 (33.3) |
| Pneumonia | 4 (12.1) |
| Upper respiratory tract infection | 3 (9.1) |
| Urinary tract infection | 2 (6.1) |
| Bronchitis | 1 (3.0) |
| Conjunctivitis | 1 (3.0) |
| COVID-19 | 1 (3.0) |
| COVID-19 pneumonia | 1 (3.0) |
| Herpes virus infection | 1 (3.0) |
| Influenza | 1 (3.0) |
| Lower respiratory tract infection | 1 (3.0) |
| Nasopharyngitis | 1 (3.0) |
|  | |
| Respiratory, thoracic and mediastinal disorders | 9 (27.3) |
| Cough | 4 (12.1) |
| Dyspnoea | 3 (9.1) |
| Productive cough | 3 (9.1) |
| Chronic obstructive pulmonary disease | 1 (3.0) |
| Pneumonitis | 1 (3.0) |
|  | |
| Vascular disorders | 9 (27.3) |
| Hypertension | 3 (9.1) |
| Arteriosclerosis | 2 (6.1) |
| Deep vein thrombosis | 1 (3.0) |
| Flushing | 1 (3.0) |
| Hypotension | 1 (3.0) |
| Venous thrombosis | 1 (3.0) |
|  | |
| Eye disorders | 8 (24.2) |
| Cataract | 3 (9.1) |
| Dry eye | 2 (6.1) |
| Eye oedema | 1 (3.0) |
| Glaucoma | 1 (3.0) |
| Macular degeneration | 1 (3.0) |
| Meibomian gland dysfunction | 1 (3.0) |
| Optic atrophy | 1 (3.0) |
| Periorbital swelling | 1 (3.0) |
| Retinal haemorrhage | 1 (3.0) |
| Vision blurred | 1 (3.0) |
| Vitreous opacities | 1 (3.0) |
|  | |
| Reproductive system and breast disorders | 6 (18.2) |
| Gynaecomastia | 3 (9.1) |
| Benign prostatic hyperplasia | 1 (3.0) |
| Breast hyperplasia | 1 (3.0) |
| Breast mass | 1 (3.0) |
| Peyronie's disease | 1 (3.0) |
|  | |
| Psychiatric disorders | 3 (9.1) |
| Insomnia | 2 (6.1) |
| Sleep disorder | 1 (3.0) |
|  | |
| Hepatobiliary disorders | 2 (6.1) |
| Hepatic function abnormal | 2 (6.1) |
|  | |
| Endocrine disorders | 1 (3.0) |
| Endocrine disorder | 1 (3.0) |

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 14.3.1.3.1.4 Summary of TEAEs by Grouped SOC and Grouped PT - Phase II part 1 treatment-naive locally-advanced or metastatic NSCLC (Safety Analysis Set)**

| System Organ Class  Preferred Term | Treatment-naive locally-advanced or metastatic NSCLC (N = 33) n (%) |
| --- | --- |
| All TEAEs | 33 (100) |
|  | |
| General disorders and administration site conditions# | 25 (75.8) |
| Oedema peripheral\* | 19 (57.6) |
| Fatigue\* | 10 (30.3) |
| Pyrexia | 4 (12.1) |
| Face oedema | 3 (9.1) |
| Malaise | 3 (9.1) |
| Chest discomfort | 2 (6.1) |
| Induration | 2 (6.1) |
| Pain | 2 (6.1) |
| Chest pain | 1 (3.0) |
| Discomfort | 1 (3.0) |
| Influenza like illness | 1 (3.0) |
| Nodule | 1 (3.0) |
| Swelling face | 1 (3.0) |
|  | |
| Metabolism and nutrition disorders# | 25 (75.8) |
| Hypertriglyceridaemia | 11 (33.3) |
| Hypoalbuminaemia | 9 (27.3) |
| Decreased appetite | 8 (24.2) |
| Hyponatraemia | 5 (15.2) |
| Hypoproteinaemia\* | 5 (15.2) |
| Hyperlipidaemia | 4 (12.1) |
| Hypercholesterolaemia\* | 3 (9.1) |
| Hypocalcaemia | 3 (9.1) |
| Hypokalaemia | 2 (6.1) |
| Hyperglycaemia | 1 (3.0) |
| Hypochloraemia | 1 (3.0) |
|  | |
| Investigations | 23 (69.7) |
| Alanine aminotransferase increased | 9 (27.3) |
| Aspartate aminotransferase increased | 8 (24.2) |
| Gamma-glutamyltransferase increased | 7 (21.2) |
| Fibrin D dimer increased | 6 (18.2) |
| Urinary occult blood positive | 4 (12.1) |
| Weight decreased | 4 (12.1) |
| Blood bilirubin increased | 3 (9.1) |
| C-reactive protein increased | 3 (9.1) |
| Electrocardiogram PR prolongation | 3 (9.1) |
| Bilirubin conjugated increased | 2 (6.1) |
| Blood alkaline phosphatase increased | 2 (6.1) |
| Total bile acids increased | 2 (6.1) |
| Blood bilirubin unconjugated increased | 1 (3.0) |
| Blood creatine phosphokinase decreased | 1 (3.0) |
| Blood creatine phosphokinase increased | 1 (3.0) |
| Blood creatinine increased | 1 (3.0) |
| Blood pressure increased | 1 (3.0) |
| Cystatin C increased | 1 (3.0) |
| Electrocardiogram QT prolonged | 1 (3.0) |
| Electrocardiogram ST segment depression | 1 (3.0) |
| Glucose urine present | 1 (3.0) |
| Lipoprotein increased | 1 (3.0) |
| Lymphocyte count decreased | 1 (3.0) |
| Neutrophil count increased | 1 (3.0) |
| Oxygen saturation decreased | 1 (3.0) |
| Weight increased | 1 (3.0) |
|  | |
| Renal and urinary disorders# | 23 (69.7) |
| Proteinuria\* | 22 (66.7) |
| Haematuria\* | 7 (21.2) |
|  | |
| Gastrointestinal disorders | 22 (66.7) |
| Diarrhoea | 19 (57.6) |
| Nausea | 5 (15.2) |
| Abdominal discomfort | 2 (6.1) |
| Abdominal distension | 2 (6.1) |
| Abdominal pain | 2 (6.1) |
| Vomiting | 2 (6.1) |
| Abdominal pain upper | 1 (3.0) |
| Chronic gastritis | 1 (3.0) |
| Enteritis | 1 (3.0) |
| Gingival swelling | 1 (3.0) |
| Stomatitis | 1 (3.0) |
|  | |
| Musculoskeletal and connective tissue disorders | 15 (45.5) |
| Arthralgia | 5 (15.2) |
| Musculoskeletal stiffness | 4 (12.1) |
| Pain in extremity | 3 (9.1) |
| Back pain | 2 (6.1) |
| Myalgia | 2 (6.1) |
| Neck pain | 2 (6.1) |
| Arthritis | 1 (3.0) |
| Bone pain | 1 (3.0) |
| Joint range of motion decreased | 1 (3.0) |
| Joint swelling | 1 (3.0) |
| Limb discomfort | 1 (3.0) |
| Osteoarthritis | 1 (3.0) |
|  | |
| Nervous system disorders | 15 (45.5) |
| Hypoaesthesia | 9 (27.3) |
| Dizziness | 2 (6.1) |
| Motor dysfunction | 2 (6.1) |
| Paraesthesia | 2 (6.1) |
| Anaesthesia | 1 (3.0) |
| Haemorrhage intracranial | 1 (3.0) |
| Headache | 1 (3.0) |
| Neuropathy peripheral | 1 (3.0) |
|  | |
| Blood and lymphatic system disorders# | 14 (42.4) |
| Anaemia | 13 (39.4) |
| Bone marrow oedema | 1 (3.0) |
| Leukocytosis\* | 1 (3.0) |
|  | |
| Skin and subcutaneous tissue disorders | 13 (39.4) |
| Pruritus | 7 (21.2) |
| Rash | 4 (12.1) |
| Pain of skin | 2 (6.1) |
| Dermal cyst | 1 (3.0) |
| Drug eruption | 1 (3.0) |
| Erythema | 1 (3.0) |
| Skin mass | 1 (3.0) |
|  | |
| Cardiac disorders | 11 (33.3) |
| Sinus bradycardia | 4 (12.1) |
| Supraventricular extrasystoles | 3 (9.1) |
| Arrhythmia | 2 (6.1) |
| Atrioventricular block first degree | 2 (6.1) |
| Atrioventricular block second degree | 1 (3.0) |
| Cardiac septal hypertrophy | 1 (3.0) |
| Cardiac valve disease | 1 (3.0) |
| Left atrial enlargement | 1 (3.0) |
| Sinus tachycardia | 1 (3.0) |
| Supraventricular tachycardia | 1 (3.0) |
| Ventricular extrasystoles | 1 (3.0) |
|  | |
| Infections and infestations | 11 (33.3) |
| Pneumonia | 4 (12.1) |
| Upper respiratory tract infection | 3 (9.1) |
| Urinary tract infection | 2 (6.1) |
| Bronchitis | 1 (3.0) |
| Conjunctivitis | 1 (3.0) |
| COVID-19 | 1 (3.0) |
| COVID-19 pneumonia | 1 (3.0) |
| Herpes virus infection | 1 (3.0) |
| Influenza | 1 (3.0) |
| Lower respiratory tract infection | 1 (3.0) |
| Nasopharyngitis | 1 (3.0) |
|  | |
| Respiratory, thoracic and mediastinal disorders | 9 (27.3) |
| Cough | 4 (12.1) |
| Dyspnoea | 3 (9.1) |
| Productive cough | 3 (9.1) |
| Chronic obstructive pulmonary disease | 1 (3.0) |
| Pneumonitis | 1 (3.0) |
|  | |
| Vascular disorders | 9 (27.3) |
| Hypertension | 3 (9.1) |
| Arteriosclerosis | 2 (6.1) |
| Deep vein thrombosis | 1 (3.0) |
| Flushing | 1 (3.0) |
| Hypotension | 1 (3.0) |
| Venous thrombosis | 1 (3.0) |
|  | |
| Eye disorders | 8 (24.2) |
| Cataract | 3 (9.1) |
| Dry eye | 2 (6.1) |
| Eye oedema | 1 (3.0) |
| Glaucoma | 1 (3.0) |
| Macular degeneration | 1 (3.0) |
| Meibomian gland dysfunction | 1 (3.0) |
| Optic atrophy | 1 (3.0) |
| Periorbital swelling | 1 (3.0) |
| Retinal haemorrhage | 1 (3.0) |
| Vision blurred | 1 (3.0) |
| Vitreous opacities | 1 (3.0) |
|  | |
| Reproductive system and breast disorders | 6 (18.2) |
| Gynaecomastia | 3 (9.1) |
| Benign prostatic hyperplasia | 1 (3.0) |
| Breast hyperplasia | 1 (3.0) |
| Breast mass | 1 (3.0) |
| Peyronie's disease | 1 (3.0) |
|  | |
| Psychiatric disorders | 3 (9.1) |
| Insomnia | 2 (6.1) |
| Sleep disorder | 1 (3.0) |
|  | |
| Hepatobiliary disorders | 2 (6.1) |
| Hepatic function abnormal | 2 (6.1) |
|  | |
| Endocrine disorders | 1 (3.0) |
| Endocrine disorder | 1 (3.0) |

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 14.3.1.3.2.2 Summary of D-1553 Related TEAEs by SOC and PT - Phase II Part 1 treatment-naive locally-advanced or metastatic NSCLC (Safety Analysis Set)**

| System Organ Class  Preferred Term | Treatment-naive locally-advanced or metastatic NSCLC (N = 33) n (%) |
| --- | --- |
| D-1553 Related TEAEs | 32 (97.0) |
|  | |
| Metabolism and nutrition disorders | 23 (69.7) |
| Hypertriglyceridaemia | 10 (30.3) |
| Decreased appetite | 7 (21.2) |
| Hypoalbuminaemia | 7 (21.2) |
| Hypoproteinaemia | 5 (15.2) |
| Hyperlipidaemia | 3 (9.1) |
| Hypercholesterolaemia | 2 (6.1) |
| Hyponatraemia | 2 (6.1) |
| Hypochloraemia | 1 (3.0) |
| Hypokalaemia | 1 (3.0) |
|  | |
| Gastrointestinal disorders | 21 (63.6) |
| Diarrhoea | 19 (57.6) |
| Nausea | 5 (15.2) |
| Abdominal discomfort | 2 (6.1) |
| Abdominal distension | 1 (3.0) |
| Abdominal pain | 1 (3.0) |
| Abdominal pain upper | 1 (3.0) |
| Enteritis | 1 (3.0) |
| Stomatitis | 1 (3.0) |
| Vomiting | 1 (3.0) |
|  | |
| General disorders and administration site conditions | 21 (63.6) |
| Oedema peripheral | 10 (30.3) |
| Fatigue | 8 (24.2) |
| Peripheral swelling | 6 (18.2) |
| Face oedema | 3 (9.1) |
| Malaise | 3 (9.1) |
| Asthenia | 2 (6.1) |
| Induration | 2 (6.1) |
| Discomfort | 1 (3.0) |
| Nodule | 1 (3.0) |
| Non-pitting oedema | 1 (3.0) |
| Swelling face | 1 (3.0) |
|  | |
| Investigations | 21 (63.6) |
| Alanine aminotransferase increased | 9 (27.3) |
| Aspartate aminotransferase increased | 8 (24.2) |
| Gamma-glutamyltransferase increased | 7 (21.2) |
| Blood bilirubin increased | 3 (9.1) |
| Electrocardiogram PR prolongation | 3 (9.1) |
| Urinary occult blood positive | 3 (9.1) |
| Bilirubin conjugated increased | 2 (6.1) |
| Blood alkaline phosphatase increased | 2 (6.1) |
| C-reactive protein increased | 2 (6.1) |
| Total bile acids increased | 2 (6.1) |
| Weight decreased | 2 (6.1) |
| Blood bilirubin unconjugated increased | 1 (3.0) |
| Blood cholesterol increased | 1 (3.0) |
| Blood creatine phosphokinase decreased | 1 (3.0) |
| Blood creatine phosphokinase increased | 1 (3.0) |
| Blood creatinine increased | 1 (3.0) |
| Blood pressure increased | 1 (3.0) |
| Cystatin C increased | 1 (3.0) |
| Electrocardiogram QT prolonged | 1 (3.0) |
| Electrocardiogram ST segment depression | 1 (3.0) |
| Fibrin D dimer increased | 1 (3.0) |
| Glucose urine present | 1 (3.0) |
| Lipoprotein increased | 1 (3.0) |
| Lymphocyte count decreased | 1 (3.0) |
| Neutrophil count increased | 1 (3.0) |
| Protein urine present | 1 (3.0) |
| Weight increased | 1 (3.0) |
| White blood cell count increased | 1 (3.0) |
|  | |
| Renal and urinary disorders | 16 (48.5) |
| Proteinuria | 13 (39.4) |
| Haematuria | 6 (18.2) |
| Albuminuria | 1 (3.0) |
|  | |
| Nervous system disorders | 12 (36.4) |
| Hypoaesthesia | 7 (21.2) |
| Paraesthesia | 2 (6.1) |
| Anaesthesia | 1 (3.0) |
| Dizziness | 1 (3.0) |
| Motor dysfunction | 1 (3.0) |
| Neuropathy peripheral | 1 (3.0) |
|  | |
| Musculoskeletal and connective tissue disorders | 11 (33.3) |
| Arthralgia | 3 (9.1) |
| Musculoskeletal stiffness | 3 (9.1) |
| Myalgia | 2 (6.1) |
| Arthritis | 1 (3.0) |
| Back pain | 1 (3.0) |
| Joint range of motion decreased | 1 (3.0) |
| Joint swelling | 1 (3.0) |
| Neck pain | 1 (3.0) |
| Osteoarthritis | 1 (3.0) |
| Pain in extremity | 1 (3.0) |
|  | |
| Blood and lymphatic system disorders | 10 (30.3) |
| Anaemia | 9 (27.3) |
| Bone marrow oedema | 1 (3.0) |
|  | |
| Skin and subcutaneous tissue disorders | 9 (27.3) |
| Pruritus | 5 (15.2) |
| Rash | 3 (9.1) |
| Pain of skin | 2 (6.1) |
| Drug eruption | 1 (3.0) |
| Erythema | 1 (3.0) |
| Skin mass | 1 (3.0) |
|  | |
| Cardiac disorders | 8 (24.2) |
| Sinus bradycardia | 3 (9.1) |
| Supraventricular extrasystoles | 2 (6.1) |
| Arrhythmia | 1 (3.0) |
| Atrioventricular block second degree | 1 (3.0) |
| Supraventricular tachycardia | 1 (3.0) |
| Ventricular extrasystoles | 1 (3.0) |
|  | |
| Eye disorders | 6 (18.2) |
| Cataract | 2 (6.1) |
| Dry eye | 1 (3.0) |
| Eye oedema | 1 (3.0) |
| Glaucoma | 1 (3.0) |
| Macular degeneration | 1 (3.0) |
| Optic atrophy | 1 (3.0) |
| Periorbital swelling | 1 (3.0) |
| Retinal haemorrhage | 1 (3.0) |
| Vision blurred | 1 (3.0) |
| Vitreous opacities | 1 (3.0) |
|  | |
| Vascular disorders | 6 (18.2) |
| Hypertension | 3 (9.1) |
| Arteriosclerosis | 2 (6.1) |
| Venous thrombosis | 1 (3.0) |
|  | |
| Reproductive system and breast disorders | 4 (12.1) |
| Gynaecomastia | 3 (9.1) |
| Breast hyperplasia | 1 (3.0) |
| Breast mass | 1 (3.0) |
|  | |
| Infections and infestations | 3 (9.1) |
| Conjunctivitis | 1 (3.0) |
| Herpes virus infection | 1 (3.0) |
| Upper respiratory tract infection | 1 (3.0) |
|  | |
| Hepatobiliary disorders | 2 (6.1) |
| Hepatic function abnormal | 2 (6.1) |
|  | |
| Respiratory, thoracic and mediastinal disorders | 2 (6.1) |
| Cough | 1 (3.0) |
| Dyspnoea | 1 (3.0) |
|  | |
| Endocrine disorders | 1 (3.0) |
| Endocrine disorder | 1 (3.0) |

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 14.3.1.3.2.4 Summary of D-1553 Related TEAEs by Grouped SOC and Grouped PT - Phase II part 1 treatment-naive locally-advanced or metastatic NSCLC (Safety Analysis Set)**

| System Organ Class  Preferred Term | Treatment-naive locally-advanced or metastatic NSCLC (N = 33) n (%) |
| --- | --- |
| D-1553 Related TEAEs | 32 (97.0) |
|  | |
| Metabolism and nutrition disorders# | 24 (72.7) |
| Hypertriglyceridaemia | 10 (30.3) |
| Decreased appetite | 7 (21.2) |
| Hypoalbuminaemia | 7 (21.2) |
| Hypoproteinaemia\* | 5 (15.2) |
| Hypercholesterolaemia\* | 3 (9.1) |
| Hyperlipidaemia | 3 (9.1) |
| Hyponatraemia | 2 (6.1) |
| Hypochloraemia | 1 (3.0) |
| Hypokalaemia | 1 (3.0) |
|  | |
| Gastrointestinal disorders | 21 (63.6) |
| Diarrhoea | 19 (57.6) |
| Nausea | 5 (15.2) |
| Abdominal discomfort | 2 (6.1) |
| Abdominal distension | 1 (3.0) |
| Abdominal pain | 1 (3.0) |
| Abdominal pain upper | 1 (3.0) |
| Enteritis | 1 (3.0) |
| Stomatitis | 1 (3.0) |
| Vomiting | 1 (3.0) |
|  | |
| General disorders and administration site conditions# | 21 (63.6) |
| Oedema peripheral\* | 16 (48.5) |
| Fatigue\* | 10 (30.3) |
| Face oedema | 3 (9.1) |
| Malaise | 3 (9.1) |
| Induration | 2 (6.1) |
| Discomfort | 1 (3.0) |
| Nodule | 1 (3.0) |
| Swelling face | 1 (3.0) |
|  | |
| Investigations | 20 (60.6) |
| Alanine aminotransferase increased | 9 (27.3) |
| Aspartate aminotransferase increased | 8 (24.2) |
| Gamma-glutamyltransferase increased | 7 (21.2) |
| Blood bilirubin increased | 3 (9.1) |
| Electrocardiogram PR prolongation | 3 (9.1) |
| Urinary occult blood positive | 3 (9.1) |
| Bilirubin conjugated increased | 2 (6.1) |
| Blood alkaline phosphatase increased | 2 (6.1) |
| C-reactive protein increased | 2 (6.1) |
| Total bile acids increased | 2 (6.1) |
| Weight decreased | 2 (6.1) |
| Blood bilirubin unconjugated increased | 1 (3.0) |
| Blood creatine phosphokinase decreased | 1 (3.0) |
| Blood creatine phosphokinase increased | 1 (3.0) |
| Blood creatinine increased | 1 (3.0) |
| Blood pressure increased | 1 (3.0) |
| Cystatin C increased | 1 (3.0) |
| Electrocardiogram QT prolonged | 1 (3.0) |
| Electrocardiogram ST segment depression | 1 (3.0) |
| Fibrin D dimer increased | 1 (3.0) |
| Glucose urine present | 1 (3.0) |
| Lipoprotein increased | 1 (3.0) |
| Lymphocyte count decreased | 1 (3.0) |
| Neutrophil count increased | 1 (3.0) |
| Weight increased | 1 (3.0) |
|  | |
| Renal and urinary disorders# | 17 (51.5) |
| Proteinuria\* | 15 (45.5) |
| Haematuria\* | 6 (18.2) |
|  | |
| Nervous system disorders | 12 (36.4) |
| Hypoaesthesia | 7 (21.2) |
| Paraesthesia | 2 (6.1) |
| Anaesthesia | 1 (3.0) |
| Dizziness | 1 (3.0) |
| Motor dysfunction | 1 (3.0) |
| Neuropathy peripheral | 1 (3.0) |
|  | |
| Musculoskeletal and connective tissue disorders | 11 (33.3) |
| Arthralgia | 3 (9.1) |
| Musculoskeletal stiffness | 3 (9.1) |
| Myalgia | 2 (6.1) |
| Arthritis | 1 (3.0) |
| Back pain | 1 (3.0) |
| Joint range of motion decreased | 1 (3.0) |
| Joint swelling | 1 (3.0) |
| Neck pain | 1 (3.0) |
| Osteoarthritis | 1 (3.0) |
| Pain in extremity | 1 (3.0) |
|  | |
| Blood and lymphatic system disorders# | 10 (30.3) |
| Anaemia | 9 (27.3) |
| Bone marrow oedema | 1 (3.0) |
| Leukocytosis\* | 1 (3.0) |
|  | |
| Skin and subcutaneous tissue disorders | 9 (27.3) |
| Pruritus | 5 (15.2) |
| Rash | 3 (9.1) |
| Pain of skin | 2 (6.1) |
| Drug eruption | 1 (3.0) |
| Erythema | 1 (3.0) |
| Skin mass | 1 (3.0) |
|  | |
| Cardiac disorders | 8 (24.2) |
| Sinus bradycardia | 3 (9.1) |
| Supraventricular extrasystoles | 2 (6.1) |
| Arrhythmia | 1 (3.0) |
| Atrioventricular block second degree | 1 (3.0) |
| Supraventricular tachycardia | 1 (3.0) |
| Ventricular extrasystoles | 1 (3.0) |
|  | |
| Eye disorders | 6 (18.2) |
| Cataract | 2 (6.1) |
| Dry eye | 1 (3.0) |
| Eye oedema | 1 (3.0) |
| Glaucoma | 1 (3.0) |
| Macular degeneration | 1 (3.0) |
| Optic atrophy | 1 (3.0) |
| Periorbital swelling | 1 (3.0) |
| Retinal haemorrhage | 1 (3.0) |
| Vision blurred | 1 (3.0) |
| Vitreous opacities | 1 (3.0) |
|  | |
| Vascular disorders | 6 (18.2) |
| Hypertension | 3 (9.1) |
| Arteriosclerosis | 2 (6.1) |
| Venous thrombosis | 1 (3.0) |
|  | |
| Reproductive system and breast disorders | 4 (12.1) |
| Gynaecomastia | 3 (9.1) |
| Breast hyperplasia | 1 (3.0) |
| Breast mass | 1 (3.0) |
|  | |
| Infections and infestations | 3 (9.1) |
| Conjunctivitis | 1 (3.0) |
| Herpes virus infection | 1 (3.0) |
| Upper respiratory tract infection | 1 (3.0) |
|  | |
| Hepatobiliary disorders | 2 (6.1) |
| Hepatic function abnormal | 2 (6.1) |
|  | |
| Respiratory, thoracic and mediastinal disorders | 2 (6.1) |
| Cough | 1 (3.0) |
| Dyspnoea | 1 (3.0) |
|  | |
| Endocrine disorders | 1 (3.0) |
| Endocrine disorder | 1 (3.0) |

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 14.3.1.3.2.8 Summary of IN10018 Related TEAEs by SOC and PT - Phase II Part 1 treatment-naive locally-advanced or metastatic NSCLC (Safety Analysis Set)**

| System Organ Class  Preferred Term | Treatment-naive locally-advanced or metastatic NSCLC (N = 33) n (%) |
| --- | --- |
| IN10018 Related TEAEs | 33 (100) |
|  | |
| Metabolism and nutrition disorders | 24 (72.7) |
| Hypertriglyceridaemia | 10 (30.3) |
| Decreased appetite | 7 (21.2) |
| Hypoalbuminaemia | 7 (21.2) |
| Hypoproteinaemia | 5 (15.2) |
| Hyperlipidaemia | 4 (12.1) |
| Hypercholesterolaemia | 2 (6.1) |
| Hyponatraemia | 2 (6.1) |
| Hypochloraemia | 1 (3.0) |
| Hypokalaemia | 1 (3.0) |
|  | |
| General disorders and administration site conditions | 23 (69.7) |
| Oedema peripheral | 13 (39.4) |
| Fatigue | 8 (24.2) |
| Peripheral swelling | 6 (18.2) |
| Face oedema | 3 (9.1) |
| Malaise | 3 (9.1) |
| Asthenia | 2 (6.1) |
| Induration | 2 (6.1) |
| Discomfort | 1 (3.0) |
| Nodule | 1 (3.0) |
| Non-pitting oedema | 1 (3.0) |
| Swelling face | 1 (3.0) |
|  | |
| Renal and urinary disorders | 22 (66.7) |
| Proteinuria | 20 (60.6) |
| Haematuria | 6 (18.2) |
| Albuminuria | 1 (3.0) |
|  | |
| Gastrointestinal disorders | 21 (63.6) |
| Diarrhoea | 19 (57.6) |
| Nausea | 5 (15.2) |
| Abdominal discomfort | 2 (6.1) |
| Abdominal distension | 1 (3.0) |
| Abdominal pain | 1 (3.0) |
| Abdominal pain upper | 1 (3.0) |
| Enteritis | 1 (3.0) |
| Stomatitis | 1 (3.0) |
| Vomiting | 1 (3.0) |
|  | |
| Investigations | 21 (63.6) |
| Alanine aminotransferase increased | 9 (27.3) |
| Aspartate aminotransferase increased | 8 (24.2) |
| Gamma-glutamyltransferase increased | 7 (21.2) |
| Blood bilirubin increased | 3 (9.1) |
| Electrocardiogram PR prolongation | 3 (9.1) |
| Urinary occult blood positive | 3 (9.1) |
| Bilirubin conjugated increased | 2 (6.1) |
| Blood alkaline phosphatase increased | 2 (6.1) |
| C-reactive protein increased | 2 (6.1) |
| Total bile acids increased | 2 (6.1) |
| Weight decreased | 2 (6.1) |
| Blood bilirubin unconjugated increased | 1 (3.0) |
| Blood cholesterol increased | 1 (3.0) |
| Blood creatine phosphokinase decreased | 1 (3.0) |
| Blood creatine phosphokinase increased | 1 (3.0) |
| Blood creatinine increased | 1 (3.0) |
| Blood pressure increased | 1 (3.0) |
| Cystatin C increased | 1 (3.0) |
| Electrocardiogram QT prolonged | 1 (3.0) |
| Electrocardiogram ST segment depression | 1 (3.0) |
| Fibrin D dimer increased | 1 (3.0) |
| Glucose urine present | 1 (3.0) |
| Lipoprotein increased | 1 (3.0) |
| Lymphocyte count decreased | 1 (3.0) |
| Neutrophil count increased | 1 (3.0) |
| Protein urine present | 1 (3.0) |
| Weight increased | 1 (3.0) |
| White blood cell count increased | 1 (3.0) |
|  | |
| Musculoskeletal and connective tissue disorders | 13 (39.4) |
| Arthralgia | 4 (12.1) |
| Musculoskeletal stiffness | 4 (12.1) |
| Myalgia | 2 (6.1) |
| Pain in extremity | 2 (6.1) |
| Arthritis | 1 (3.0) |
| Back pain | 1 (3.0) |
| Joint range of motion decreased | 1 (3.0) |
| Joint swelling | 1 (3.0) |
| Limb discomfort | 1 (3.0) |
| Neck pain | 1 (3.0) |
| Osteoarthritis | 1 (3.0) |
|  | |
| Nervous system disorders | 13 (39.4) |
| Hypoaesthesia | 8 (24.2) |
| Motor dysfunction | 2 (6.1) |
| Paraesthesia | 2 (6.1) |
| Anaesthesia | 1 (3.0) |
| Dizziness | 1 (3.0) |
| Neuropathy peripheral | 1 (3.0) |
|  | |
| Blood and lymphatic system disorders | 10 (30.3) |
| Anaemia | 9 (27.3) |
| Bone marrow oedema | 1 (3.0) |
|  | |
| Skin and subcutaneous tissue disorders | 9 (27.3) |
| Pruritus | 5 (15.2) |
| Rash | 3 (9.1) |
| Pain of skin | 2 (6.1) |
| Drug eruption | 1 (3.0) |
| Erythema | 1 (3.0) |
| Skin mass | 1 (3.0) |
|  | |
| Cardiac disorders | 8 (24.2) |
| Sinus bradycardia | 3 (9.1) |
| Supraventricular extrasystoles | 2 (6.1) |
| Arrhythmia | 1 (3.0) |
| Atrioventricular block second degree | 1 (3.0) |
| Supraventricular tachycardia | 1 (3.0) |
| Ventricular extrasystoles | 1 (3.0) |
|  | |
| Eye disorders | 6 (18.2) |
| Cataract | 2 (6.1) |
| Dry eye | 1 (3.0) |
| Eye oedema | 1 (3.0) |
| Glaucoma | 1 (3.0) |
| Macular degeneration | 1 (3.0) |
| Optic atrophy | 1 (3.0) |
| Periorbital swelling | 1 (3.0) |
| Retinal haemorrhage | 1 (3.0) |
| Vision blurred | 1 (3.0) |
| Vitreous opacities | 1 (3.0) |
|  | |
| Vascular disorders | 6 (18.2) |
| Hypertension | 3 (9.1) |
| Arteriosclerosis | 2 (6.1) |
| Venous thrombosis | 1 (3.0) |
|  | |
| Reproductive system and breast disorders | 4 (12.1) |
| Gynaecomastia | 3 (9.1) |
| Breast hyperplasia | 1 (3.0) |
| Breast mass | 1 (3.0) |
|  | |
| Infections and infestations | 3 (9.1) |
| Conjunctivitis | 1 (3.0) |
| Herpes virus infection | 1 (3.0) |
| Upper respiratory tract infection | 1 (3.0) |
|  | |
| Hepatobiliary disorders | 2 (6.1) |
| Hepatic function abnormal | 2 (6.1) |
|  | |
| Respiratory, thoracic and mediastinal disorders | 2 (6.1) |
| Cough | 1 (3.0) |
| Dyspnoea | 1 (3.0) |
|  | |
| Endocrine disorders | 1 (3.0) |
| Endocrine disorder | 1 (3.0) |

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 14.3.1.3.2.10 Summary of IN10018 Related TEAEs by Grouped SOC and Grouped PT - Phase II part 1 treatment-naive locally-advanced or metastatic NSCLC (Safety Analysis Set)**

| System Organ Class  Preferred Term | Treatment-naive locally-advanced or metastatic NSCLC (N = 33) n (%) |
| --- | --- |
| IN10018 Related TEAEs | 33 (100) |
|  | |
| Metabolism and nutrition disorders# | 25 (75.8) |
| Hypertriglyceridaemia | 10 (30.3) |
| Decreased appetite | 7 (21.2) |
| Hypoalbuminaemia | 7 (21.2) |
| Hypoproteinaemia\* | 5 (15.2) |
| Hyperlipidaemia | 4 (12.1) |
| Hypercholesterolaemia\* | 3 (9.1) |
| Hyponatraemia | 2 (6.1) |
| Hypochloraemia | 1 (3.0) |
| Hypokalaemia | 1 (3.0) |
|  | |
| General disorders and administration site conditions# | 23 (69.7) |
| Oedema peripheral\* | 19 (57.6) |
| Fatigue\* | 10 (30.3) |
| Face oedema | 3 (9.1) |
| Malaise | 3 (9.1) |
| Induration | 2 (6.1) |
| Discomfort | 1 (3.0) |
| Nodule | 1 (3.0) |
| Swelling face | 1 (3.0) |
|  | |
| Renal and urinary disorders# | 23 (69.7) |
| Proteinuria\* | 22 (66.7) |
| Haematuria\* | 6 (18.2) |
|  | |
| Gastrointestinal disorders | 21 (63.6) |
| Diarrhoea | 19 (57.6) |
| Nausea | 5 (15.2) |
| Abdominal discomfort | 2 (6.1) |
| Abdominal distension | 1 (3.0) |
| Abdominal pain | 1 (3.0) |
| Abdominal pain upper | 1 (3.0) |
| Enteritis | 1 (3.0) |
| Stomatitis | 1 (3.0) |
| Vomiting | 1 (3.0) |
|  | |
| Investigations | 20 (60.6) |
| Alanine aminotransferase increased | 9 (27.3) |
| Aspartate aminotransferase increased | 8 (24.2) |
| Gamma-glutamyltransferase increased | 7 (21.2) |
| Blood bilirubin increased | 3 (9.1) |
| Electrocardiogram PR prolongation | 3 (9.1) |
| Urinary occult blood positive | 3 (9.1) |
| Bilirubin conjugated increased | 2 (6.1) |
| Blood alkaline phosphatase increased | 2 (6.1) |
| C-reactive protein increased | 2 (6.1) |
| Total bile acids increased | 2 (6.1) |
| Weight decreased | 2 (6.1) |
| Blood bilirubin unconjugated increased | 1 (3.0) |
| Blood creatine phosphokinase decreased | 1 (3.0) |
| Blood creatine phosphokinase increased | 1 (3.0) |
| Blood creatinine increased | 1 (3.0) |
| Blood pressure increased | 1 (3.0) |
| Cystatin C increased | 1 (3.0) |
| Electrocardiogram QT prolonged | 1 (3.0) |
| Electrocardiogram ST segment depression | 1 (3.0) |
| Fibrin D dimer increased | 1 (3.0) |
| Glucose urine present | 1 (3.0) |
| Lipoprotein increased | 1 (3.0) |
| Lymphocyte count decreased | 1 (3.0) |
| Neutrophil count increased | 1 (3.0) |
| Weight increased | 1 (3.0) |
|  | |
| Musculoskeletal and connective tissue disorders | 13 (39.4) |
| Arthralgia | 4 (12.1) |
| Musculoskeletal stiffness | 4 (12.1) |
| Myalgia | 2 (6.1) |
| Pain in extremity | 2 (6.1) |
| Arthritis | 1 (3.0) |
| Back pain | 1 (3.0) |
| Joint range of motion decreased | 1 (3.0) |
| Joint swelling | 1 (3.0) |
| Limb discomfort | 1 (3.0) |
| Neck pain | 1 (3.0) |
| Osteoarthritis | 1 (3.0) |
|  | |
| Nervous system disorders | 13 (39.4) |
| Hypoaesthesia | 8 (24.2) |
| Motor dysfunction | 2 (6.1) |
| Paraesthesia | 2 (6.1) |
| Anaesthesia | 1 (3.0) |
| Dizziness | 1 (3.0) |
| Neuropathy peripheral | 1 (3.0) |
|  | |
| Blood and lymphatic system disorders# | 10 (30.3) |
| Anaemia | 9 (27.3) |
| Bone marrow oedema | 1 (3.0) |
| Leukocytosis\* | 1 (3.0) |
|  | |
| Skin and subcutaneous tissue disorders | 9 (27.3) |
| Pruritus | 5 (15.2) |
| Rash | 3 (9.1) |
| Pain of skin | 2 (6.1) |
| Drug eruption | 1 (3.0) |
| Erythema | 1 (3.0) |
| Skin mass | 1 (3.0) |
|  | |
| Cardiac disorders | 8 (24.2) |
| Sinus bradycardia | 3 (9.1) |
| Supraventricular extrasystoles | 2 (6.1) |
| Arrhythmia | 1 (3.0) |
| Atrioventricular block second degree | 1 (3.0) |
| Supraventricular tachycardia | 1 (3.0) |
| Ventricular extrasystoles | 1 (3.0) |
|  | |
| Eye disorders | 6 (18.2) |
| Cataract | 2 (6.1) |
| Dry eye | 1 (3.0) |
| Eye oedema | 1 (3.0) |
| Glaucoma | 1 (3.0) |
| Macular degeneration | 1 (3.0) |
| Optic atrophy | 1 (3.0) |
| Periorbital swelling | 1 (3.0) |
| Retinal haemorrhage | 1 (3.0) |
| Vision blurred | 1 (3.0) |
| Vitreous opacities | 1 (3.0) |
|  | |
| Vascular disorders | 6 (18.2) |
| Hypertension | 3 (9.1) |
| Arteriosclerosis | 2 (6.1) |
| Venous thrombosis | 1 (3.0) |
|  | |
| Reproductive system and breast disorders | 4 (12.1) |
| Gynaecomastia | 3 (9.1) |
| Breast hyperplasia | 1 (3.0) |
| Breast mass | 1 (3.0) |
|  | |
| Infections and infestations | 3 (9.1) |
| Conjunctivitis | 1 (3.0) |
| Herpes virus infection | 1 (3.0) |
| Upper respiratory tract infection | 1 (3.0) |
|  | |
| Hepatobiliary disorders | 2 (6.1) |
| Hepatic function abnormal | 2 (6.1) |
|  | |
| Respiratory, thoracic and mediastinal disorders | 2 (6.1) |
| Cough | 1 (3.0) |
| Dyspnoea | 1 (3.0) |
|  | |
| Endocrine disorders | 1 (3.0) |
| Endocrine disorder | 1 (3.0) |

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 14.3.1.3.3.2 Summary of TEAEs by SOC, PT and Severity - Phase II Part 1 treatment-naive locally-advanced or metastatic NSCLC (Safety Analysis Set)**

|  | Total (N = 33) n (%) | | | | | |
| --- | --- | --- | --- | --- | --- | --- |
| System Organ Class  Preferred Term | Grade 1 | Grade 2 | Grade 3 | Grade 4 | Grade 5 | Total |
| All TEAEs | 4 (12.1) | 18 (54.5) | 9 (27.3) | 0 | 2 (6.1) | 33 (100) |
|  | | | | | | |
| General disorders and administration site conditions | 15 (45.5) | 10 (30.3) | 0 | 0 | 0 | 25 (75.8) |
| Oedema peripheral | 8 (24.2) | 5 (15.2) | 0 | 0 | 0 | 13 (39.4) |
| Fatigue | 8 (24.2) | 0 | 0 | 0 | 0 | 8 (24.2) |
| Peripheral swelling | 2 (6.1) | 4 (12.1) | 0 | 0 | 0 | 6 (18.2) |
| Pyrexia | 3 (9.1) | 1 (3.0) | 0 | 0 | 0 | 4 (12.1) |
| Face oedema | 2 (6.1) | 1 (3.0) | 0 | 0 | 0 | 3 (9.1) |
| Malaise | 3 (9.1) | 0 | 0 | 0 | 0 | 3 (9.1) |
| Asthenia | 2 (6.1) | 0 | 0 | 0 | 0 | 2 (6.1) |
| Chest discomfort | 0 | 2 (6.1) | 0 | 0 | 0 | 2 (6.1) |
| Induration | 2 (6.1) | 0 | 0 | 0 | 0 | 2 (6.1) |
| Pain | 2 (6.1) | 0 | 0 | 0 | 0 | 2 (6.1) |
| Chest pain | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Discomfort | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Influenza like illness | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Nodule | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Non-pitting oedema | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Swelling face | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
|  | | | | | | |
| Metabolism and nutrition disorders | 17 (51.5) | 7 (21.2) | 1 (3.0) | 0 | 0 | 25 (75.8) |
| Hypertriglyceridaemia | 11 (33.3) | 0 | 0 | 0 | 0 | 11 (33.3) |
| Hypoalbuminaemia | 8 (24.2) | 1 (3.0) | 0 | 0 | 0 | 9 (27.3) |
| Decreased appetite | 6 (18.2) | 2 (6.1) | 0 | 0 | 0 | 8 (24.2) |
| Hyponatraemia | 5 (15.2) | 0 | 0 | 0 | 0 | 5 (15.2) |
| Hypoproteinaemia | 4 (12.1) | 1 (3.0) | 0 | 0 | 0 | 5 (15.2) |
| Hyperlipidaemia | 2 (6.1) | 2 (6.1) | 0 | 0 | 0 | 4 (12.1) |
| Hypocalcaemia | 2 (6.1) | 1 (3.0) | 0 | 0 | 0 | 3 (9.1) |
| Hypercholesterolaemia | 2 (6.1) | 0 | 0 | 0 | 0 | 2 (6.1) |
| Hypokalaemia | 0 | 1 (3.0) | 1 (3.0) | 0 | 0 | 2 (6.1) |
| Hyperglycaemia | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Hypochloraemia | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
|  | | | | | | |
| Investigations | 17 (51.5) | 6 (18.2) | 1 (3.0) | 0 | 0 | 24 (72.7) |
| Alanine aminotransferase increased | 9 (27.3) | 0 | 0 | 0 | 0 | 9 (27.3) |
| Aspartate aminotransferase increased | 8 (24.2) | 0 | 0 | 0 | 0 | 8 (24.2) |
| Gamma-glutamyltransferase increased | 4 (12.1) | 3 (9.1) | 0 | 0 | 0 | 7 (21.2) |
| Fibrin D dimer increased | 4 (12.1) | 2 (6.1) | 0 | 0 | 0 | 6 (18.2) |
| Urinary occult blood positive | 4 (12.1) | 0 | 0 | 0 | 0 | 4 (12.1) |
| Weight decreased | 2 (6.1) | 2 (6.1) | 0 | 0 | 0 | 4 (12.1) |
| Blood bilirubin increased | 2 (6.1) | 1 (3.0) | 0 | 0 | 0 | 3 (9.1) |
| C-reactive protein increased | 2 (6.1) | 0 | 1 (3.0) | 0 | 0 | 3 (9.1) |
| Electrocardiogram PR prolongation | 3 (9.1) | 0 | 0 | 0 | 0 | 3 (9.1) |
| Bilirubin conjugated increased | 2 (6.1) | 0 | 0 | 0 | 0 | 2 (6.1) |
| Blood alkaline phosphatase increased | 2 (6.1) | 0 | 0 | 0 | 0 | 2 (6.1) |
| Total bile acids increased | 1 (3.0) | 1 (3.0) | 0 | 0 | 0 | 2 (6.1) |
| Blood bilirubin unconjugated increased | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Blood cholesterol increased | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Blood creatine phosphokinase decreased | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Blood creatine phosphokinase increased | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Blood creatinine increased | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Blood pressure increased | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Cystatin C increased | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Electrocardiogram QT prolonged | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Electrocardiogram ST segment depression | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Glucose urine present | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Lipoprotein increased | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Lymphocyte count decreased | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Neutrophil count increased | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Oxygen saturation decreased | 0 | 1 (3.0) | 0 | 0 | 0 | 1 (3.0) |
| Protein urine present | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Weight increased | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| White blood cell count increased | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
|  | | | | | | |
| Gastrointestinal disorders | 12 (36.4) | 7 (21.2) | 3 (9.1) | 0 | 0 | 22 (66.7) |
| Diarrhoea | 11 (33.3) | 6 (18.2) | 2 (6.1) | 0 | 0 | 19 (57.6) |
| Nausea | 4 (12.1) | 1 (3.0) | 0 | 0 | 0 | 5 (15.2) |
| Abdominal discomfort | 2 (6.1) | 0 | 0 | 0 | 0 | 2 (6.1) |
| Abdominal distension | 2 (6.1) | 0 | 0 | 0 | 0 | 2 (6.1) |
| Abdominal pain | 2 (6.1) | 0 | 0 | 0 | 0 | 2 (6.1) |
| Vomiting | 2 (6.1) | 0 | 0 | 0 | 0 | 2 (6.1) |
| Abdominal pain upper | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Chronic gastritis | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Enteritis | 0 | 0 | 1 (3.0) | 0 | 0 | 1 (3.0) |
| Gingival swelling | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Stomatitis | 0 | 1 (3.0) | 0 | 0 | 0 | 1 (3.0) |
|  | | | | | | |
| Renal and urinary disorders | 9 (27.3) | 11 (33.3) | 2 (6.1) | 0 | 0 | 22 (66.7) |
| Proteinuria | 7 (21.2) | 11 (33.3) | 2 (6.1) | 0 | 0 | 20 (60.6) |
| Haematuria | 7 (21.2) | 0 | 0 | 0 | 0 | 7 (21.2) |
| Albuminuria | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
|  | | | | | | |
| Musculoskeletal and connective tissue disorders | 9 (27.3) | 6 (18.2) | 0 | 0 | 0 | 15 (45.5) |
| Arthralgia | 5 (15.2) | 0 | 0 | 0 | 0 | 5 (15.2) |
| Musculoskeletal stiffness | 1 (3.0) | 3 (9.1) | 0 | 0 | 0 | 4 (12.1) |
| Pain in extremity | 2 (6.1) | 1 (3.0) | 0 | 0 | 0 | 3 (9.1) |
| Back pain | 2 (6.1) | 0 | 0 | 0 | 0 | 2 (6.1) |
| Myalgia | 2 (6.1) | 0 | 0 | 0 | 0 | 2 (6.1) |
| Neck pain | 1 (3.0) | 1 (3.0) | 0 | 0 | 0 | 2 (6.1) |
| Arthritis | 0 | 1 (3.0) | 0 | 0 | 0 | 1 (3.0) |
| Bone pain | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Joint range of motion decreased | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Joint swelling | 0 | 1 (3.0) | 0 | 0 | 0 | 1 (3.0) |
| Limb discomfort | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Osteoarthritis | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
|  | | | | | | |
| Nervous system disorders | 9 (27.3) | 5 (15.2) | 0 | 0 | 1 (3.0) | 15 (45.5) |
| Hypoaesthesia | 6 (18.2) | 3 (9.1) | 0 | 0 | 0 | 9 (27.3) |
| Dizziness | 1 (3.0) | 1 (3.0) | 0 | 0 | 0 | 2 (6.1) |
| Motor dysfunction | 2 (6.1) | 0 | 0 | 0 | 0 | 2 (6.1) |
| Paraesthesia | 2 (6.1) | 0 | 0 | 0 | 0 | 2 (6.1) |
| Anaesthesia | 0 | 1 (3.0) | 0 | 0 | 0 | 1 (3.0) |
| Haemorrhage intracranial | 0 | 0 | 0 | 0 | 1 (3.0) | 1 (3.0) |
| Headache | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Neuropathy peripheral | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
|  | | | | | | |
| Blood and lymphatic system disorders | 11 (33.3) | 2 (6.1) | 1 (3.0) | 0 | 0 | 14 (42.4) |
| Anaemia | 11 (33.3) | 1 (3.0) | 1 (3.0) | 0 | 0 | 13 (39.4) |
| Bone marrow oedema | 0 | 1 (3.0) | 0 | 0 | 0 | 1 (3.0) |
|  | | | | | | |
| Skin and subcutaneous tissue disorders | 11 (33.3) | 2 (6.1) | 0 | 0 | 0 | 13 (39.4) |
| Pruritus | 5 (15.2) | 2 (6.1) | 0 | 0 | 0 | 7 (21.2) |
| Rash | 4 (12.1) | 0 | 0 | 0 | 0 | 4 (12.1) |
| Pain of skin | 2 (6.1) | 0 | 0 | 0 | 0 | 2 (6.1) |
| Dermal cyst | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Drug eruption | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Erythema | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Skin mass | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
|  | | | | | | |
| Cardiac disorders | 11 (33.3) | 0 | 0 | 0 | 0 | 11 (33.3) |
| Sinus bradycardia | 4 (12.1) | 0 | 0 | 0 | 0 | 4 (12.1) |
| Supraventricular extrasystoles | 3 (9.1) | 0 | 0 | 0 | 0 | 3 (9.1) |
| Arrhythmia | 2 (6.1) | 0 | 0 | 0 | 0 | 2 (6.1) |
| Atrioventricular block first degree | 2 (6.1) | 0 | 0 | 0 | 0 | 2 (6.1) |
| Atrioventricular block second degree | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Cardiac septal hypertrophy | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Cardiac valve disease | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Left atrial enlargement | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Sinus tachycardia | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Supraventricular tachycardia | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Ventricular extrasystoles | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
|  | | | | | | |
| Infections and infestations | 4 (12.1) | 3 (9.1) | 3 (9.1) | 0 | 1 (3.0) | 11 (33.3) |
| Pneumonia | 2 (6.1) | 0 | 2 (6.1) | 0 | 0 | 4 (12.1) |
| Upper respiratory tract infection | 1 (3.0) | 2 (6.1) | 0 | 0 | 0 | 3 (9.1) |
| Urinary tract infection | 2 (6.1) | 0 | 0 | 0 | 0 | 2 (6.1) |
| Bronchitis | 0 | 1 (3.0) | 0 | 0 | 0 | 1 (3.0) |
| Conjunctivitis | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| COVID-19 | 0 | 1 (3.0) | 0 | 0 | 0 | 1 (3.0) |
| COVID-19 pneumonia | 0 | 0 | 0 | 0 | 1 (3.0) | 1 (3.0) |
| Herpes virus infection | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Influenza | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Lower respiratory tract infection | 0 | 0 | 1 (3.0) | 0 | 0 | 1 (3.0) |
| Nasopharyngitis | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
|  | | | | | | |
| Respiratory, thoracic and mediastinal disorders | 5 (15.2) | 3 (9.1) | 1 (3.0) | 0 | 0 | 9 (27.3) |
| Cough | 3 (9.1) | 1 (3.0) | 0 | 0 | 0 | 4 (12.1) |
| Dyspnoea | 1 (3.0) | 2 (6.1) | 0 | 0 | 0 | 3 (9.1) |
| Productive cough | 1 (3.0) | 2 (6.1) | 0 | 0 | 0 | 3 (9.1) |
| Chronic obstructive pulmonary disease | 0 | 0 | 1 (3.0) | 0 | 0 | 1 (3.0) |
| Pneumonitis | 0 | 1 (3.0) | 0 | 0 | 0 | 1 (3.0) |
|  | | | | | | |
| Vascular disorders | 2 (6.1) | 6 (18.2) | 1 (3.0) | 0 | 0 | 9 (27.3) |
| Hypertension | 0 | 2 (6.1) | 1 (3.0) | 0 | 0 | 3 (9.1) |
| Arteriosclerosis | 0 | 2 (6.1) | 0 | 0 | 0 | 2 (6.1) |
| Deep vein thrombosis | 0 | 1 (3.0) | 0 | 0 | 0 | 1 (3.0) |
| Flushing | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Hypotension | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Venous thrombosis | 0 | 1 (3.0) | 0 | 0 | 0 | 1 (3.0) |
|  | | | | | | |
| Eye disorders | 7 (21.2) | 1 (3.0) | 0 | 0 | 0 | 8 (24.2) |
| Cataract | 2 (6.1) | 1 (3.0) | 0 | 0 | 0 | 3 (9.1) |
| Dry eye | 1 (3.0) | 1 (3.0) | 0 | 0 | 0 | 2 (6.1) |
| Eye oedema | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Glaucoma | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Macular degeneration | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Meibomian gland dysfunction | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Optic atrophy | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Periorbital swelling | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Retinal haemorrhage | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Vision blurred | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Vitreous opacities | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
|  | | | | | | |
| Reproductive system and breast disorders | 4 (12.1) | 2 (6.1) | 0 | 0 | 0 | 6 (18.2) |
| Gynaecomastia | 2 (6.1) | 1 (3.0) | 0 | 0 | 0 | 3 (9.1) |
| Benign prostatic hyperplasia | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Breast hyperplasia | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Breast mass | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Peyronie's disease | 0 | 1 (3.0) | 0 | 0 | 0 | 1 (3.0) |
|  | | | | | | |
| Psychiatric disorders | 1 (3.0) | 2 (6.1) | 0 | 0 | 0 | 3 (9.1) |
| Insomnia | 1 (3.0) | 1 (3.0) | 0 | 0 | 0 | 2 (6.1) |
| Sleep disorder | 0 | 1 (3.0) | 0 | 0 | 0 | 1 (3.0) |
|  | | | | | | |
| Hepatobiliary disorders | 1 (3.0) | 0 | 1 (3.0) | 0 | 0 | 2 (6.1) |
| Hepatic function abnormal | 1 (3.0) | 0 | 1 (3.0) | 0 | 0 | 2 (6.1) |
|  | | | | | | |
| Endocrine disorders | 0 | 1 (3.0) | 0 | 0 | 0 | 1 (3.0) |
| Endocrine disorder | 0 | 1 (3.0) | 0 | 0 | 0 | 1 (3.0) |

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

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

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

**Table 14.3.1.3.3.4 Summary of TEAEs by Grouped SOC and Grouped PT and Severity - Phase II part 1 treatment-naive locally-advanced or metastatic NSCLC (Safety Analysis Set)**

|  | Total (N = 33) n (%) | | | | | |
| --- | --- | --- | --- | --- | --- | --- |
| System Organ Class  Preferred Term | Grade 1 | Grade 2 | Grade 3 | Grade 4 | Grade 5 | Total |
| All TEAEs | 4 (12.1) | 18 (54.5) | 9 (27.3) | 0 | 2 (6.1) | 33 (100) |
|  | | | | | | |
| General disorders and administration site conditions# | 15 (45.5) | 10 (30.3) | 0 | 0 | 0 | 25 (75.8) |
| Oedema peripheral\* | 10 (30.3) | 9 (27.3) | 0 | 0 | 0 | 19 (57.6) |
| Fatigue\* | 10 (30.3) | 0 | 0 | 0 | 0 | 10 (30.3) |
| Pyrexia | 3 (9.1) | 1 (3.0) | 0 | 0 | 0 | 4 (12.1) |
| Face oedema | 2 (6.1) | 1 (3.0) | 0 | 0 | 0 | 3 (9.1) |
| Malaise | 3 (9.1) | 0 | 0 | 0 | 0 | 3 (9.1) |
| Chest discomfort | 0 | 2 (6.1) | 0 | 0 | 0 | 2 (6.1) |
| Induration | 2 (6.1) | 0 | 0 | 0 | 0 | 2 (6.1) |
| Pain | 2 (6.1) | 0 | 0 | 0 | 0 | 2 (6.1) |
| Chest pain | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Discomfort | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Influenza like illness | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Nodule | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Swelling face | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
|  | | | | | | |
| Metabolism and nutrition disorders# | 17 (51.5) | 7 (21.2) | 1 (3.0) | 0 | 0 | 25 (75.8) |
| Hypertriglyceridaemia | 11 (33.3) | 0 | 0 | 0 | 0 | 11 (33.3) |
| Hypoalbuminaemia | 8 (24.2) | 1 (3.0) | 0 | 0 | 0 | 9 (27.3) |
| Decreased appetite | 6 (18.2) | 2 (6.1) | 0 | 0 | 0 | 8 (24.2) |
| Hyponatraemia | 5 (15.2) | 0 | 0 | 0 | 0 | 5 (15.2) |
| Hypoproteinaemia\* | 4 (12.1) | 1 (3.0) | 0 | 0 | 0 | 5 (15.2) |
| Hyperlipidaemia | 2 (6.1) | 2 (6.1) | 0 | 0 | 0 | 4 (12.1) |
| Hypercholesterolaemia\* | 3 (9.1) | 0 | 0 | 0 | 0 | 3 (9.1) |
| Hypocalcaemia | 2 (6.1) | 1 (3.0) | 0 | 0 | 0 | 3 (9.1) |
| Hypokalaemia | 0 | 1 (3.0) | 1 (3.0) | 0 | 0 | 2 (6.1) |
| Hyperglycaemia | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Hypochloraemia | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
|  | | | | | | |
| Investigations | 16 (48.5) | 6 (18.2) | 1 (3.0) | 0 | 0 | 23 (69.7) |
| Alanine aminotransferase increased | 9 (27.3) | 0 | 0 | 0 | 0 | 9 (27.3) |
| Aspartate aminotransferase increased | 8 (24.2) | 0 | 0 | 0 | 0 | 8 (24.2) |
| Gamma-glutamyltransferase increased | 4 (12.1) | 3 (9.1) | 0 | 0 | 0 | 7 (21.2) |
| Fibrin D dimer increased | 4 (12.1) | 2 (6.1) | 0 | 0 | 0 | 6 (18.2) |
| Urinary occult blood positive | 4 (12.1) | 0 | 0 | 0 | 0 | 4 (12.1) |
| Weight decreased | 2 (6.1) | 2 (6.1) | 0 | 0 | 0 | 4 (12.1) |
| Blood bilirubin increased | 2 (6.1) | 1 (3.0) | 0 | 0 | 0 | 3 (9.1) |
| C-reactive protein increased | 2 (6.1) | 0 | 1 (3.0) | 0 | 0 | 3 (9.1) |
| Electrocardiogram PR prolongation | 3 (9.1) | 0 | 0 | 0 | 0 | 3 (9.1) |
| Bilirubin conjugated increased | 2 (6.1) | 0 | 0 | 0 | 0 | 2 (6.1) |
| Blood alkaline phosphatase increased | 2 (6.1) | 0 | 0 | 0 | 0 | 2 (6.1) |
| Total bile acids increased | 1 (3.0) | 1 (3.0) | 0 | 0 | 0 | 2 (6.1) |
| Blood bilirubin unconjugated increased | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Blood creatine phosphokinase decreased | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Blood creatine phosphokinase increased | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Blood creatinine increased | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Blood pressure increased | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Cystatin C increased | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Electrocardiogram QT prolonged | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Electrocardiogram ST segment depression | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Glucose urine present | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Lipoprotein increased | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Lymphocyte count decreased | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Neutrophil count increased | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Oxygen saturation decreased | 0 | 1 (3.0) | 0 | 0 | 0 | 1 (3.0) |
| Weight increased | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
|  | | | | | | |
| Renal and urinary disorders# | 10 (30.3) | 11 (33.3) | 2 (6.1) | 0 | 0 | 23 (69.7) |
| Proteinuria\* | 9 (27.3) | 11 (33.3) | 2 (6.1) | 0 | 0 | 22 (66.7) |
| Haematuria\* | 7 (21.2) | 0 | 0 | 0 | 0 | 7 (21.2) |
|  | | | | | | |
| Gastrointestinal disorders | 12 (36.4) | 7 (21.2) | 3 (9.1) | 0 | 0 | 22 (66.7) |
| Diarrhoea | 11 (33.3) | 6 (18.2) | 2 (6.1) | 0 | 0 | 19 (57.6) |
| Nausea | 4 (12.1) | 1 (3.0) | 0 | 0 | 0 | 5 (15.2) |
| Abdominal discomfort | 2 (6.1) | 0 | 0 | 0 | 0 | 2 (6.1) |
| Abdominal distension | 2 (6.1) | 0 | 0 | 0 | 0 | 2 (6.1) |
| Abdominal pain | 2 (6.1) | 0 | 0 | 0 | 0 | 2 (6.1) |
| Vomiting | 2 (6.1) | 0 | 0 | 0 | 0 | 2 (6.1) |
| Abdominal pain upper | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Chronic gastritis | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Enteritis | 0 | 0 | 1 (3.0) | 0 | 0 | 1 (3.0) |
| Gingival swelling | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Stomatitis | 0 | 1 (3.0) | 0 | 0 | 0 | 1 (3.0) |
|  | | | | | | |
| Musculoskeletal and connective tissue disorders | 9 (27.3) | 6 (18.2) | 0 | 0 | 0 | 15 (45.5) |
| Arthralgia | 5 (15.2) | 0 | 0 | 0 | 0 | 5 (15.2) |
| Musculoskeletal stiffness | 1 (3.0) | 3 (9.1) | 0 | 0 | 0 | 4 (12.1) |
| Pain in extremity | 2 (6.1) | 1 (3.0) | 0 | 0 | 0 | 3 (9.1) |
| Back pain | 2 (6.1) | 0 | 0 | 0 | 0 | 2 (6.1) |
| Myalgia | 2 (6.1) | 0 | 0 | 0 | 0 | 2 (6.1) |
| Neck pain | 1 (3.0) | 1 (3.0) | 0 | 0 | 0 | 2 (6.1) |
| Arthritis | 0 | 1 (3.0) | 0 | 0 | 0 | 1 (3.0) |
| Bone pain | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Joint range of motion decreased | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Joint swelling | 0 | 1 (3.0) | 0 | 0 | 0 | 1 (3.0) |
| Limb discomfort | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Osteoarthritis | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
|  | | | | | | |
| Nervous system disorders | 9 (27.3) | 5 (15.2) | 0 | 0 | 1 (3.0) | 15 (45.5) |
| Hypoaesthesia | 6 (18.2) | 3 (9.1) | 0 | 0 | 0 | 9 (27.3) |
| Dizziness | 1 (3.0) | 1 (3.0) | 0 | 0 | 0 | 2 (6.1) |
| Motor dysfunction | 2 (6.1) | 0 | 0 | 0 | 0 | 2 (6.1) |
| Paraesthesia | 2 (6.1) | 0 | 0 | 0 | 0 | 2 (6.1) |
| Anaesthesia | 0 | 1 (3.0) | 0 | 0 | 0 | 1 (3.0) |
| Haemorrhage intracranial | 0 | 0 | 0 | 0 | 1 (3.0) | 1 (3.0) |
| Headache | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Neuropathy peripheral | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
|  | | | | | | |
| Blood and lymphatic system disorders# | 11 (33.3) | 2 (6.1) | 1 (3.0) | 0 | 0 | 14 (42.4) |
| Anaemia | 11 (33.3) | 1 (3.0) | 1 (3.0) | 0 | 0 | 13 (39.4) |
| Bone marrow oedema | 0 | 1 (3.0) | 0 | 0 | 0 | 1 (3.0) |
| Leukocytosis\* | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
|  | | | | | | |
| Skin and subcutaneous tissue disorders | 11 (33.3) | 2 (6.1) | 0 | 0 | 0 | 13 (39.4) |
| Pruritus | 5 (15.2) | 2 (6.1) | 0 | 0 | 0 | 7 (21.2) |
| Rash | 4 (12.1) | 0 | 0 | 0 | 0 | 4 (12.1) |
| Pain of skin | 2 (6.1) | 0 | 0 | 0 | 0 | 2 (6.1) |
| Dermal cyst | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Drug eruption | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Erythema | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Skin mass | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
|  | | | | | | |
| Cardiac disorders | 11 (33.3) | 0 | 0 | 0 | 0 | 11 (33.3) |
| Sinus bradycardia | 4 (12.1) | 0 | 0 | 0 | 0 | 4 (12.1) |
| Supraventricular extrasystoles | 3 (9.1) | 0 | 0 | 0 | 0 | 3 (9.1) |
| Arrhythmia | 2 (6.1) | 0 | 0 | 0 | 0 | 2 (6.1) |
| Atrioventricular block first degree | 2 (6.1) | 0 | 0 | 0 | 0 | 2 (6.1) |
| Atrioventricular block second degree | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Cardiac septal hypertrophy | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Cardiac valve disease | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Left atrial enlargement | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Sinus tachycardia | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Supraventricular tachycardia | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Ventricular extrasystoles | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
|  | | | | | | |
| Infections and infestations | 4 (12.1) | 3 (9.1) | 3 (9.1) | 0 | 1 (3.0) | 11 (33.3) |
| Pneumonia | 2 (6.1) | 0 | 2 (6.1) | 0 | 0 | 4 (12.1) |
| Upper respiratory tract infection | 1 (3.0) | 2 (6.1) | 0 | 0 | 0 | 3 (9.1) |
| Urinary tract infection | 2 (6.1) | 0 | 0 | 0 | 0 | 2 (6.1) |
| Bronchitis | 0 | 1 (3.0) | 0 | 0 | 0 | 1 (3.0) |
| Conjunctivitis | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| COVID-19 | 0 | 1 (3.0) | 0 | 0 | 0 | 1 (3.0) |
| COVID-19 pneumonia | 0 | 0 | 0 | 0 | 1 (3.0) | 1 (3.0) |
| Herpes virus infection | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Influenza | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Lower respiratory tract infection | 0 | 0 | 1 (3.0) | 0 | 0 | 1 (3.0) |
| Nasopharyngitis | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
|  | | | | | | |
| Respiratory, thoracic and mediastinal disorders | 5 (15.2) | 3 (9.1) | 1 (3.0) | 0 | 0 | 9 (27.3) |
| Cough | 3 (9.1) | 1 (3.0) | 0 | 0 | 0 | 4 (12.1) |
| Dyspnoea | 1 (3.0) | 2 (6.1) | 0 | 0 | 0 | 3 (9.1) |
| Productive cough | 1 (3.0) | 2 (6.1) | 0 | 0 | 0 | 3 (9.1) |
| Chronic obstructive pulmonary disease | 0 | 0 | 1 (3.0) | 0 | 0 | 1 (3.0) |
| Pneumonitis | 0 | 1 (3.0) | 0 | 0 | 0 | 1 (3.0) |
|  | | | | | | |
| Vascular disorders | 2 (6.1) | 6 (18.2) | 1 (3.0) | 0 | 0 | 9 (27.3) |
| Hypertension | 0 | 2 (6.1) | 1 (3.0) | 0 | 0 | 3 (9.1) |
| Arteriosclerosis | 0 | 2 (6.1) | 0 | 0 | 0 | 2 (6.1) |
| Deep vein thrombosis | 0 | 1 (3.0) | 0 | 0 | 0 | 1 (3.0) |
| Flushing | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Hypotension | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Venous thrombosis | 0 | 1 (3.0) | 0 | 0 | 0 | 1 (3.0) |
|  | | | | | | |
| Eye disorders | 7 (21.2) | 1 (3.0) | 0 | 0 | 0 | 8 (24.2) |
| Cataract | 2 (6.1) | 1 (3.0) | 0 | 0 | 0 | 3 (9.1) |
| Dry eye | 1 (3.0) | 1 (3.0) | 0 | 0 | 0 | 2 (6.1) |
| Eye oedema | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Glaucoma | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Macular degeneration | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Meibomian gland dysfunction | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Optic atrophy | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Periorbital swelling | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Retinal haemorrhage | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Vision blurred | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Vitreous opacities | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
|  | | | | | | |
| Reproductive system and breast disorders | 4 (12.1) | 2 (6.1) | 0 | 0 | 0 | 6 (18.2) |
| Gynaecomastia | 2 (6.1) | 1 (3.0) | 0 | 0 | 0 | 3 (9.1) |
| Benign prostatic hyperplasia | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Breast hyperplasia | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Breast mass | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Peyronie's disease | 0 | 1 (3.0) | 0 | 0 | 0 | 1 (3.0) |
|  | | | | | | |
| Psychiatric disorders | 1 (3.0) | 2 (6.1) | 0 | 0 | 0 | 3 (9.1) |
| Insomnia | 1 (3.0) | 1 (3.0) | 0 | 0 | 0 | 2 (6.1) |
| Sleep disorder | 0 | 1 (3.0) | 0 | 0 | 0 | 1 (3.0) |
|  | | | | | | |
| Hepatobiliary disorders | 1 (3.0) | 0 | 1 (3.0) | 0 | 0 | 2 (6.1) |
| Hepatic function abnormal | 1 (3.0) | 0 | 1 (3.0) | 0 | 0 | 2 (6.1) |
|  | | | | | | |
| Endocrine disorders | 0 | 1 (3.0) | 0 | 0 | 0 | 1 (3.0) |
| Endocrine disorder | 0 | 1 (3.0) | 0 | 0 | 0 | 1 (3.0) |

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 14.3.1.3.4.2 Summary of D-1553 Related TEAEs by SOC, PT and Severity - Phase II Part 1 treatment-naive locally-advanced or metastatic NSCLC (Safety Analysis Set)**

|  | Total (N = 33) n (%) | | | | | |
| --- | --- | --- | --- | --- | --- | --- |
| System Organ Class  Preferred Term | Grade 1 | Grade 2 | Grade 3 | Grade 4 | Grade 5 | Total |
| All TEAEs | 7 (21.2) | 19 (57.6) | 6 (18.2) | 0 | 0 | 32 (97.0) |
|  | | | | | | |
| Metabolism and nutrition disorders | 17 (51.5) | 6 (18.2) | 0 | 0 | 0 | 23 (69.7) |
| Hypertriglyceridaemia | 10 (30.3) | 0 | 0 | 0 | 0 | 10 (30.3) |
| Decreased appetite | 5 (15.2) | 2 (6.1) | 0 | 0 | 0 | 7 (21.2) |
| Hypoalbuminaemia | 7 (21.2) | 0 | 0 | 0 | 0 | 7 (21.2) |
| Hypoproteinaemia | 4 (12.1) | 1 (3.0) | 0 | 0 | 0 | 5 (15.2) |
| Hyperlipidaemia | 1 (3.0) | 2 (6.1) | 0 | 0 | 0 | 3 (9.1) |
| Hypercholesterolaemia | 2 (6.1) | 0 | 0 | 0 | 0 | 2 (6.1) |
| Hyponatraemia | 2 (6.1) | 0 | 0 | 0 | 0 | 2 (6.1) |
| Hypochloraemia | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Hypokalaemia | 0 | 1 (3.0) | 0 | 0 | 0 | 1 (3.0) |
|  | | | | | | |
| Gastrointestinal disorders | 11 (33.3) | 7 (21.2) | 3 (9.1) | 0 | 0 | 21 (63.6) |
| Diarrhoea | 11 (33.3) | 6 (18.2) | 2 (6.1) | 0 | 0 | 19 (57.6) |
| Nausea | 4 (12.1) | 1 (3.0) | 0 | 0 | 0 | 5 (15.2) |
| Abdominal discomfort | 2 (6.1) | 0 | 0 | 0 | 0 | 2 (6.1) |
| Abdominal distension | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Abdominal pain | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Abdominal pain upper | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Enteritis | 0 | 0 | 1 (3.0) | 0 | 0 | 1 (3.0) |
| Stomatitis | 0 | 1 (3.0) | 0 | 0 | 0 | 1 (3.0) |
| Vomiting | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
|  | | | | | | |
| General disorders and administration site conditions | 12 (36.4) | 9 (27.3) | 0 | 0 | 0 | 21 (63.6) |
| Oedema peripheral | 5 (15.2) | 5 (15.2) | 0 | 0 | 0 | 10 (30.3) |
| Fatigue | 8 (24.2) | 0 | 0 | 0 | 0 | 8 (24.2) |
| Peripheral swelling | 2 (6.1) | 4 (12.1) | 0 | 0 | 0 | 6 (18.2) |
| Face oedema | 2 (6.1) | 1 (3.0) | 0 | 0 | 0 | 3 (9.1) |
| Malaise | 3 (9.1) | 0 | 0 | 0 | 0 | 3 (9.1) |
| Asthenia | 2 (6.1) | 0 | 0 | 0 | 0 | 2 (6.1) |
| Induration | 2 (6.1) | 0 | 0 | 0 | 0 | 2 (6.1) |
| Discomfort | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Nodule | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Non-pitting oedema | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Swelling face | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
|  | | | | | | |
| Investigations | 18 (54.5) | 3 (9.1) | 0 | 0 | 0 | 21 (63.6) |
| Alanine aminotransferase increased | 9 (27.3) | 0 | 0 | 0 | 0 | 9 (27.3) |
| Aspartate aminotransferase increased | 8 (24.2) | 0 | 0 | 0 | 0 | 8 (24.2) |
| Gamma-glutamyltransferase increased | 4 (12.1) | 3 (9.1) | 0 | 0 | 0 | 7 (21.2) |
| Blood bilirubin increased | 2 (6.1) | 1 (3.0) | 0 | 0 | 0 | 3 (9.1) |
| Electrocardiogram PR prolongation | 3 (9.1) | 0 | 0 | 0 | 0 | 3 (9.1) |
| Urinary occult blood positive | 3 (9.1) | 0 | 0 | 0 | 0 | 3 (9.1) |
| Bilirubin conjugated increased | 2 (6.1) | 0 | 0 | 0 | 0 | 2 (6.1) |
| Blood alkaline phosphatase increased | 2 (6.1) | 0 | 0 | 0 | 0 | 2 (6.1) |
| C-reactive protein increased | 2 (6.1) | 0 | 0 | 0 | 0 | 2 (6.1) |
| Total bile acids increased | 1 (3.0) | 1 (3.0) | 0 | 0 | 0 | 2 (6.1) |
| Weight decreased | 1 (3.0) | 1 (3.0) | 0 | 0 | 0 | 2 (6.1) |
| Blood bilirubin unconjugated increased | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Blood cholesterol increased | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Blood creatine phosphokinase decreased | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Blood creatine phosphokinase increased | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Blood creatinine increased | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Blood pressure increased | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Cystatin C increased | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Electrocardiogram QT prolonged | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Electrocardiogram ST segment depression | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Fibrin D dimer increased | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Glucose urine present | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Lipoprotein increased | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Lymphocyte count decreased | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Neutrophil count increased | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Protein urine present | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Weight increased | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| White blood cell count increased | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
|  | | | | | | |
| Renal and urinary disorders | 7 (21.2) | 7 (21.2) | 2 (6.1) | 0 | 0 | 16 (48.5) |
| Proteinuria | 4 (12.1) | 7 (21.2) | 2 (6.1) | 0 | 0 | 13 (39.4) |
| Haematuria | 6 (18.2) | 0 | 0 | 0 | 0 | 6 (18.2) |
| Albuminuria | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
|  | | | | | | |
| Nervous system disorders | 8 (24.2) | 4 (12.1) | 0 | 0 | 0 | 12 (36.4) |
| Hypoaesthesia | 4 (12.1) | 3 (9.1) | 0 | 0 | 0 | 7 (21.2) |
| Paraesthesia | 2 (6.1) | 0 | 0 | 0 | 0 | 2 (6.1) |
| Anaesthesia | 0 | 1 (3.0) | 0 | 0 | 0 | 1 (3.0) |
| Dizziness | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Motor dysfunction | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Neuropathy peripheral | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
|  | | | | | | |
| Musculoskeletal and connective tissue disorders | 5 (15.2) | 6 (18.2) | 0 | 0 | 0 | 11 (33.3) |
| Arthralgia | 3 (9.1) | 0 | 0 | 0 | 0 | 3 (9.1) |
| Musculoskeletal stiffness | 0 | 3 (9.1) | 0 | 0 | 0 | 3 (9.1) |
| Myalgia | 2 (6.1) | 0 | 0 | 0 | 0 | 2 (6.1) |
| Arthritis | 0 | 1 (3.0) | 0 | 0 | 0 | 1 (3.0) |
| Back pain | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Joint range of motion decreased | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Joint swelling | 0 | 1 (3.0) | 0 | 0 | 0 | 1 (3.0) |
| Neck pain | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Osteoarthritis | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Pain in extremity | 0 | 1 (3.0) | 0 | 0 | 0 | 1 (3.0) |
|  | | | | | | |
| Blood and lymphatic system disorders | 9 (27.3) | 1 (3.0) | 0 | 0 | 0 | 10 (30.3) |
| Anaemia | 9 (27.3) | 0 | 0 | 0 | 0 | 9 (27.3) |
| Bone marrow oedema | 0 | 1 (3.0) | 0 | 0 | 0 | 1 (3.0) |
|  | | | | | | |
| Skin and subcutaneous tissue disorders | 8 (24.2) | 1 (3.0) | 0 | 0 | 0 | 9 (27.3) |
| Pruritus | 4 (12.1) | 1 (3.0) | 0 | 0 | 0 | 5 (15.2) |
| Rash | 3 (9.1) | 0 | 0 | 0 | 0 | 3 (9.1) |
| Pain of skin | 2 (6.1) | 0 | 0 | 0 | 0 | 2 (6.1) |
| Drug eruption | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Erythema | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Skin mass | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
|  | | | | | | |
| Cardiac disorders | 8 (24.2) | 0 | 0 | 0 | 0 | 8 (24.2) |
| Sinus bradycardia | 3 (9.1) | 0 | 0 | 0 | 0 | 3 (9.1) |
| Supraventricular extrasystoles | 2 (6.1) | 0 | 0 | 0 | 0 | 2 (6.1) |
| Arrhythmia | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Atrioventricular block second degree | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Supraventricular tachycardia | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Ventricular extrasystoles | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
|  | | | | | | |
| Eye disorders | 5 (15.2) | 1 (3.0) | 0 | 0 | 0 | 6 (18.2) |
| Cataract | 1 (3.0) | 1 (3.0) | 0 | 0 | 0 | 2 (6.1) |
| Dry eye | 0 | 1 (3.0) | 0 | 0 | 0 | 1 (3.0) |
| Eye oedema | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Glaucoma | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Macular degeneration | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Optic atrophy | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Periorbital swelling | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Retinal haemorrhage | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Vision blurred | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Vitreous opacities | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
|  | | | | | | |
| Vascular disorders | 0 | 5 (15.2) | 1 (3.0) | 0 | 0 | 6 (18.2) |
| Hypertension | 0 | 2 (6.1) | 1 (3.0) | 0 | 0 | 3 (9.1) |
| Arteriosclerosis | 0 | 2 (6.1) | 0 | 0 | 0 | 2 (6.1) |
| Venous thrombosis | 0 | 1 (3.0) | 0 | 0 | 0 | 1 (3.0) |
|  | | | | | | |
| Reproductive system and breast disorders | 3 (9.1) | 1 (3.0) | 0 | 0 | 0 | 4 (12.1) |
| Gynaecomastia | 2 (6.1) | 1 (3.0) | 0 | 0 | 0 | 3 (9.1) |
| Breast hyperplasia | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Breast mass | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
|  | | | | | | |
| Infections and infestations | 3 (9.1) | 0 | 0 | 0 | 0 | 3 (9.1) |
| Conjunctivitis | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Herpes virus infection | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Upper respiratory tract infection | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
|  | | | | | | |
| Hepatobiliary disorders | 1 (3.0) | 0 | 1 (3.0) | 0 | 0 | 2 (6.1) |
| Hepatic function abnormal | 1 (3.0) | 0 | 1 (3.0) | 0 | 0 | 2 (6.1) |
|  | | | | | | |
| Respiratory, thoracic and mediastinal disorders | 2 (6.1) | 0 | 0 | 0 | 0 | 2 (6.1) |
| Cough | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Dyspnoea | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
|  | | | | | | |
| Endocrine disorders | 0 | 1 (3.0) | 0 | 0 | 0 | 1 (3.0) |
| Endocrine disorder | 0 | 1 (3.0) | 0 | 0 | 0 | 1 (3.0) |

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 14.3.1.3.4.4 Summary of D-1553 Related TEAEs by Grouped SOC and Grouped PT and Severity - Phase II part 1 treatment-naive locally-advanced or metastatic NSCLC (Safety Analysis Set)**

|  | Total (N = 33) n (%) | | | | | |
| --- | --- | --- | --- | --- | --- | --- |
| System Organ Class  Preferred Term | Grade 1 | Grade 2 | Grade 3 | Grade 4 | Grade 5 | Total |
| All TEAEs | 7 (21.2) | 19 (57.6) | 6 (18.2) | 0 | 0 | 32 (97.0) |
|  | | | | | | |
| Metabolism and nutrition disorders# | 18 (54.5) | 6 (18.2) | 0 | 0 | 0 | 24 (72.7) |
| Hypertriglyceridaemia | 10 (30.3) | 0 | 0 | 0 | 0 | 10 (30.3) |
| Decreased appetite | 5 (15.2) | 2 (6.1) | 0 | 0 | 0 | 7 (21.2) |
| Hypoalbuminaemia | 7 (21.2) | 0 | 0 | 0 | 0 | 7 (21.2) |
| Hypoproteinaemia\* | 4 (12.1) | 1 (3.0) | 0 | 0 | 0 | 5 (15.2) |
| Hypercholesterolaemia\* | 3 (9.1) | 0 | 0 | 0 | 0 | 3 (9.1) |
| Hyperlipidaemia | 1 (3.0) | 2 (6.1) | 0 | 0 | 0 | 3 (9.1) |
| Hyponatraemia | 2 (6.1) | 0 | 0 | 0 | 0 | 2 (6.1) |
| Hypochloraemia | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Hypokalaemia | 0 | 1 (3.0) | 0 | 0 | 0 | 1 (3.0) |
|  | | | | | | |
| Gastrointestinal disorders | 11 (33.3) | 7 (21.2) | 3 (9.1) | 0 | 0 | 21 (63.6) |
| Diarrhoea | 11 (33.3) | 6 (18.2) | 2 (6.1) | 0 | 0 | 19 (57.6) |
| Nausea | 4 (12.1) | 1 (3.0) | 0 | 0 | 0 | 5 (15.2) |
| Abdominal discomfort | 2 (6.1) | 0 | 0 | 0 | 0 | 2 (6.1) |
| Abdominal distension | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Abdominal pain | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Abdominal pain upper | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Enteritis | 0 | 0 | 1 (3.0) | 0 | 0 | 1 (3.0) |
| Stomatitis | 0 | 1 (3.0) | 0 | 0 | 0 | 1 (3.0) |
| Vomiting | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
|  | | | | | | |
| General disorders and administration site conditions# | 12 (36.4) | 9 (27.3) | 0 | 0 | 0 | 21 (63.6) |
| Oedema peripheral\* | 7 (21.2) | 9 (27.3) | 0 | 0 | 0 | 16 (48.5) |
| Fatigue\* | 10 (30.3) | 0 | 0 | 0 | 0 | 10 (30.3) |
| Face oedema | 2 (6.1) | 1 (3.0) | 0 | 0 | 0 | 3 (9.1) |
| Malaise | 3 (9.1) | 0 | 0 | 0 | 0 | 3 (9.1) |
| Induration | 2 (6.1) | 0 | 0 | 0 | 0 | 2 (6.1) |
| Discomfort | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Nodule | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Swelling face | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
|  | | | | | | |
| Investigations | 17 (51.5) | 3 (9.1) | 0 | 0 | 0 | 20 (60.6) |
| Alanine aminotransferase increased | 9 (27.3) | 0 | 0 | 0 | 0 | 9 (27.3) |
| Aspartate aminotransferase increased | 8 (24.2) | 0 | 0 | 0 | 0 | 8 (24.2) |
| Gamma-glutamyltransferase increased | 4 (12.1) | 3 (9.1) | 0 | 0 | 0 | 7 (21.2) |
| Blood bilirubin increased | 2 (6.1) | 1 (3.0) | 0 | 0 | 0 | 3 (9.1) |
| Electrocardiogram PR prolongation | 3 (9.1) | 0 | 0 | 0 | 0 | 3 (9.1) |
| Urinary occult blood positive | 3 (9.1) | 0 | 0 | 0 | 0 | 3 (9.1) |
| Bilirubin conjugated increased | 2 (6.1) | 0 | 0 | 0 | 0 | 2 (6.1) |
| Blood alkaline phosphatase increased | 2 (6.1) | 0 | 0 | 0 | 0 | 2 (6.1) |
| C-reactive protein increased | 2 (6.1) | 0 | 0 | 0 | 0 | 2 (6.1) |
| Total bile acids increased | 1 (3.0) | 1 (3.0) | 0 | 0 | 0 | 2 (6.1) |
| Weight decreased | 1 (3.0) | 1 (3.0) | 0 | 0 | 0 | 2 (6.1) |
| Blood bilirubin unconjugated increased | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Blood creatine phosphokinase decreased | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Blood creatine phosphokinase increased | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Blood creatinine increased | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Blood pressure increased | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Cystatin C increased | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Electrocardiogram QT prolonged | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Electrocardiogram ST segment depression | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Fibrin D dimer increased | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Glucose urine present | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Lipoprotein increased | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Lymphocyte count decreased | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Neutrophil count increased | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Weight increased | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
|  | | | | | | |
| Renal and urinary disorders# | 8 (24.2) | 7 (21.2) | 2 (6.1) | 0 | 0 | 17 (51.5) |
| Proteinuria\* | 6 (18.2) | 7 (21.2) | 2 (6.1) | 0 | 0 | 15 (45.5) |
| Haematuria\* | 6 (18.2) | 0 | 0 | 0 | 0 | 6 (18.2) |
|  | | | | | | |
| Nervous system disorders | 8 (24.2) | 4 (12.1) | 0 | 0 | 0 | 12 (36.4) |
| Hypoaesthesia | 4 (12.1) | 3 (9.1) | 0 | 0 | 0 | 7 (21.2) |
| Paraesthesia | 2 (6.1) | 0 | 0 | 0 | 0 | 2 (6.1) |
| Anaesthesia | 0 | 1 (3.0) | 0 | 0 | 0 | 1 (3.0) |
| Dizziness | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Motor dysfunction | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Neuropathy peripheral | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
|  | | | | | | |
| Musculoskeletal and connective tissue disorders | 5 (15.2) | 6 (18.2) | 0 | 0 | 0 | 11 (33.3) |
| Arthralgia | 3 (9.1) | 0 | 0 | 0 | 0 | 3 (9.1) |
| Musculoskeletal stiffness | 0 | 3 (9.1) | 0 | 0 | 0 | 3 (9.1) |
| Myalgia | 2 (6.1) | 0 | 0 | 0 | 0 | 2 (6.1) |
| Arthritis | 0 | 1 (3.0) | 0 | 0 | 0 | 1 (3.0) |
| Back pain | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Joint range of motion decreased | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Joint swelling | 0 | 1 (3.0) | 0 | 0 | 0 | 1 (3.0) |
| Neck pain | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Osteoarthritis | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Pain in extremity | 0 | 1 (3.0) | 0 | 0 | 0 | 1 (3.0) |
|  | | | | | | |
| Blood and lymphatic system disorders# | 9 (27.3) | 1 (3.0) | 0 | 0 | 0 | 10 (30.3) |
| Anaemia | 9 (27.3) | 0 | 0 | 0 | 0 | 9 (27.3) |
| Bone marrow oedema | 0 | 1 (3.0) | 0 | 0 | 0 | 1 (3.0) |
| Leukocytosis\* | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
|  | | | | | | |
| Skin and subcutaneous tissue disorders | 8 (24.2) | 1 (3.0) | 0 | 0 | 0 | 9 (27.3) |
| Pruritus | 4 (12.1) | 1 (3.0) | 0 | 0 | 0 | 5 (15.2) |
| Rash | 3 (9.1) | 0 | 0 | 0 | 0 | 3 (9.1) |
| Pain of skin | 2 (6.1) | 0 | 0 | 0 | 0 | 2 (6.1) |
| Drug eruption | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Erythema | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Skin mass | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
|  | | | | | | |
| Cardiac disorders | 8 (24.2) | 0 | 0 | 0 | 0 | 8 (24.2) |
| Sinus bradycardia | 3 (9.1) | 0 | 0 | 0 | 0 | 3 (9.1) |
| Supraventricular extrasystoles | 2 (6.1) | 0 | 0 | 0 | 0 | 2 (6.1) |
| Arrhythmia | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Atrioventricular block second degree | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Supraventricular tachycardia | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Ventricular extrasystoles | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
|  | | | | | | |
| Eye disorders | 5 (15.2) | 1 (3.0) | 0 | 0 | 0 | 6 (18.2) |
| Cataract | 1 (3.0) | 1 (3.0) | 0 | 0 | 0 | 2 (6.1) |
| Dry eye | 0 | 1 (3.0) | 0 | 0 | 0 | 1 (3.0) |
| Eye oedema | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Glaucoma | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Macular degeneration | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Optic atrophy | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Periorbital swelling | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Retinal haemorrhage | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Vision blurred | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Vitreous opacities | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
|  | | | | | | |
| Vascular disorders | 0 | 5 (15.2) | 1 (3.0) | 0 | 0 | 6 (18.2) |
| Hypertension | 0 | 2 (6.1) | 1 (3.0) | 0 | 0 | 3 (9.1) |
| Arteriosclerosis | 0 | 2 (6.1) | 0 | 0 | 0 | 2 (6.1) |
| Venous thrombosis | 0 | 1 (3.0) | 0 | 0 | 0 | 1 (3.0) |
|  | | | | | | |
| Reproductive system and breast disorders | 3 (9.1) | 1 (3.0) | 0 | 0 | 0 | 4 (12.1) |
| Gynaecomastia | 2 (6.1) | 1 (3.0) | 0 | 0 | 0 | 3 (9.1) |
| Breast hyperplasia | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Breast mass | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
|  | | | | | | |
| Infections and infestations | 3 (9.1) | 0 | 0 | 0 | 0 | 3 (9.1) |
| Conjunctivitis | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Herpes virus infection | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Upper respiratory tract infection | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
|  | | | | | | |
| Hepatobiliary disorders | 1 (3.0) | 0 | 1 (3.0) | 0 | 0 | 2 (6.1) |
| Hepatic function abnormal | 1 (3.0) | 0 | 1 (3.0) | 0 | 0 | 2 (6.1) |
|  | | | | | | |
| Respiratory, thoracic and mediastinal disorders | 2 (6.1) | 0 | 0 | 0 | 0 | 2 (6.1) |
| Cough | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Dyspnoea | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
|  | | | | | | |
| Endocrine disorders | 0 | 1 (3.0) | 0 | 0 | 0 | 1 (3.0) |
| Endocrine disorder | 0 | 1 (3.0) | 0 | 0 | 0 | 1 (3.0) |

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 14.3.1.3.4.8 Summary of IN10018 Related TEAEs by SOC, PT and Severity - Phase II Part 1 treatment-naive locally-advanced or metastatic NSCLC (Safety Analysis Set)**

|  | Total (N = 33) n (%) | | | | | |
| --- | --- | --- | --- | --- | --- | --- |
| System Organ Class  Preferred Term | Grade 1 | Grade 2 | Grade 3 | Grade 4 | Grade 5 | Total |
| All TEAEs | 7 (21.2) | 20 (60.6) | 6 (18.2) | 0 | 0 | 33 (100) |
|  | | | | | | |
| Metabolism and nutrition disorders | 18 (54.5) | 6 (18.2) | 0 | 0 | 0 | 24 (72.7) |
| Hypertriglyceridaemia | 10 (30.3) | 0 | 0 | 0 | 0 | 10 (30.3) |
| Decreased appetite | 5 (15.2) | 2 (6.1) | 0 | 0 | 0 | 7 (21.2) |
| Hypoalbuminaemia | 7 (21.2) | 0 | 0 | 0 | 0 | 7 (21.2) |
| Hypoproteinaemia | 4 (12.1) | 1 (3.0) | 0 | 0 | 0 | 5 (15.2) |
| Hyperlipidaemia | 2 (6.1) | 2 (6.1) | 0 | 0 | 0 | 4 (12.1) |
| Hypercholesterolaemia | 2 (6.1) | 0 | 0 | 0 | 0 | 2 (6.1) |
| Hyponatraemia | 2 (6.1) | 0 | 0 | 0 | 0 | 2 (6.1) |
| Hypochloraemia | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Hypokalaemia | 0 | 1 (3.0) | 0 | 0 | 0 | 1 (3.0) |
|  | | | | | | |
| General disorders and administration site conditions | 14 (42.4) | 9 (27.3) | 0 | 0 | 0 | 23 (69.7) |
| Oedema peripheral | 8 (24.2) | 5 (15.2) | 0 | 0 | 0 | 13 (39.4) |
| Fatigue | 8 (24.2) | 0 | 0 | 0 | 0 | 8 (24.2) |
| Peripheral swelling | 2 (6.1) | 4 (12.1) | 0 | 0 | 0 | 6 (18.2) |
| Face oedema | 2 (6.1) | 1 (3.0) | 0 | 0 | 0 | 3 (9.1) |
| Malaise | 3 (9.1) | 0 | 0 | 0 | 0 | 3 (9.1) |
| Asthenia | 2 (6.1) | 0 | 0 | 0 | 0 | 2 (6.1) |
| Induration | 2 (6.1) | 0 | 0 | 0 | 0 | 2 (6.1) |
| Discomfort | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Nodule | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Non-pitting oedema | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Swelling face | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
|  | | | | | | |
| Renal and urinary disorders | 9 (27.3) | 11 (33.3) | 2 (6.1) | 0 | 0 | 22 (66.7) |
| Proteinuria | 7 (21.2) | 11 (33.3) | 2 (6.1) | 0 | 0 | 20 (60.6) |
| Haematuria | 6 (18.2) | 0 | 0 | 0 | 0 | 6 (18.2) |
| Albuminuria | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
|  | | | | | | |
| Gastrointestinal disorders | 11 (33.3) | 7 (21.2) | 3 (9.1) | 0 | 0 | 21 (63.6) |
| Diarrhoea | 11 (33.3) | 6 (18.2) | 2 (6.1) | 0 | 0 | 19 (57.6) |
| Nausea | 4 (12.1) | 1 (3.0) | 0 | 0 | 0 | 5 (15.2) |
| Abdominal discomfort | 2 (6.1) | 0 | 0 | 0 | 0 | 2 (6.1) |
| Abdominal distension | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Abdominal pain | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Abdominal pain upper | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Enteritis | 0 | 0 | 1 (3.0) | 0 | 0 | 1 (3.0) |
| Stomatitis | 0 | 1 (3.0) | 0 | 0 | 0 | 1 (3.0) |
| Vomiting | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
|  | | | | | | |
| Investigations | 18 (54.5) | 3 (9.1) | 0 | 0 | 0 | 21 (63.6) |
| Alanine aminotransferase increased | 9 (27.3) | 0 | 0 | 0 | 0 | 9 (27.3) |
| Aspartate aminotransferase increased | 8 (24.2) | 0 | 0 | 0 | 0 | 8 (24.2) |
| Gamma-glutamyltransferase increased | 4 (12.1) | 3 (9.1) | 0 | 0 | 0 | 7 (21.2) |
| Blood bilirubin increased | 2 (6.1) | 1 (3.0) | 0 | 0 | 0 | 3 (9.1) |
| Electrocardiogram PR prolongation | 3 (9.1) | 0 | 0 | 0 | 0 | 3 (9.1) |
| Urinary occult blood positive | 3 (9.1) | 0 | 0 | 0 | 0 | 3 (9.1) |
| Bilirubin conjugated increased | 2 (6.1) | 0 | 0 | 0 | 0 | 2 (6.1) |
| Blood alkaline phosphatase increased | 2 (6.1) | 0 | 0 | 0 | 0 | 2 (6.1) |
| C-reactive protein increased | 2 (6.1) | 0 | 0 | 0 | 0 | 2 (6.1) |
| Total bile acids increased | 1 (3.0) | 1 (3.0) | 0 | 0 | 0 | 2 (6.1) |
| Weight decreased | 1 (3.0) | 1 (3.0) | 0 | 0 | 0 | 2 (6.1) |
| Blood bilirubin unconjugated increased | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Blood cholesterol increased | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Blood creatine phosphokinase decreased | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Blood creatine phosphokinase increased | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Blood creatinine increased | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Blood pressure increased | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Cystatin C increased | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Electrocardiogram QT prolonged | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Electrocardiogram ST segment depression | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Fibrin D dimer increased | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Glucose urine present | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Lipoprotein increased | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Lymphocyte count decreased | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Neutrophil count increased | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Protein urine present | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Weight increased | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| White blood cell count increased | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
|  | | | | | | |
| Musculoskeletal and connective tissue disorders | 7 (21.2) | 6 (18.2) | 0 | 0 | 0 | 13 (39.4) |
| Arthralgia | 4 (12.1) | 0 | 0 | 0 | 0 | 4 (12.1) |
| Musculoskeletal stiffness | 1 (3.0) | 3 (9.1) | 0 | 0 | 0 | 4 (12.1) |
| Myalgia | 2 (6.1) | 0 | 0 | 0 | 0 | 2 (6.1) |
| Pain in extremity | 1 (3.0) | 1 (3.0) | 0 | 0 | 0 | 2 (6.1) |
| Arthritis | 0 | 1 (3.0) | 0 | 0 | 0 | 1 (3.0) |
| Back pain | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Joint range of motion decreased | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Joint swelling | 0 | 1 (3.0) | 0 | 0 | 0 | 1 (3.0) |
| Limb discomfort | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Neck pain | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Osteoarthritis | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
|  | | | | | | |
| Nervous system disorders | 9 (27.3) | 4 (12.1) | 0 | 0 | 0 | 13 (39.4) |
| Hypoaesthesia | 5 (15.2) | 3 (9.1) | 0 | 0 | 0 | 8 (24.2) |
| Motor dysfunction | 2 (6.1) | 0 | 0 | 0 | 0 | 2 (6.1) |
| Paraesthesia | 2 (6.1) | 0 | 0 | 0 | 0 | 2 (6.1) |
| Anaesthesia | 0 | 1 (3.0) | 0 | 0 | 0 | 1 (3.0) |
| Dizziness | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Neuropathy peripheral | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
|  | | | | | | |
| Blood and lymphatic system disorders | 9 (27.3) | 1 (3.0) | 0 | 0 | 0 | 10 (30.3) |
| Anaemia | 9 (27.3) | 0 | 0 | 0 | 0 | 9 (27.3) |
| Bone marrow oedema | 0 | 1 (3.0) | 0 | 0 | 0 | 1 (3.0) |
|  | | | | | | |
| Skin and subcutaneous tissue disorders | 8 (24.2) | 1 (3.0) | 0 | 0 | 0 | 9 (27.3) |
| Pruritus | 4 (12.1) | 1 (3.0) | 0 | 0 | 0 | 5 (15.2) |
| Rash | 3 (9.1) | 0 | 0 | 0 | 0 | 3 (9.1) |
| Pain of skin | 2 (6.1) | 0 | 0 | 0 | 0 | 2 (6.1) |
| Drug eruption | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Erythema | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Skin mass | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
|  | | | | | | |
| Cardiac disorders | 8 (24.2) | 0 | 0 | 0 | 0 | 8 (24.2) |
| Sinus bradycardia | 3 (9.1) | 0 | 0 | 0 | 0 | 3 (9.1) |
| Supraventricular extrasystoles | 2 (6.1) | 0 | 0 | 0 | 0 | 2 (6.1) |
| Arrhythmia | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Atrioventricular block second degree | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Supraventricular tachycardia | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Ventricular extrasystoles | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
|  | | | | | | |
| Eye disorders | 5 (15.2) | 1 (3.0) | 0 | 0 | 0 | 6 (18.2) |
| Cataract | 1 (3.0) | 1 (3.0) | 0 | 0 | 0 | 2 (6.1) |
| Dry eye | 0 | 1 (3.0) | 0 | 0 | 0 | 1 (3.0) |
| Eye oedema | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Glaucoma | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Macular degeneration | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Optic atrophy | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Periorbital swelling | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Retinal haemorrhage | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Vision blurred | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Vitreous opacities | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
|  | | | | | | |
| Vascular disorders | 0 | 5 (15.2) | 1 (3.0) | 0 | 0 | 6 (18.2) |
| Hypertension | 0 | 2 (6.1) | 1 (3.0) | 0 | 0 | 3 (9.1) |
| Arteriosclerosis | 0 | 2 (6.1) | 0 | 0 | 0 | 2 (6.1) |
| Venous thrombosis | 0 | 1 (3.0) | 0 | 0 | 0 | 1 (3.0) |
|  | | | | | | |
| Reproductive system and breast disorders | 3 (9.1) | 1 (3.0) | 0 | 0 | 0 | 4 (12.1) |
| Gynaecomastia | 2 (6.1) | 1 (3.0) | 0 | 0 | 0 | 3 (9.1) |
| Breast hyperplasia | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Breast mass | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
|  | | | | | | |
| Infections and infestations | 3 (9.1) | 0 | 0 | 0 | 0 | 3 (9.1) |
| Conjunctivitis | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Herpes virus infection | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Upper respiratory tract infection | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
|  | | | | | | |
| Hepatobiliary disorders | 1 (3.0) | 0 | 1 (3.0) | 0 | 0 | 2 (6.1) |
| Hepatic function abnormal | 1 (3.0) | 0 | 1 (3.0) | 0 | 0 | 2 (6.1) |
|  | | | | | | |
| Respiratory, thoracic and mediastinal disorders | 2 (6.1) | 0 | 0 | 0 | 0 | 2 (6.1) |
| Cough | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Dyspnoea | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
|  | | | | | | |
| Endocrine disorders | 0 | 1 (3.0) | 0 | 0 | 0 | 1 (3.0) |
| Endocrine disorder | 0 | 1 (3.0) | 0 | 0 | 0 | 1 (3.0) |

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 14.3.1.3.4.10 Summary of IN10018 Related TEAEs by Grouped SOC and Grouped PT and Severity - Phase II part 1 treatment-naive locally-advanced or metastatic NSCLC (Safety Analysis Set)**

|  | Total (N = 33) n (%) | | | | | |
| --- | --- | --- | --- | --- | --- | --- |
| System Organ Class  Preferred Term | Grade 1 | Grade 2 | Grade 3 | Grade 4 | Grade 5 | Total |
| All TEAEs | 7 (21.2) | 20 (60.6) | 6 (18.2) | 0 | 0 | 33 (100) |
|  | | | | | | |
| Metabolism and nutrition disorders# | 19 (57.6) | 6 (18.2) | 0 | 0 | 0 | 25 (75.8) |
| Hypertriglyceridaemia | 10 (30.3) | 0 | 0 | 0 | 0 | 10 (30.3) |
| Decreased appetite | 5 (15.2) | 2 (6.1) | 0 | 0 | 0 | 7 (21.2) |
| Hypoalbuminaemia | 7 (21.2) | 0 | 0 | 0 | 0 | 7 (21.2) |
| Hypoproteinaemia\* | 4 (12.1) | 1 (3.0) | 0 | 0 | 0 | 5 (15.2) |
| Hyperlipidaemia | 2 (6.1) | 2 (6.1) | 0 | 0 | 0 | 4 (12.1) |
| Hypercholesterolaemia\* | 3 (9.1) | 0 | 0 | 0 | 0 | 3 (9.1) |
| Hyponatraemia | 2 (6.1) | 0 | 0 | 0 | 0 | 2 (6.1) |
| Hypochloraemia | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Hypokalaemia | 0 | 1 (3.0) | 0 | 0 | 0 | 1 (3.0) |
|  | | | | | | |
| General disorders and administration site conditions# | 14 (42.4) | 9 (27.3) | 0 | 0 | 0 | 23 (69.7) |
| Oedema peripheral\* | 10 (30.3) | 9 (27.3) | 0 | 0 | 0 | 19 (57.6) |
| Fatigue\* | 10 (30.3) | 0 | 0 | 0 | 0 | 10 (30.3) |
| Face oedema | 2 (6.1) | 1 (3.0) | 0 | 0 | 0 | 3 (9.1) |
| Malaise | 3 (9.1) | 0 | 0 | 0 | 0 | 3 (9.1) |
| Induration | 2 (6.1) | 0 | 0 | 0 | 0 | 2 (6.1) |
| Discomfort | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Nodule | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Swelling face | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
|  | | | | | | |
| Renal and urinary disorders# | 10 (30.3) | 11 (33.3) | 2 (6.1) | 0 | 0 | 23 (69.7) |
| Proteinuria\* | 9 (27.3) | 11 (33.3) | 2 (6.1) | 0 | 0 | 22 (66.7) |
| Haematuria\* | 6 (18.2) | 0 | 0 | 0 | 0 | 6 (18.2) |
|  | | | | | | |
| Gastrointestinal disorders | 11 (33.3) | 7 (21.2) | 3 (9.1) | 0 | 0 | 21 (63.6) |
| Diarrhoea | 11 (33.3) | 6 (18.2) | 2 (6.1) | 0 | 0 | 19 (57.6) |
| Nausea | 4 (12.1) | 1 (3.0) | 0 | 0 | 0 | 5 (15.2) |
| Abdominal discomfort | 2 (6.1) | 0 | 0 | 0 | 0 | 2 (6.1) |
| Abdominal distension | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Abdominal pain | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Abdominal pain upper | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Enteritis | 0 | 0 | 1 (3.0) | 0 | 0 | 1 (3.0) |
| Stomatitis | 0 | 1 (3.0) | 0 | 0 | 0 | 1 (3.0) |
| Vomiting | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
|  | | | | | | |
| Investigations | 17 (51.5) | 3 (9.1) | 0 | 0 | 0 | 20 (60.6) |
| Alanine aminotransferase increased | 9 (27.3) | 0 | 0 | 0 | 0 | 9 (27.3) |
| Aspartate aminotransferase increased | 8 (24.2) | 0 | 0 | 0 | 0 | 8 (24.2) |
| Gamma-glutamyltransferase increased | 4 (12.1) | 3 (9.1) | 0 | 0 | 0 | 7 (21.2) |
| Blood bilirubin increased | 2 (6.1) | 1 (3.0) | 0 | 0 | 0 | 3 (9.1) |
| Electrocardiogram PR prolongation | 3 (9.1) | 0 | 0 | 0 | 0 | 3 (9.1) |
| Urinary occult blood positive | 3 (9.1) | 0 | 0 | 0 | 0 | 3 (9.1) |
| Bilirubin conjugated increased | 2 (6.1) | 0 | 0 | 0 | 0 | 2 (6.1) |
| Blood alkaline phosphatase increased | 2 (6.1) | 0 | 0 | 0 | 0 | 2 (6.1) |
| C-reactive protein increased | 2 (6.1) | 0 | 0 | 0 | 0 | 2 (6.1) |
| Total bile acids increased | 1 (3.0) | 1 (3.0) | 0 | 0 | 0 | 2 (6.1) |
| Weight decreased | 1 (3.0) | 1 (3.0) | 0 | 0 | 0 | 2 (6.1) |
| Blood bilirubin unconjugated increased | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Blood creatine phosphokinase decreased | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Blood creatine phosphokinase increased | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Blood creatinine increased | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Blood pressure increased | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Cystatin C increased | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Electrocardiogram QT prolonged | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Electrocardiogram ST segment depression | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Fibrin D dimer increased | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Glucose urine present | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Lipoprotein increased | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Lymphocyte count decreased | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Neutrophil count increased | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Weight increased | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
|  | | | | | | |
| Musculoskeletal and connective tissue disorders | 7 (21.2) | 6 (18.2) | 0 | 0 | 0 | 13 (39.4) |
| Arthralgia | 4 (12.1) | 0 | 0 | 0 | 0 | 4 (12.1) |
| Musculoskeletal stiffness | 1 (3.0) | 3 (9.1) | 0 | 0 | 0 | 4 (12.1) |
| Myalgia | 2 (6.1) | 0 | 0 | 0 | 0 | 2 (6.1) |
| Pain in extremity | 1 (3.0) | 1 (3.0) | 0 | 0 | 0 | 2 (6.1) |
| Arthritis | 0 | 1 (3.0) | 0 | 0 | 0 | 1 (3.0) |
| Back pain | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Joint range of motion decreased | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Joint swelling | 0 | 1 (3.0) | 0 | 0 | 0 | 1 (3.0) |
| Limb discomfort | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Neck pain | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Osteoarthritis | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
|  | | | | | | |
| Nervous system disorders | 9 (27.3) | 4 (12.1) | 0 | 0 | 0 | 13 (39.4) |
| Hypoaesthesia | 5 (15.2) | 3 (9.1) | 0 | 0 | 0 | 8 (24.2) |
| Motor dysfunction | 2 (6.1) | 0 | 0 | 0 | 0 | 2 (6.1) |
| Paraesthesia | 2 (6.1) | 0 | 0 | 0 | 0 | 2 (6.1) |
| Anaesthesia | 0 | 1 (3.0) | 0 | 0 | 0 | 1 (3.0) |
| Dizziness | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Neuropathy peripheral | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
|  | | | | | | |
| Blood and lymphatic system disorders# | 9 (27.3) | 1 (3.0) | 0 | 0 | 0 | 10 (30.3) |
| Anaemia | 9 (27.3) | 0 | 0 | 0 | 0 | 9 (27.3) |
| Bone marrow oedema | 0 | 1 (3.0) | 0 | 0 | 0 | 1 (3.0) |
| Leukocytosis\* | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
|  | | | | | | |
| Skin and subcutaneous tissue disorders | 8 (24.2) | 1 (3.0) | 0 | 0 | 0 | 9 (27.3) |
| Pruritus | 4 (12.1) | 1 (3.0) | 0 | 0 | 0 | 5 (15.2) |
| Rash | 3 (9.1) | 0 | 0 | 0 | 0 | 3 (9.1) |
| Pain of skin | 2 (6.1) | 0 | 0 | 0 | 0 | 2 (6.1) |
| Drug eruption | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Erythema | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Skin mass | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
|  | | | | | | |
| Cardiac disorders | 8 (24.2) | 0 | 0 | 0 | 0 | 8 (24.2) |
| Sinus bradycardia | 3 (9.1) | 0 | 0 | 0 | 0 | 3 (9.1) |
| Supraventricular extrasystoles | 2 (6.1) | 0 | 0 | 0 | 0 | 2 (6.1) |
| Arrhythmia | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Atrioventricular block second degree | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Supraventricular tachycardia | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Ventricular extrasystoles | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
|  | | | | | | |
| Eye disorders | 5 (15.2) | 1 (3.0) | 0 | 0 | 0 | 6 (18.2) |
| Cataract | 1 (3.0) | 1 (3.0) | 0 | 0 | 0 | 2 (6.1) |
| Dry eye | 0 | 1 (3.0) | 0 | 0 | 0 | 1 (3.0) |
| Eye oedema | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Glaucoma | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Macular degeneration | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Optic atrophy | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Periorbital swelling | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Retinal haemorrhage | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Vision blurred | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Vitreous opacities | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
|  | | | | | | |
| Vascular disorders | 0 | 5 (15.2) | 1 (3.0) | 0 | 0 | 6 (18.2) |
| Hypertension | 0 | 2 (6.1) | 1 (3.0) | 0 | 0 | 3 (9.1) |
| Arteriosclerosis | 0 | 2 (6.1) | 0 | 0 | 0 | 2 (6.1) |
| Venous thrombosis | 0 | 1 (3.0) | 0 | 0 | 0 | 1 (3.0) |
|  | | | | | | |
| Reproductive system and breast disorders | 3 (9.1) | 1 (3.0) | 0 | 0 | 0 | 4 (12.1) |
| Gynaecomastia | 2 (6.1) | 1 (3.0) | 0 | 0 | 0 | 3 (9.1) |
| Breast hyperplasia | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Breast mass | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
|  | | | | | | |
| Infections and infestations | 3 (9.1) | 0 | 0 | 0 | 0 | 3 (9.1) |
| Conjunctivitis | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Herpes virus infection | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Upper respiratory tract infection | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
|  | | | | | | |
| Hepatobiliary disorders | 1 (3.0) | 0 | 1 (3.0) | 0 | 0 | 2 (6.1) |
| Hepatic function abnormal | 1 (3.0) | 0 | 1 (3.0) | 0 | 0 | 2 (6.1) |
|  | | | | | | |
| Respiratory, thoracic and mediastinal disorders | 2 (6.1) | 0 | 0 | 0 | 0 | 2 (6.1) |
| Cough | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
| Dyspnoea | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
|  | | | | | | |
| Endocrine disorders | 0 | 1 (3.0) | 0 | 0 | 0 | 1 (3.0) |
| Endocrine disorder | 0 | 1 (3.0) | 0 | 0 | 0 | 1 (3.0) |

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 14.3.1.4.1.2 Summary of CTCAE Grade 3/4 TEAEs by SOC and PT - Phase II part 1 treatment-naive locally-advanced or metastatic NSCLC (Safety Analysis Set)**

| System Organ Class  Preferred Term | Treatment-naive locally-advanced or metastatic NSCLC (N = 33) n (%) |
| --- | --- |
| CTCAE Grade 3/4 TEAEs | 9 (27.3) |
|  | |
| Gastrointestinal disorders | 3 (9.1) |
| Diarrhoea | 2 (6.1) |
| Enteritis | 1 (3.0) |
|  | |
| Infections and infestations | 3 (9.1) |
| Pneumonia | 2 (6.1) |
| Lower respiratory tract infection | 1 (3.0) |
|  | |
| Renal and urinary disorders | 2 (6.1) |
| Proteinuria | 2 (6.1) |
|  | |
| Blood and lymphatic system disorders | 1 (3.0) |
| Anaemia | 1 (3.0) |
|  | |
| Hepatobiliary disorders | 1 (3.0) |
| Hepatic function abnormal | 1 (3.0) |
|  | |
| Investigations | 1 (3.0) |
| C-reactive protein increased | 1 (3.0) |
|  | |
| Metabolism and nutrition disorders | 1 (3.0) |
| Hypokalaemia | 1 (3.0) |
|  | |
| Respiratory, thoracic and mediastinal disorders | 1 (3.0) |
| Chronic obstructive pulmonary disease | 1 (3.0) |
|  | |
| Vascular disorders | 1 (3.0) |
| Hypertension | 1 (3.0) |

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 14.3.1.4.1.4 Summary of CTCAE Grade 3/4 TEAEs by Grouped SOC and Grouped PT - Phase II part 1 treatment-naive locally-advanced or metastatic NSCLC (Safety Analysis Set)**

| System Organ Class  Preferred Term | Treatment-naive locally-advanced or metastatic NSCLC (N = 33) n (%) |
| --- | --- |
| CTCAE Grade 3/4 TEAEs | 9 (27.3) |
|  | |
| Gastrointestinal disorders | 3 (9.1) |
| Diarrhoea | 2 (6.1) |
| Enteritis | 1 (3.0) |
|  | |
| Infections and infestations | 3 (9.1) |
| Pneumonia | 2 (6.1) |
| Lower respiratory tract infection | 1 (3.0) |
|  | |
| Renal and urinary disorders# | 2 (6.1) |
| Proteinuria\* | 2 (6.1) |
|  | |
| Blood and lymphatic system disorders# | 1 (3.0) |
| Anaemia | 1 (3.0) |
|  | |
| Hepatobiliary disorders | 1 (3.0) |
| Hepatic function abnormal | 1 (3.0) |
|  | |
| Investigations | 1 (3.0) |
| C-reactive protein increased | 1 (3.0) |
|  | |
| Metabolism and nutrition disorders# | 1 (3.0) |
| Hypokalaemia | 1 (3.0) |
|  | |
| Respiratory, thoracic and mediastinal disorders | 1 (3.0) |
| Chronic obstructive pulmonary disease | 1 (3.0) |
|  | |
| Vascular disorders | 1 (3.0) |
| Hypertension | 1 (3.0) |

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 14.3.1.4.2.2 Summary of D-1553 Related CTCAE Grade 3/4 TEAEs by SOC and PT - Phase II part 1 treatment-naive locally-advanced or metastatic NSCLC (Safety Analysis Set)**

| System Organ Class  Preferred Term | Treatment-naive locally-advanced or metastatic NSCLC (N = 33) n (%) |
| --- | --- |
| D-1553 Related CTCAE Grade 3/4 TEAEs | 6 (18.2) |
|  | |
| Gastrointestinal disorders | 3 (9.1) |
| Diarrhoea | 2 (6.1) |
| Enteritis | 1 (3.0) |
|  | |
| Renal and urinary disorders | 2 (6.1) |
| Proteinuria | 2 (6.1) |
|  | |
| Hepatobiliary disorders | 1 (3.0) |
| Hepatic function abnormal | 1 (3.0) |
|  | |
| Vascular disorders | 1 (3.0) |
| Hypertension | 1 (3.0) |

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.

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 14.3.1.4.2.4 Summary of D-1553 Related CTCAE Grade 3/4 TEAEs by Grouped SOC and Grouped PT - Phase II part 1 treatment-naive locally-advanced or metastatic NSCLC (Safety Analysis Set)**

| System Organ Class  Preferred Term | Treatment-naive locally-advanced or metastatic NSCLC (N = 33) n (%) |
| --- | --- |
| D-1553 Related CTCAE Grade 3/4 TEAEs | 6 (18.2) |
|  | |
| Gastrointestinal disorders | 3 (9.1) |
| Diarrhoea | 2 (6.1) |
| Enteritis | 1 (3.0) |
|  | |
| Renal and urinary disorders# | 2 (6.1) |
| Proteinuria\* | 2 (6.1) |
|  | |
| Hepatobiliary disorders | 1 (3.0) |
| Hepatic function abnormal | 1 (3.0) |
|  | |
| Vascular disorders | 1 (3.0) |
| Hypertension | 1 (3.0) |

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.

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 14.3.1.4.2.8 Summary of IN10018 Related CTCAE Grade 3/4 TEAEs by SOC and PT - Phase II part 1 treatment-naive locally-advanced or metastatic NSCLC (Safety Analysis Set)**

| System Organ Class  Preferred Term | Treatment-naive locally-advanced or metastatic NSCLC (N = 33) n (%) |
| --- | --- |
| IN10018 Related CTCAE Grade 3/4 TEAEs | 6 (18.2) |
|  | |
| Gastrointestinal disorders | 3 (9.1) |
| Diarrhoea | 2 (6.1) |
| Enteritis | 1 (3.0) |
|  | |
| Renal and urinary disorders | 2 (6.1) |
| Proteinuria | 2 (6.1) |
|  | |
| Hepatobiliary disorders | 1 (3.0) |
| Hepatic function abnormal | 1 (3.0) |
|  | |
| Vascular disorders | 1 (3.0) |
| Hypertension | 1 (3.0) |

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

|  |  |  |
| --- | --- | --- |
| 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 14.3.1.4.2.10 Summary of IN10018 Related CTCAE Grade 3/4 TEAEs by Grouped SOC and Grouped PT - Phase II part 1 treatment-naive locally-advanced or metastatic NSCLC (Safety Analysis Set)**

| System Organ Class  Preferred Term | Treatment-naive locally-advanced or metastatic NSCLC (N = 33) n (%) |
| --- | --- |
| IN10018 Related CTCAE Grade 3/4 TEAEs | 6 (18.2) |
|  | |
| Gastrointestinal disorders | 3 (9.1) |
| Diarrhoea | 2 (6.1) |
| Enteritis | 1 (3.0) |
|  | |
| Renal and urinary disorders# | 2 (6.1) |
| Proteinuria\* | 2 (6.1) |
|  | |
| Hepatobiliary disorders | 1 (3.0) |
| Hepatic function abnormal | 1 (3.0) |
|  | |
| Vascular disorders | 1 (3.0) |
| Hypertension | 1 (3.0) |

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 14.3.1.5.1.2 Summary of TEAEs Leading to D-1553 Dose Reduction by SOC and PT - Phase II part 1 treatment-naive locally-advanced or metastatic NSCLC (Safety Analysis Set)**

| System Organ Class  Preferred Term | Treatment-naive locally-advanced or metastatic NSCLC (N = 33) n (%) |
| --- | --- |
| TEAEs Leading to D-1553 Dose Reduction | 1 (3.0) |
|  | |
| Gastrointestinal disorders | 1 (3.0) |
| Diarrhoea | 1 (3.0) |

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 14.3.1.5.1.4 Summary of TEAEs Leading to D-1553 Dose Reduction by Grouped SOC and Grouped PT - Phase II part 1 treatment-naive locally-advanced or metastatic NSCLC (Safety Analysis Set)**

| System Organ Class  Preferred Term | Treatment-naive locally-advanced or metastatic NSCLC (N = 33) n (%) |
| --- | --- |
| TEAEs Leading to D-1553 Dose Reduction | 1 (3.0) |
|  | |
| Gastrointestinal disorders | 1 (3.0) |
| Diarrhoea | 1 (3.0) |

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 14.3.1.5.1.8 Summary of TEAEs Leading to IN10018 Dose Reduction by SOC and PT - Phase II part 1 treatment-naive locally-advanced or metastatic NSCLC (Safety Analysis Set)**

| System Organ Class  Preferred Term | Treatment-naive locally-advanced or metastatic NSCLC (N = 33) n (%) |
| --- | --- |
| TEAEs Leading to IN10018 Dose Reduction | 5 (15.2) |
|  | |
| Renal and urinary disorders | 3 (9.1) |
| Proteinuria | 3 (9.1) |
|  | |
| Gastrointestinal disorders | 1 (3.0) |
| Diarrhoea | 1 (3.0) |
|  | |
| General disorders and administration site conditions | 1 (3.0) |
| Oedema peripheral | 1 (3.0) |

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 14.3.1.5.1.10 Summary of TEAEs Leading to IN10018 Dose Reduction by Grouped SOC and Grouped PT - Phase II part 1 treatment-naive locally-advanced or metastatic NSCLC (Safety Analysis Set)**

| System Organ Class  Preferred Term | Treatment-naive locally-advanced or metastatic NSCLC (N = 33) n (%) |
| --- | --- |
| TEAEs Leading to IN10018 Dose Reduction | 5 (15.2) |
|  | |
| Renal and urinary disorders# | 3 (9.1) |
| Proteinuria\* | 3 (9.1) |
|  | |
| Gastrointestinal disorders | 1 (3.0) |
| Diarrhoea | 1 (3.0) |
|  | |
| General disorders and administration site conditions# | 1 (3.0) |
| Oedema peripheral\* | 1 (3.0) |

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 14.3.1.5.2.2 Summary of D-1553 Related TEAEs Leading to D-1553 Dose Reduction by SOC and PT - Phase II part 1 treatment-naive locally-advanced or metastatic NSCLC (Safety Analysis Set)**

| System Organ Class  Preferred Term | Treatment-naive locally-advanced or metastatic NSCLC (N = 33) n (%) |
| --- | --- |
| D-1553 Related TEAEs Leading to D-1553 Dose Reduction | 1 (3.0) |
|  | |
| Gastrointestinal disorders | 1 (3.0) |
| Diarrhoea | 1 (3.0) |

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 14.3.1.5.2.4 Summary of D-1553 Related TEAEs Leading to D-1553 Dose Reduction by Grouped SOC and Grouped PT - Phase II part 1 treatment-naive locally-advanced or metastatic NSCLC (Safety Analysis Set)**

| System Organ Class  Preferred Term | Treatment-naive locally-advanced or metastatic NSCLC (N = 33) n (%) |
| --- | --- |
| D-1553 Related TEAEs Leading to D-1553 Dose Reduction | 1 (3.0) |
|  | |
| Gastrointestinal disorders | 1 (3.0) |
| Diarrhoea | 1 (3.0) |

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 14.3.1.5.2.8 Summary of IN10018 Related TEAEs Leading to IN10018 Dose Reduction by SOC and PT - Phase II part 1 treatment-naive locally-advanced or metastatic NSCLC (Safety Analysis Set)**

| System Organ Class  Preferred Term | Treatment-naive locally-advanced or metastatic NSCLC (N = 33) n (%) |
| --- | --- |
| IN10018 Related TEAEs Leading to IN10018 Dose Reduction | 5 (15.2) |
|  | |
| Renal and urinary disorders | 3 (9.1) |
| Proteinuria | 3 (9.1) |
|  | |
| Gastrointestinal disorders | 1 (3.0) |
| Diarrhoea | 1 (3.0) |
|  | |
| General disorders and administration site conditions | 1 (3.0) |
| Oedema peripheral | 1 (3.0) |

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 14.3.1.5.2.10 Summary of IN10018 Related TEAEs Leading to IN10018 Dose Reduction by Grouped SOC and Grouped PT - Phase II part 1 treatment-naive locally-advanced or metastatic NSCLC (Safety Analysis Set)**

| System Organ Class  Preferred Term | Treatment-naive locally-advanced or metastatic NSCLC (N = 33) n (%) |
| --- | --- |
| IN10018 Related TEAEs Leading to IN10018 Dose Reduction | 5 (15.2) |
|  | |
| Renal and urinary disorders# | 3 (9.1) |
| Proteinuria\* | 3 (9.1) |
|  | |
| Gastrointestinal disorders | 1 (3.0) |
| Diarrhoea | 1 (3.0) |
|  | |
| General disorders and administration site conditions# | 1 (3.0) |
| Oedema peripheral\* | 1 (3.0) |

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 |

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

**Table 14.3.1.6.1.2 Summary of TEAEs Leading to D-1553 Drug Interruption by SOC and PT - Phase II part 1 treatment-naive locally-advanced or metastatic NSCLC (Safety Analysis Set)**

| System Organ Class  Preferred Term | Treatment-naive locally-advanced or metastatic NSCLC (N = 33) n (%) |
| --- | --- |
| TEAEs Leading to D-1553 Drug Interruption | 11 (33.3) |
|  | |
| General disorders and administration site conditions | 5 (15.2) |
| Oedema peripheral | 2 (6.1) |
| Peripheral swelling | 2 (6.1) |
| Face oedema | 1 (3.0) |
| Pyrexia | 1 (3.0) |
|  | |
| Gastrointestinal disorders | 3 (9.1) |
| Diarrhoea | 1 (3.0) |
| Enteritis | 1 (3.0) |
| Vomiting | 1 (3.0) |
|  | |
| Infections and infestations | 2 (6.1) |
| COVID-19 pneumonia | 1 (3.0) |
| Pneumonia | 1 (3.0) |
|  | |
| Nervous system disorders | 2 (6.1) |
| Haemorrhage intracranial | 1 (3.0) |
| Hypoaesthesia | 1 (3.0) |
|  | |
| Respiratory, thoracic and mediastinal disorders | 2 (6.1) |
| Cough | 1 (3.0) |
| Dyspnoea | 1 (3.0) |
|  | |
| Hepatobiliary disorders | 1 (3.0) |
| Hepatic function abnormal | 1 (3.0) |
|  | |
| Metabolism and nutrition disorders | 1 (3.0) |
| Decreased appetite | 1 (3.0) |
|  | |
| Musculoskeletal and connective tissue disorders | 1 (3.0) |
| Musculoskeletal stiffness | 1 (3.0) |
|  | |
| Renal and urinary disorders | 1 (3.0) |
| Proteinuria | 1 (3.0) |

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 14.3.1.6.1.4 Summary of TEAEs Leading to D-1553 Drug Interruption by Grouped SOC and Grouped PT - Phase II part 1 treatment-naive locally-advanced or metastatic NSCLC (Safety Analysis Set)**

| System Organ Class  Preferred Term | Treatment-naive locally-advanced or metastatic NSCLC (N = 33) n (%) |
| --- | --- |
| TEAEs Leading to D-1553 Drug Interruption | 11 (33.3) |
|  | |
| General disorders and administration site conditions# | 5 (15.2) |
| Oedema peripheral\* | 4 (12.1) |
| Face oedema | 1 (3.0) |
| Pyrexia | 1 (3.0) |
|  | |
| Gastrointestinal disorders | 3 (9.1) |
| Diarrhoea | 1 (3.0) |
| Enteritis | 1 (3.0) |
| Vomiting | 1 (3.0) |
|  | |
| Infections and infestations | 2 (6.1) |
| COVID-19 pneumonia | 1 (3.0) |
| Pneumonia | 1 (3.0) |
|  | |
| Nervous system disorders | 2 (6.1) |
| Haemorrhage intracranial | 1 (3.0) |
| Hypoaesthesia | 1 (3.0) |
|  | |
| Respiratory, thoracic and mediastinal disorders | 2 (6.1) |
| Cough | 1 (3.0) |
| Dyspnoea | 1 (3.0) |
|  | |
| Hepatobiliary disorders | 1 (3.0) |
| Hepatic function abnormal | 1 (3.0) |
|  | |
| Metabolism and nutrition disorders# | 1 (3.0) |
| Decreased appetite | 1 (3.0) |
|  | |
| Musculoskeletal and connective tissue disorders | 1 (3.0) |
| Musculoskeletal stiffness | 1 (3.0) |
|  | |
| Renal and urinary disorders# | 1 (3.0) |
| Proteinuria\* | 1 (3.0) |

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

**Table 14.3.1.6.1.8 Summary of TEAEs Leading to IN10018 Drug Interruption by SOC and PT - Phase II part 1 treatment-naive locally-advanced or metastatic NSCLC (Safety Analysis Set)**

| System Organ Class  Preferred Term | Treatment-naive locally-advanced or metastatic NSCLC (N = 33) n (%) |
| --- | --- |
| TEAEs Leading to IN10018 Drug Interruption | 17 (51.5) |
|  | |
| General disorders and administration site conditions | 8 (24.2) |
| Oedema peripheral | 4 (12.1) |
| Peripheral swelling | 2 (6.1) |
| Face oedema | 1 (3.0) |
| Pyrexia | 1 (3.0) |
| Swelling face | 1 (3.0) |
|  | |
| Renal and urinary disorders | 6 (18.2) |
| Proteinuria | 6 (18.2) |
|  | |
| Musculoskeletal and connective tissue disorders | 4 (12.1) |
| Musculoskeletal stiffness | 2 (6.1) |
| Arthralgia | 1 (3.0) |
| Joint swelling | 1 (3.0) |
| Pain in extremity | 1 (3.0) |
|  | |
| Nervous system disorders | 4 (12.1) |
| Hypoaesthesia | 2 (6.1) |
| Anaesthesia | 1 (3.0) |
| Haemorrhage intracranial | 1 (3.0) |
|  | |
| Gastrointestinal disorders | 3 (9.1) |
| Diarrhoea | 1 (3.0) |
| Enteritis | 1 (3.0) |
| Vomiting | 1 (3.0) |
|  | |
| Infections and infestations | 2 (6.1) |
| COVID-19 pneumonia | 1 (3.0) |
| Pneumonia | 1 (3.0) |
|  | |
| Respiratory, thoracic and mediastinal disorders | 2 (6.1) |
| Cough | 1 (3.0) |
| Dyspnoea | 1 (3.0) |
|  | |
| Hepatobiliary disorders | 1 (3.0) |
| Hepatic function abnormal | 1 (3.0) |
|  | |
| Metabolism and nutrition disorders | 1 (3.0) |
| Decreased appetite | 1 (3.0) |

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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**Table 14.3.1.6.1.10 Summary of TEAEs Leading to IN10018 Drug Interruption by Grouped SOC and Grouped PT - Phase II part 1 treatment-naive locally-advanced or metastatic NSCLC (Safety Analysis Set)**

| System Organ Class  Preferred Term | Treatment-naive locally-advanced or metastatic NSCLC (N = 33) n (%) |
| --- | --- |
| TEAEs Leading to IN10018 Drug Interruption | 17 (51.5) |
|  | |
| General disorders and administration site conditions# | 8 (24.2) |
| Oedema peripheral\* | 6 (18.2) |
| Face oedema | 1 (3.0) |
| Pyrexia | 1 (3.0) |
| Swelling face | 1 (3.0) |
|  | |
| Renal and urinary disorders# | 6 (18.2) |
| Proteinuria\* | 6 (18.2) |
|  | |
| Musculoskeletal and connective tissue disorders | 4 (12.1) |
| Musculoskeletal stiffness | 2 (6.1) |
| Arthralgia | 1 (3.0) |
| Joint swelling | 1 (3.0) |
| Pain in extremity | 1 (3.0) |
|  | |
| Nervous system disorders | 4 (12.1) |
| Hypoaesthesia | 2 (6.1) |
| Anaesthesia | 1 (3.0) |
| Haemorrhage intracranial | 1 (3.0) |
|  | |
| Gastrointestinal disorders | 3 (9.1) |
| Diarrhoea | 1 (3.0) |
| Enteritis | 1 (3.0) |
| Vomiting | 1 (3.0) |
|  | |
| Infections and infestations | 2 (6.1) |
| COVID-19 pneumonia | 1 (3.0) |
| Pneumonia | 1 (3.0) |
|  | |
| Respiratory, thoracic and mediastinal disorders | 2 (6.1) |
| Cough | 1 (3.0) |
| Dyspnoea | 1 (3.0) |
|  | |
| Hepatobiliary disorders | 1 (3.0) |
| Hepatic function abnormal | 1 (3.0) |
|  | |
| Metabolism and nutrition disorders# | 1 (3.0) |
| Decreased appetite | 1 (3.0) |

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

**Table 14.3.1.6.2.2 Summary of D-1553 Related TEAEs Leading to D-1553 Drug Interruption by SOC and PT - Phase II part 1 treatment-naive locally-advanced or metastatic NSCLC (Safety Analysis Set)**

| System Organ Class  Preferred Term | Treatment-naive locally-advanced or metastatic NSCLC (N = 33) n (%) |
| --- | --- |
| D-1553 Related TEAEs Leading to D-1553 Drug Interruption | 7 (21.2) |
|  | |
| General disorders and administration site conditions | 4 (12.1) |
| Oedema peripheral | 2 (6.1) |
| Peripheral swelling | 2 (6.1) |
| Face oedema | 1 (3.0) |
|  | |
| Gastrointestinal disorders | 3 (9.1) |
| Diarrhoea | 1 (3.0) |
| Enteritis | 1 (3.0) |
| Vomiting | 1 (3.0) |
|  | |
| Hepatobiliary disorders | 1 (3.0) |
| Hepatic function abnormal | 1 (3.0) |
|  | |
| Metabolism and nutrition disorders | 1 (3.0) |
| Decreased appetite | 1 (3.0) |
|  | |
| Musculoskeletal and connective tissue disorders | 1 (3.0) |
| Musculoskeletal stiffness | 1 (3.0) |
|  | |
| Nervous system disorders | 1 (3.0) |
| Hypoaesthesia | 1 (3.0) |
|  | |
| Renal and urinary disorders | 1 (3.0) |
| Proteinuria | 1 (3.0) |
|  | |
| Respiratory, thoracic and mediastinal disorders | 1 (3.0) |
| Dyspnoea | 1 (3.0) |

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

**Table 14.3.1.6.2.4 Summary of D-1553 Related TEAEs Leading to D-1553 Drug Interruption by Grouped SOC and Grouped PT - Phase II part 1 treatment-naive locally-advanced or metastatic NSCLC (Safety Analysis Set)**

| System Organ Class  Preferred Term | Treatment-naive locally-advanced or metastatic NSCLC (N = 33) n (%) |
| --- | --- |
| D-1553 Related TEAEs Leading to D-1553 Drug Interruption | 7 (21.2) |
|  | |
| General disorders and administration site conditions# | 4 (12.1) |
| Oedema peripheral\* | 4 (12.1) |
| Face oedema | 1 (3.0) |
|  | |
| Gastrointestinal disorders | 3 (9.1) |
| Diarrhoea | 1 (3.0) |
| Enteritis | 1 (3.0) |
| Vomiting | 1 (3.0) |
|  | |
| Hepatobiliary disorders | 1 (3.0) |
| Hepatic function abnormal | 1 (3.0) |
|  | |
| Metabolism and nutrition disorders# | 1 (3.0) |
| Decreased appetite | 1 (3.0) |
|  | |
| Musculoskeletal and connective tissue disorders | 1 (3.0) |
| Musculoskeletal stiffness | 1 (3.0) |
|  | |
| Nervous system disorders | 1 (3.0) |
| Hypoaesthesia | 1 (3.0) |
|  | |
| Renal and urinary disorders# | 1 (3.0) |
| Proteinuria\* | 1 (3.0) |
|  | |
| Respiratory, thoracic and mediastinal disorders | 1 (3.0) |
| Dyspnoea | 1 (3.0) |

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

**Table 14.3.1.6.2.8 Summary of IN10018 Related TEAEs Leading to IN10018 Drug Interruption by SOC and PT - Phase II part 1 treatment-naive locally-advanced or metastatic NSCLC (Safety Analysis Set)**

| System Organ Class  Preferred Term | Treatment-naive locally-advanced or metastatic NSCLC (N = 33) n (%) |
| --- | --- |
| IN10018 Related TEAEs Leading to IN10018 Drug Interruption | 15 (45.5) |
|  | |
| General disorders and administration site conditions | 7 (21.2) |
| Oedema peripheral | 4 (12.1) |
| Peripheral swelling | 2 (6.1) |
| Face oedema | 1 (3.0) |
| Swelling face | 1 (3.0) |
|  | |
| Renal and urinary disorders | 6 (18.2) |
| Proteinuria | 6 (18.2) |
|  | |
| Musculoskeletal and connective tissue disorders | 4 (12.1) |
| Musculoskeletal stiffness | 2 (6.1) |
| Arthralgia | 1 (3.0) |
| Joint swelling | 1 (3.0) |
| Pain in extremity | 1 (3.0) |
|  | |
| Gastrointestinal disorders | 3 (9.1) |
| Diarrhoea | 1 (3.0) |
| Enteritis | 1 (3.0) |
| Vomiting | 1 (3.0) |
|  | |
| Nervous system disorders | 3 (9.1) |
| Hypoaesthesia | 2 (6.1) |
| Anaesthesia | 1 (3.0) |
|  | |
| Hepatobiliary disorders | 1 (3.0) |
| Hepatic function abnormal | 1 (3.0) |
|  | |
| Metabolism and nutrition disorders | 1 (3.0) |
| Decreased appetite | 1 (3.0) |
|  | |
| Respiratory, thoracic and mediastinal disorders | 1 (3.0) |
| Dyspnoea | 1 (3.0) |

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 14.3.1.6.2.10 Summary of IN10018 Related TEAEs Leading to IN10018 Drug Interruption by Grouped SOC and Grouped PT - Phase II part 1 treatment-naive locally-advanced or metastatic NSCLC (Safety Analysis Set)**

| System Organ Class  Preferred Term | Treatment-naive locally-advanced or metastatic NSCLC (N = 33) n (%) |
| --- | --- |
| IN10018 Related TEAEs Leading to IN10018 Drug Interruption | 15 (45.5) |
|  | |
| General disorders and administration site conditions# | 7 (21.2) |
| Oedema peripheral\* | 6 (18.2) |
| Face oedema | 1 (3.0) |
| Swelling face | 1 (3.0) |
|  | |
| Renal and urinary disorders# | 6 (18.2) |
| Proteinuria\* | 6 (18.2) |
|  | |
| Musculoskeletal and connective tissue disorders | 4 (12.1) |
| Musculoskeletal stiffness | 2 (6.1) |
| Arthralgia | 1 (3.0) |
| Joint swelling | 1 (3.0) |
| Pain in extremity | 1 (3.0) |
|  | |
| Gastrointestinal disorders | 3 (9.1) |
| Diarrhoea | 1 (3.0) |
| Enteritis | 1 (3.0) |
| Vomiting | 1 (3.0) |
|  | |
| Nervous system disorders | 3 (9.1) |
| Hypoaesthesia | 2 (6.1) |
| Anaesthesia | 1 (3.0) |
|  | |
| Hepatobiliary disorders | 1 (3.0) |
| Hepatic function abnormal | 1 (3.0) |
|  | |
| Metabolism and nutrition disorders# | 1 (3.0) |
| Decreased appetite | 1 (3.0) |
|  | |
| Respiratory, thoracic and mediastinal disorders | 1 (3.0) |
| Dyspnoea | 1 (3.0) |

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

**Table 14.3.1.7.1.2 Summary of TEAEs Leading to D-1553 Drug Withdrawn by SOC and PT - Phase II part 1 treatment-naive locally-advanced or metastatic NSCLC (Safety Analysis Set)**

| System Organ Class  Preferred Term | Treatment-naive locally-advanced or metastatic NSCLC (N = 33) n (%) |
| --- | --- |
| TEAEs Leading to D-1553 Drug Withdrawn | 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 14.3.1.7.1.4 Summary of TEAEs Leading to D-1553 Drug Withdrawn by Grouped SOC and Grouped PT - Phase II part 1 treatment-naive locally-advanced or metastatic NSCLC (Safety Analysis Set)**

| System Organ Class  Preferred Term | Treatment-naive locally-advanced or metastatic NSCLC (N = 33) n (%) |
| --- | --- |
| TEAEs Leading to D-1553 Drug Withdrawn | 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 14.3.1.7.1.8 Summary of TEAEs Leading to IN10018 Drug Withdrawn by SOC and PT - Phase II part 1 treatment-naive locally-advanced or metastatic NSCLC (Safety Analysis Set)**

| System Organ Class  Preferred Term | Treatment-naive locally-advanced or metastatic NSCLC (N = 33) n (%) |
| --- | --- |
| TEAEs Leading to IN10018 Drug Withdrawn | 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 14.3.1.7.1.10 Summary of TEAEs Leading to IN10018 Drug Withdrawn by Grouped SOC and Grouped PT - Phase II part 1 treatment-naive locally-advanced or metastatic NSCLC (Safety Analysis Set)**

| System Organ Class  Preferred Term | Treatment-naive locally-advanced or metastatic NSCLC (N = 33) n (%) |
| --- | --- |
| TEAEs Leading to IN10018 Drug Withdrawn | 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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| **InxMed (Shanghai) Co., Ltd.  Protocol No. IN10018-602** |  |

**Table 14.3.1.7.2.2 Summary of D-1553 Related TEAEs Leading to D-1553 Drug Withdrawn by SOC and PT - Phase II part 1 treatment-naive locally-advanced or metastatic NSCLC (Safety Analysis Set)**

| System Organ Class  Preferred Term | Treatment-naive locally-advanced or metastatic NSCLC (N = 33) n (%) |
| --- | --- |
| D-1553 Related TEAEs Leading to D-1553 Drug Withdrawn | 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 14.3.1.7.2.4 Summary of D-1553 Related TEAEs Leading to D-1553 Drug Withdrawn by Grouped SOC and Grouped PT - Phase II part 1 treatment-naive locally-advanced or metastatic NSCLC (Safety Analysis Set)**

| System Organ Class  Preferred Term | Treatment-naive locally-advanced or metastatic NSCLC (N = 33) n (%) |
| --- | --- |
| D-1553 Related TEAEs Leading to D-1553 Drug Withdrawn | 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 14.3.1.7.2.8 Summary of IN10018 Related TEAEs Leading to IN10018 Drug Withdrawn by SOC and PT - Phase II part 1 treatment-naive locally-advanced or metastatic NSCLC (Safety Analysis Set)**

| System Organ Class  Preferred Term | Treatment-naive locally-advanced or metastatic NSCLC (N = 33) n (%) |
| --- | --- |
| IN10018 Related TEAEs Leading to IN10018 Drug Withdrawn | 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 14.3.1.7.2.10 Summary of IN10018 Related TEAEs Leading to IN10018 Drug Withdrawn by Grouped SOC and Grouped PT - Phase II part 1 treatment-naive locally-advanced or metastatic NSCLC (Safety Analysis Set)**

| System Organ Class  Preferred Term | Treatment-naive locally-advanced or metastatic NSCLC (N = 33) n (%) |
| --- | --- |
| IN10018 Related TEAEs Leading to IN10018 Drug Withdrawn | 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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| --- | --- | --- |
| 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 14.3.1.8.1.2 Summary of AESI by SOC and PT - Phase II part 1 treatment-naive locally-advanced or metastatic NSCLC (Safety Analysis Set)**

| System Organ Class  Preferred Term | Treatment-naive locally-advanced or metastatic NSCLC (N = 33) n (%) |
| --- | --- |
| All AESIs | 4 (12.1) |
|  | |
| Renal and urinary disorders | 4 (12.1) |
| Proteinuria | 4 (12.1) |

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 14.3.1.8.1.4 Summary of AESI by Grouped SOC and Grouped PT - Phase II part 1 treatment-naive locally-advanced or metastatic NSCLC (Safety Analysis Set)**

| System Organ Class  Preferred Term | Treatment-naive locally-advanced or metastatic NSCLC (N = 33) n (%) |
| --- | --- |
| All AESIs | 4 (12.1) |
|  | |
| Renal and urinary disorders# | 4 (12.1) |
| Proteinuria\* | 4 (12.1) |

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 14.3.1.8.2.2 Summary of AESI with CTCAE Grade 3/4 by SOC and PT - Phase II part 1 treatment-naive locally-advanced or metastatic NSCLC (Safety Analysis Set)**

| System Organ Class  Preferred Term | Treatment-naive locally-advanced or metastatic NSCLC (N = 33) n (%) |
| --- | --- |
| AESI with CTCAE Grade 3/4 | 1 (3.0) |
|  | |
| Renal and urinary disorders | 1 (3.0) |
| Proteinuria | 1 (3.0) |

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 14.3.1.8.2.4 Summary of AESI with CTCAE Grade 3/4 by Grouped SOC and Grouped PT - Phase II part 1 treatment-naive locally-advanced or metastatic NSCLC (Safety Analysis Set)**

| System Organ Class  Preferred Term | Treatment-naive locally-advanced or metastatic NSCLC (N = 33) n (%) |
| --- | --- |
| AESI with CTCAE Grade 3/4 | 1 (3.0) |
|  | |
| Renal and urinary disorders# | 1 (3.0) |
| Proteinuria\* | 1 (3.0) |

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

**Table 14.3.1.8.3.2 Summary of D-1553 Related AESI by SOC and PT - Phase II part 1 treatment-naive locally-advanced or metastatic NSCLC (Safety Analysis Set)**

| System Organ Class  Preferred Term | Treatment-naive locally-advanced or metastatic NSCLC (N = 33) n (%) |
| --- | --- |
| D-1553 Related AESI | 4 (12.1) |
|  | |
| Renal and urinary disorders | 4 (12.1) |
| Proteinuria | 4 (12.1) |

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 14.3.1.8.3.4 Summary of D-1553 Related AESI by Grouped SOC and Grouped PT - Phase II part 1 treatment-naive locally-advanced or metastatic NSCLC (Safety Analysis Set)**

| System Organ Class  Preferred Term | Treatment-naive locally-advanced or metastatic NSCLC (N = 33) n (%) |
| --- | --- |
| D-1553 Related AESI | 4 (12.1) |
|  | |
| Renal and urinary disorders# | 4 (12.1) |
| Proteinuria\* | 4 (12.1) |

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

**Table 14.3.1.8.4.2 Summary of IN10018 Related AESI by SOC and PT - Phase II part 1 treatment-naive locally-advanced or metastatic NSCLC (Safety Analysis Set)**

| System Organ Class  Preferred Term | Treatment-naive locally-advanced or metastatic NSCLC (N = 33) n (%) |
| --- | --- |
| IN10018 Related AESI | 4 (12.1) |
|  | |
| Renal and urinary disorders | 4 (12.1) |
| Proteinuria | 4 (12.1) |

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 14.3.1.8.4.4 Summary of IN10018 Related AESI by Grouped SOC and Grouped PT - Phase II part 1 treatment-naive locally-advanced or metastatic NSCLC (Safety Analysis Set)**

| System Organ Class  Preferred Term | Treatment-naive locally-advanced or metastatic NSCLC (N = 33) n (%) |
| --- | --- |
| IN10018 Related AESI | 4 (12.1) |
|  | |
| Renal and urinary disorders# | 4 (12.1) |
| Proteinuria\* | 4 (12.1) |

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 14.3.1.9.1.2 Summary of SAEs by SOC and PT - Phase II part 1 treatment-naive locally-advanced or metastatic NSCLC (Safety Analysis Set)**

| System Organ Class  Preferred Term | Treatment-naive locally-advanced or metastatic NSCLC (N = 33) n (%) |
| --- | --- |
| All SAEs | 7 (21.2) |
|  | |
| Infections and infestations | 6 (18.2) |
| Pneumonia | 2 (6.1) |
| Bronchitis | 1 (3.0) |
| COVID-19 | 1 (3.0) |
| COVID-19 pneumonia | 1 (3.0) |
| Lower respiratory tract infection | 1 (3.0) |
|  | |
| Gastrointestinal disorders | 2 (6.1) |
| Diarrhoea | 1 (3.0) |
| Enteritis | 1 (3.0) |
|  | |
| General disorders and administration site conditions | 1 (3.0) |
| Oedema peripheral | 1 (3.0) |
|  | |
| Nervous system disorders | 1 (3.0) |
| Haemorrhage intracranial | 1 (3.0) |
|  | |
| Renal and urinary disorders | 1 (3.0) |
| Proteinuria | 1 (3.0) |
|  | |
| Respiratory, thoracic and mediastinal disorders | 1 (3.0) |
| Chronic obstructive pulmonary disease | 1 (3.0) |

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 14.3.1.9.2.2 Summary of D-1553 Related SAEs by SOC and PT - Phase II part 1 treatment-naive locally-advanced or metastatic NSCLC (Safety Analysis Set)**

| System Organ Class  Preferred Term | Treatment-naive locally-advanced or metastatic NSCLC (N = 33) n (%) |
| --- | --- |
| D-1553 Related SAEs | 4 (12.1) |
|  | |
| Gastrointestinal disorders | 2 (6.1) |
| Diarrhoea | 1 (3.0) |
| Enteritis | 1 (3.0) |
|  | |
| General disorders and administration site conditions | 1 (3.0) |
| Oedema peripheral | 1 (3.0) |
|  | |
| Renal and urinary disorders | 1 (3.0) |
| Proteinuria | 1 (3.0) |

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 14.3.1.9.2.5 Summary of IN10018 Related SAEs by SOC and PT - Phase II part 1 treatment-naive locally-advanced or metastatic NSCLC (Safety Analysis Set)**

| System Organ Class  Preferred Term | Treatment-naive locally-advanced or metastatic NSCLC (N = 33) n (%) |
| --- | --- |
| IN10018 Related SAEs | 4 (12.1) |
|  | |
| Gastrointestinal disorders | 2 (6.1) |
| Diarrhoea | 1 (3.0) |
| Enteritis | 1 (3.0) |
|  | |
| General disorders and administration site conditions | 1 (3.0) |
| Oedema peripheral | 1 (3.0) |
|  | |
| Renal and urinary disorders | 1 (3.0) |
| Proteinuria | 1 (3.0) |

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 14.3.1.10.1.2 Summary of TEAEs Leading to Death by SOC and PT - Phase II part 1 treatment-naive locally-advanced or metastatic NSCLC (Safety Analysis Set)**

| System Organ Class  Preferred Term | Treatment-naive locally-advanced or metastatic NSCLC (N = 33) n (%) |
| --- | --- |
| TEAEs Leading to Death | 2 (6.1) |
|  | |
| Infections and infestations | 1 (3.0) |
| COVID-19 pneumonia | 1 (3.0) |
|  | |
| Nervous system disorders | 1 (3.0) |
| Haemorrhage intracranial | 1 (3.0) |

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 |

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

**Table 14.3.1.10.2.2 Summary of D-1553 Related TEAEs Leading to Death by SOC and PT - Phase II part 1 treatment-naive locally-advanced or metastatic NSCLC (Safety Analysis Set)**

| System Organ Class  Preferred Term | Treatment-naive locally-advanced or metastatic NSCLC (N = 33) n (%) |
| --- | --- |
| D-1553 Related TEAEs Leading to Death | 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 14.3.1.10.2.5 Summary of IN10018 Related TEAEs Leading to Death by SOC and PT - Phase II part 1 treatment-naive locally-advanced or metastatic NSCLC (Safety Analysis Set)**

| System Organ Class  Preferred Term | Treatment-naive locally-advanced or metastatic NSCLC (N = 33) n (%) |
| --- | --- |
| IN10018 Related TEAEs Leading to Death | 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 14.3.1.11.2 Summary of Deaths - Phase II part 1 treatment-naive locally-advanced or metastatic NSCLC (Safety Analysis Set)**

|  | Treatment-naive locally-advanced or metastatic NSCLC (N = 33) n (%) |
| --- | --- |
| All Deaths | 3 (9.1) |
|  | |
| On-treatment Deaths | 1 (3.0) |
| Progressive Disease (PD) | 0 |
| Adverse Events | 1 (3.0) |
| Unknown | 0 |
| Other | 0 |
|  | |
| Safety follow-up Deaths | 1 (3.0) |
| Progressive Disease (PD) | 0 |
| Adverse Events | 1 (3.0) |
| Unknown | 0 |
| Other | 0 |
|  | |
| Survival follow-up Deaths | 1 (3.0) |
| Progressive Disease (PD) | 1 (3.0) |
| Adverse Events | 0 |
| Unknown | 0 |
| Other | 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 |

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

**Table 14.3.1.12.1.2 Summary of Abnormal Liver Function by PT and Severity - Phase II part 1 treatment-naive locally-advanced or metastatic NSCLC (Safety Analysis Set)**

|  | Total (N = 33) n (%) | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Preferred Term | Grade 1 | Grade 2 | Grade 3 | Grade 4 | Grade 5 | ≥Grade 3 | Total |
| Subjects with At Least One Abnormal Liver Function | 12 (36.4) | 3 (9.1) | 1 (3.0) | 0 | 0 | 1 (3.0) | 16 (48.5) |
|  | | | | | | | |
| Alanine aminotransferase increased | 9 (27.3) | 0 | 0 | 0 | 0 | 0 | 9 (27.3) |
|  | | | | | | | |
| Aspartate aminotransferase increased | 8 (24.2) | 0 | 0 | 0 | 0 | 0 | 8 (24.2) |
|  | | | | | | | |
| Gamma-glutamyltransferase increased | 4 (12.1) | 3 (9.1) | 0 | 0 | 0 | 0 | 7 (21.2) |
|  | | | | | | | |
| Blood bilirubin increased | 2 (6.1) | 1 (3.0) | 0 | 0 | 0 | 0 | 3 (9.1) |
|  | | | | | | | |
| Bilirubin conjugated increased | 2 (6.1) | 0 | 0 | 0 | 0 | 0 | 2 (6.1) |
|  | | | | | | | |
| Hepatic function abnormal | 1 (3.0) | 0 | 1 (3.0) | 0 | 0 | 1 (3.0) | 2 (6.1) |
|  | | | | | | | |
| Total bile acids increased | 1 (3.0) | 1 (3.0) | 0 | 0 | 0 | 0 | 2 (6.1) |
|  | | | | | | | |
| Blood bilirubin unconjugated increased | 1 (3.0) | 0 | 0 | 0 | 0 | 0 | 1 (3.0) |
|  | | | | | | | |
| Subjects with At Least One D-1553 Related Abnormal Liver Function | 12 (36.4) | 3 (9.1) | 1 (3.0) | 0 | 0 | 1 (3.0) | 16 (48.5) |
|  | | | | | | | |
| Alanine aminotransferase increased | 9 (27.3) | 0 | 0 | 0 | 0 | 0 | 9 (27.3) |
|  | | | | | | | |
| Aspartate aminotransferase increased | 8 (24.2) | 0 | 0 | 0 | 0 | 0 | 8 (24.2) |
|  | | | | | | | |
| Gamma-glutamyltransferase increased | 4 (12.1) | 3 (9.1) | 0 | 0 | 0 | 0 | 7 (21.2) |
|  | | | | | | | |
| Blood bilirubin increased | 2 (6.1) | 1 (3.0) | 0 | 0 | 0 | 0 | 3 (9.1) |
|  | | | | | | | |
| Bilirubin conjugated increased | 2 (6.1) | 0 | 0 | 0 | 0 | 0 | 2 (6.1) |
|  | | | | | | | |
| Hepatic function abnormal | 1 (3.0) | 0 | 1 (3.0) | 0 | 0 | 1 (3.0) | 2 (6.1) |
|  | | | | | | | |
| Total bile acids increased | 1 (3.0) | 1 (3.0) | 0 | 0 | 0 | 0 | 2 (6.1) |
|  | | | | | | | |
| Blood bilirubin unconjugated increased | 1 (3.0) | 0 | 0 | 0 | 0 | 0 | 1 (3.0) |
|  | | | | | | | |
| Subjects with At Least One IN10018 Related Abnormal Liver Function | 12 (36.4) | 3 (9.1) | 1 (3.0) | 0 | 0 | 1 (3.0) | 16 (48.5) |
|  | | | | | | | |
| Alanine aminotransferase increased | 9 (27.3) | 0 | 0 | 0 | 0 | 0 | 9 (27.3) |
|  | | | | | | | |
| Aspartate aminotransferase increased | 8 (24.2) | 0 | 0 | 0 | 0 | 0 | 8 (24.2) |
|  | | | | | | | |
| Gamma-glutamyltransferase increased | 4 (12.1) | 3 (9.1) | 0 | 0 | 0 | 0 | 7 (21.2) |
|  | | | | | | | |
| Blood bilirubin increased | 2 (6.1) | 1 (3.0) | 0 | 0 | 0 | 0 | 3 (9.1) |
|  | | | | | | | |
| Bilirubin conjugated increased | 2 (6.1) | 0 | 0 | 0 | 0 | 0 | 2 (6.1) |
|  | | | | | | | |
| Hepatic function abnormal | 1 (3.0) | 0 | 1 (3.0) | 0 | 0 | 1 (3.0) | 2 (6.1) |
|  | | | | | | | |
| Total bile acids increased | 1 (3.0) | 1 (3.0) | 0 | 0 | 0 | 0 | 2 (6.1) |
|  | | | | | | | |
| Blood bilirubin unconjugated increased | 1 (3.0) | 0 | 0 | 0 | 0 | 0 | 1 (3.0) |

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

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

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

**Table 14.3.1.12.2.2 Incidence and Prevalence of Abnormal Liver Function over Time - Phase II part 1 treatment-naive locally-advanced or metastatic NSCLC (Safety Analysis Set)**

|  | Treatment-naive locally- advanced or metastatic  NSCLC (N = 33) [n/# at risk (%)] |
| --- | --- |
| Incidence |  |
| Abnormal Liver Function |  |
| 1st 30 days | 12 / 33 (36.4) |
| 2nd 30 days | 4 / 33 (12.1) |
| 3rd 30 days | 3 / 31 (9.7) |
| > 3rd 30 days | 5 / 29 (17.2) |
|  | |
| D-1553 Related Abnormal Liver Function |  |
| 1st 30 days | 12 / 33 (36.4) |
| 2nd 30 days | 4 / 33 (12.1) |
| 3rd 30 days | 3 / 31 (9.7) |
| > 3rd 30 days | 5 / 29 (17.2) |
|  | |
| CTCAE 3/4 Abnormal Liver Function |  |
| 1st 30 days | 0 / 33 |
| 2nd 30 days | 0 / 33 |
| 3rd 30 days | 0 / 31 |
| > 3rd 30 days | 0 / 29 |
|  | |
| CTCAE 3/4 D-1553 Related Abnormal Liver Function |  |
| 1st 30 days | 0 / 33 |
| 2nd 30 days | 0 / 33 |
| 3rd 30 days | 0 / 31 |
| > 3rd 30 days | 0 / 29 |
|  | |
| AESI of Abnormal Liver Function |  |
| 1st 30 days | 0 / 33 |
| 2nd 30 days | 0 / 33 |
| 3rd 30 days | 0 / 31 |
| > 3rd 30 days | 0 / 29 |
|  | |
| AESI of D-1553 Related Abnormal Liver Function |  |
| 1st 30 days | 0 / 33 |
| 2nd 30 days | 0 / 33 |
| 3rd 30 days | 0 / 31 |
| > 3rd 30 days | 0 / 29 |
|  | |
| Prevalence |  |
| Abnormal Liver Function |  |
| 1st 30 days | 12 / 33 (36.4) |
| 2nd 30 days | 10 / 33 (30.3) |
| 3rd 30 days | 8 / 31 (25.8) |
| > 3rd 30 days | 7 / 29 (24.1) |
|  | |
| D-1553 Related Abnormal Liver Function |  |
| 1st 30 days | 12 / 33 (36.4) |
| 2nd 30 days | 10 / 33 (30.3) |
| 3rd 30 days | 8 / 31 (25.8) |
| > 3rd 30 days | 7 / 29 (24.1) |
|  | |
| CTCAE 3/4 Abnormal Liver Function |  |
| 1st 30 days | 1 / 33 (3.0) |
| 2nd 30 days | 1 / 33 (3.0) |
| 3rd 30 days | 1 / 31 (3.2) |
| > 3rd 30 days | 0 / 29 |
|  | |
| CTCAE 3/4 D-1553 Related Abnormal Liver Function |  |
| 1st 30 days | 1 / 33 (3.0) |
| 2nd 30 days | 1 / 33 (3.0) |
| 3rd 30 days | 1 / 31 (3.2) |
| > 3rd 30 days | 0 / 29 |
|  | |
| AESI of Abnormal Liver Function |  |
| 1st 30 days | 0 / 33 |
| 2nd 30 days | 0 / 33 |
| 3rd 30 days | 0 / 31 |
| > 3rd 30 days | 0 / 29 |
|  | |
| AESI of D-1553 Related Abnormal Liver Function |  |
| 1st 30 days | 0 / 33 |
| 2nd 30 days | 0 / 33 |
| 3rd 30 days | 0 / 31 |
| > 3rd 30 days | 0 / 29 |

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 |

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

**Table 14.3.1.13.1.2 Summary of Proteinuria by Grouped PT and Severity - Phase II part 1 treatment-naive locally-advanced or metastatic NSCLC (Safety Analysis Set)**

|  | Total (N = 33) n (%) | | | |
| --- | --- | --- | --- | --- |
| Preferred Term | Grade 1 | Grade 2 | Grade 3 | Total |
| Subjects with At Least One Proteinuria | 9 (27.3) | 11 (33.3) | 2 (6.1) | 22 (66.7) |
|  | | | | |
| Proteinuria\* | 9 (27.3) | 11 (33.3) | 2 (6.1) | 22 (66.7) |
|  | | | | |
| Subjects with At Least One D-1553 Related Proteinuria | 6 (18.2) | 7 (21.2) | 2 (6.1) | 15 (45.5) |
|  | | | | |
| Proteinuria\* | 6 (18.2) | 7 (21.2) | 2 (6.1) | 15 (45.5) |
|  | | | | |
| Subjects with At Least One IN10018 Related Proteinuria | 9 (27.3) | 11 (33.3) | 2 (6.1) | 22 (66.7) |
|  | | | | |
| Proteinuria\* | 9 (27.3) | 11 (33.3) | 2 (6.1) | 22 (66.7) |

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

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

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

**Table 14.3.1.13.2.2 Incidence and Prevalence of Proteinuria over Time - Phase II part 1 treatment-naive locally-advanced or metastatic NSCLC (Safety Analysis Set)**

|  | Treatment-naive locally- advanced or metastatic  NSCLC (N = 33) [n/# at risk (%)] |
| --- | --- |
| Incidence |  |
| Proteinuria |  |
| 1st 30 days | 15 / 33 (45.5) |
| 2nd 30 days | 4 / 33 (12.1) |
| 3rd 30 days | 9 / 31 (29.0) |
| > 3rd 30 days | 10 / 29 (34.5) |
|  | |
| IN10018 Related Proteinuria |  |
| 1st 30 days | 15 / 33 (45.5) |
| 2nd 30 days | 4 / 33 (12.1) |
| 3rd 30 days | 9 / 31 (29.0) |
| > 3rd 30 days | 10 / 29 (34.5) |
|  | |
| CTCAE 3 Proteinuria |  |
| 1st 30 days | 0 / 33 |
| 2nd 30 days | 0 / 33 |
| 3rd 30 days | 0 / 31 |
| > 3rd 30 days | 0 / 29 |
|  | |
| CTCAE 3 IN10018 Related Proteinuria |  |
| 1st 30 days | 0 / 33 |
| 2nd 30 days | 0 / 33 |
| 3rd 30 days | 0 / 31 |
| > 3rd 30 days | 0 / 29 |
|  | |
| AESI of Proteinuria |  |
| 1st 30 days | 3 / 33 (9.1) |
| 2nd 30 days | 0 / 33 |
| 3rd 30 days | 2 / 31 (6.5) |
| > 3rd 30 days | 1 / 29 (3.4) |
|  | |
| AESI of IN10018 Related Proteinuria |  |
| 1st 30 days | 3 / 33 (9.1) |
| 2nd 30 days | 0 / 33 |
| 3rd 30 days | 2 / 31 (6.5) |
| > 3rd 30 days | 1 / 29 (3.4) |
|  | |
| Prevalence |  |
| Proteinuria |  |
| 1st 30 days | 15 / 33 (45.5) |
| 2nd 30 days | 17 / 33 (51.5) |
| 3rd 30 days | 19 / 31 (61.3) |
| > 3rd 30 days | 18 / 29 (62.1) |
|  | |
| IN10018 Related Proteinuria |  |
| 1st 30 days | 15 / 33 (45.5) |
| 2nd 30 days | 17 / 33 (51.5) |
| 3rd 30 days | 19 / 31 (61.3) |
| > 3rd 30 days | 18 / 29 (62.1) |
|  | |
| CTCAE 3 Proteinuria |  |
| 1st 30 days | 1 / 33 (3.0) |
| 2nd 30 days | 1 / 33 (3.0) |
| 3rd 30 days | 0 / 31 |
| > 3rd 30 days | 1 / 29 (3.4) |
|  | |
| CTCAE 3 IN10018 Related Proteinuria |  |
| 1st 30 days | 1 / 33 (3.0) |
| 2nd 30 days | 1 / 33 (3.0) |
| 3rd 30 days | 0 / 31 |
| > 3rd 30 days | 1 / 29 (3.4) |
|  | |
| AESI of Proteinuria |  |
| 1st 30 days | 3 / 33 (9.1) |
| 2nd 30 days | 3 / 33 (9.1) |
| 3rd 30 days | 4 / 31 (12.9) |
| > 3rd 30 days | 2 / 29 (6.9) |
|  | |
| AESI of IN10018 Related Proteinuria |  |
| 1st 30 days | 3 / 33 (9.1) |
| 2nd 30 days | 3 / 33 (9.1) |
| 3rd 30 days | 4 / 31 (12.9) |
| > 3rd 30 days | 2 / 29 (6.9) |

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 14.3.5.1.1.2 Summary of Hematology Results - Phase II part 1 treatment-naive locally-advanced or metastatic NSCLC (Safety Analysis Set)**

|  | | Observed Value | | | | Change from Baseline | | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Parameter | Visit | n | Mean (STD) | Median (Q1, Q3) | Min, Max | n | Mean (STD) | Median (Q1, Q3) | Min, Max |
| Erythrocytes (10^12/L) (N = 33) | Baseline | 33 | 4.343 (0.5170) | 4.420 (4.050, 4.620) | 2.99, 5.45 |  |  |  |  |
|  | C1D8 | 33 | 4.328 (0.4986) | 4.410 (4.060, 4.650) | 2.75, 5.32 | 33 | -0.014 (0.2035) | -0.020 (-0.160, 0.080) | -0.34, 0.52 |
|  | C2D1 | 32 | 4.436 (0.8243) | 4.485 (4.060, 4.730) | 2.76, 7.82 | 32 | 0.081 (0.6401) | 0.025 (-0.180, 0.130) | -0.43, 3.40 |
|  | C3D1 | 31 | 4.258 (0.5930) | 4.260 (3.880, 4.660) | 2.84, 5.56 | 31 | -0.103 (0.2981) | -0.120 (-0.250, 0.110) | -0.62, 0.59 |
|  | C4D1 | 30 | 4.244 (0.5860) | 4.260 (4.030, 4.530) | 2.70, 5.99 | 30 | -0.129 (0.3527) | -0.160 (-0.390, 0.110) | -0.73, 0.54 |
|  | C5D1 | 28 | 4.105 (0.5749) | 4.170 (3.770, 4.525) | 2.53, 4.99 | 28 | -0.228 (0.3003) | -0.370 (-0.500, 0.080) | -0.63, 0.27 |
|  | C6D1 | 27 | 4.115 (0.5862) | 4.170 (3.930, 4.490) | 2.51, 5.00 | 27 | -0.219 (0.2810) | -0.190 (-0.420, -0.020) | -0.81, 0.32 |
|  | C7D1 | 23 | 4.118 (0.5231) | 4.190 (3.900, 4.480) | 2.35, 4.86 | 23 | -0.289 (0.3415) | -0.270 (-0.530, -0.060) | -1.21, 0.23 |
|  | C8D1 | 15 | 4.103 (0.5565) | 4.200 (3.870, 4.440) | 2.43, 4.83 | 15 | -0.191 (0.2348) | -0.250 (-0.360, -0.020) | -0.56, 0.20 |
|  | C9D1 | 11 | 4.090 (0.7670) | 4.210 (3.720, 4.530) | 2.13, 4.90 | 11 | -0.214 (0.2674) | -0.150 (-0.270, -0.050) | -0.86, 0.07 |
|  | C10D1 | 6 | 3.982 (1.0134) | 4.065 (3.680, 4.510) | 2.26, 5.31 | 6 | -0.263 (0.4484) | -0.370 (-0.620, 0.050) | -0.73, 0.46 |
|  | C11D1 | 6 | 3.973 (0.9893) | 4.175 (3.860, 4.570) | 2.14, 4.92 | 6 | -0.272 (0.3995) | -0.205 (-0.560, 0.070) | -0.85, 0.12 |
|  | C12D1 | 5 | 3.956 (1.0791) | 4.350 (3.830, 4.580) | 2.15, 4.87 | 5 | -0.254 (0.3965) | -0.100 (-0.470, 0.020) | -0.84, 0.12 |
|  | C13D1 | 4 | 4.530 (0.3667) | 4.495 (4.290, 4.770) | 4.12, 5.01 | 4 | 0.015 (0.1439) | 0.040 (-0.085, 0.115) | -0.18, 0.16 |
|  | C14D1 | 4 | 4.370 (0.3766) | 4.365 (4.105, 4.635) | 3.92, 4.83 | 4 | -0.145 (0.1700) | -0.090 (-0.270, -0.020) | -0.38, -0.02 |
|  | C15D1 | 3 | 4.427 (0.4934) | 4.360 (3.970, 4.950) | 3.97, 4.95 | 3 | -0.107 (0.2155) | -0.090 (-0.330, 0.100) | -0.33, 0.10 |
|  | C16D1 | 2 | 4.060 (0.3536) | 4.060 (3.810, 4.310) | 3.81, 4.31 | 2 | -0.315 (0.2475) | -0.315 (-0.490, -0.140) | -0.49, -0.14 |
|  | C17D1 | 2 | 4.130 (0.0566) | 4.130 (4.090, 4.170) | 4.09, 4.17 | 2 | -0.245 (0.1626) | -0.245 (-0.360, -0.130) | -0.36, -0.13 |
|  | C18D1 | 1 | 3.860 (NA) | 3.860 (3.860, 3.860) | 3.86, 3.86 | 1 | -0.440 (NA) | -0.440 (-0.440, -0.440) | -0.44, -0.44 |
|  | End of Treatment | 4 | 3.883 (1.5674) | 3.450 (2.910, 4.855) | 2.50, 6.13 | 4 | -0.210 (0.6193) | -0.425 (-0.630, 0.210) | -0.67, 0.68 |
|  | | | | | | | | | |
| Hemoglobin (g/L) (N = 33) | Baseline | 33 | 132.1 (16.03) | 134.0 (123.0, 146.0) | 93, 158 |  |  |  |  |
|  | C1D8 | 33 | 131.4 (15.76) | 132.0 (123.0, 144.0) | 83, 156 | 33 | -0.7 (6.48) | -2.0 (-5.0, 1.0) | -10, 15 |
|  | C2D1 | 32 | 132.2 (16.35) | 136.0 (120.5, 144.5) | 91, 163 | 32 | -0.5 (7.06) | 1.5 (-6.0, 4.0) | -14, 14 |
|  | C3D1 | 31 | 129.6 (17.66) | 133.0 (119.0, 142.0) | 83, 162 | 31 | -3.6 (9.89) | -5.0 (-9.0, 5.0) | -26, 19 |
|  | C4D1 | 30 | 130.5 (17.82) | 131.5 (121.0, 141.0) | 79, 178 | 30 | -3.0 (12.06) | -2.0 (-11.0, 7.0) | -28, 20 |
|  | C5D1 | 28 | 126.6 (17.54) | 129.5 (113.0, 137.0) | 79, 157 | 28 | -5.9 (9.41) | -8.0 (-13.5, 1.0) | -18, 10 |
|  | C6D1 | 27 | 129.0 (16.73) | 131.0 (118.0, 140.0) | 82, 158 | 27 | -3.8 (8.54) | -3.0 (-10.0, 2.0) | -19, 15 |
|  | C7D1 | 23 | 130.7 (16.48) | 130.0 (118.0, 143.0) | 97, 157 | 23 | -3.8 (11.13) | -3.0 (-8.0, 4.0) | -34, 18 |
|  | C8D1 | 15 | 128.1 (15.82) | 129.0 (115.0, 138.0) | 99, 154 | 15 | -3.1 (7.28) | -3.0 (-9.0, 0.0) | -17, 12 |
|  | C9D1 | 11 | 133.1 (25.13) | 135.0 (115.0, 156.0) | 88, 173 | 11 | -0.1 (10.67) | -2.0 (-4.0, 5.0) | -17, 23 |
|  | C10D1 | 6 | 130.2 (25.47) | 129.5 (113.0, 155.0) | 93, 161 | 6 | -3.8 (10.83) | -5.5 (-10.0, 7.0) | -19, 10 |
|  | C11D1 | 6 | 129.2 (25.78) | 137.5 (110.0, 151.0) | 87, 152 | 6 | -4.8 (11.21) | -3.0 (-13.0, 4.0) | -22, 8 |
|  | C12D1 | 5 | 132.6 (26.25) | 137.0 (131.0, 152.0) | 89, 154 | 5 | -1.8 (7.33) | 1.0 (-8.0, 3.0) | -11, 6 |
|  | C13D1 | 4 | 148.0 (9.97) | 148.0 (139.5, 156.5) | 138, 158 | 4 | 5.0 (3.46) | 4.0 (3.0, 7.0) | 2, 10 |
|  | C14D1 | 4 | 140.5 (7.94) | 139.5 (134.0, 147.0) | 133, 150 | 4 | -2.5 (1.73) | -2.5 (-4.0, -1.0) | -4, -1 |
|  | C15D1 | 3 | 142.0 (9.54) | 137.0 (136.0, 153.0) | 136, 153 | 3 | 0.7 (3.21) | 2.0 (-3.0, 3.0) | -3, 3 |
|  | C16D1 | 2 | 134.0 (4.24) | 134.0 (131.0, 137.0) | 131, 137 | 2 | -2.5 (7.78) | -2.5 (-8.0, 3.0) | -8, 3 |
|  | C17D1 | 2 | 134.0 (9.90) | 134.0 (127.0, 141.0) | 127, 141 | 2 | -2.5 (6.36) | -2.5 (-7.0, 2.0) | -7, 2 |
|  | C18D1 | 1 | 138.0 (NA) | 138.0 (138.0, 138.0) | 138, 138 | 1 | -1.0 (NA) | -1.0 (-1.0, -1.0) | -1, -1 |
|  | End of Treatment | 4 | 117.3 (47.01) | 103.5 (88.0, 146.5) | 77, 185 | 4 | -8.0 (23.90) | -16.0 (-21.5, 5.5) | -27, 27 |
|  | | | | | | | | | |
| Hematocrit (%) (N = 33) | Baseline | 33 | 39.879 (4.7214) | 39.700 (37.700, 43.600) | 29.30, 48.50 |  |  |  |  |
|  | C1D8 | 33 | 39.612 (4.4566) | 39.700 (37.100, 42.700) | 26.90, 47.30 | 33 | -0.267 (1.9539) | -0.400 (-1.700, 0.500) | -3.00, 5.00 |
|  | C2D1 | 32 | 40.013 (4.5944) | 40.350 (37.300, 43.600) | 27.90, 48.10 | 32 | -0.069 (1.9860) | 0.100 (-1.500, 1.200) | -3.40, 5.20 |
|  | C3D1 | 31 | 39.426 (5.2321) | 39.700 (36.100, 43.000) | 26.60, 49.60 | 31 | -0.739 (2.9630) | -0.900 (-2.600, 0.800) | -7.20, 6.10 |
|  | C4D1 | 30 | 39.330 (5.0655) | 38.450 (36.600, 41.600) | 25.90, 54.90 | 30 | -0.903 (3.4693) | -0.750 (-3.100, 1.300) | -8.40, 6.40 |
|  | C5D1 | 28 | 38.257 (4.9058) | 38.950 (34.850, 41.550) | 25.90, 46.00 | 28 | -1.689 (2.7684) | -1.700 (-4.300, 0.300) | -6.30, 3.90 |
|  | C6D1 | 27 | 38.481 (4.9102) | 39.200 (34.900, 41.900) | 25.40, 46.00 | 27 | -1.500 (2.6553) | -1.700 (-3.800, 0.700) | -7.40, 3.20 |
|  | C7D1 | 23 | 37.539 (7.3788) | 37.700 (35.700, 40.900) | 10.60, 47.10 | 23 | -2.904 (7.3476) | -1.900 (-3.500, 0.400) | -33.60, 3.20 |
|  | C8D1 | 15 | 38.807 (4.4870) | 38.200 (36.800, 41.500) | 28.10, 46.80 | 15 | -0.760 (2.2724) | -1.200 (-2.400, 1.800) | -4.80, 2.60 |
|  | C9D1 | 11 | 38.864 (6.3913) | 39.500 (35.200, 45.200) | 24.80, 45.70 | 11 | -1.055 (2.2129) | -1.100 (-3.100, 0.700) | -4.50, 2.90 |
|  | C10D1 | 6 | 38.917 (7.8438) | 38.200 (35.300, 46.000) | 27.10, 48.70 | 6 | -0.583 (3.9398) | -1.300 (-3.200, 1.600) | -5.20, 5.90 |
|  | C11D1 | 6 | 38.633 (7.7801) | 40.350 (35.200, 45.000) | 25.20, 45.70 | 6 | -0.867 (3.1646) | -0.750 (-4.100, 2.200) | -4.20, 2.40 |
|  | C12D1 | 5 | 38.840 (8.0469) | 40.400 (36.700, 44.800) | 26.10, 46.20 | 5 | -0.680 (2.7225) | -0.200 (-3.200, 1.800) | -3.80, 2.00 |
|  | C13D1 | 4 | 43.225 (3.4903) | 43.850 (40.400, 46.050) | 38.90, 46.30 | 4 | 1.150 (2.0952) | 1.350 (-0.150, 2.450) | -1.60, 3.50 |
|  | C14D1 | 4 | 42.025 (3.5594) | 42.450 (39.100, 44.950) | 37.80, 45.40 | 4 | -0.050 (1.9330) | 0.400 (-1.450, 1.350) | -2.70, 1.70 |
|  | C15D1 | 3 | 41.133 (4.4658) | 40.700 (36.900, 45.800) | 36.90, 45.80 | 3 | -0.167 (3.3081) | 0.100 (-3.600, 3.000) | -3.60, 3.00 |
|  | C16D1 | 2 | 38.000 (2.2627) | 38.000 (36.400, 39.600) | 36.40, 39.60 | 2 | -2.550 (2.1920) | -2.550 (-4.100, -1.000) | -4.10, -1.00 |
|  | C17D1 | 2 | 38.450 (1.6263) | 38.450 (37.300, 39.600) | 37.30, 39.60 | 2 | -2.100 (1.6971) | -2.100 (-3.300, -0.900) | -3.30, -0.90 |
|  | C18D1 | 1 | 36.600 (NA) | 36.600 (36.600, 36.600) | 36.60, 36.60 | 1 | -3.900 (NA) | -3.900 (-3.900, -3.900) | -3.90, -3.90 |
|  | End of Treatment | 4 | 36.150 (13.2034) | 32.300 (28.100, 44.200) | 24.80, 55.20 | 4 | -2.700 (6.3098) | -5.400 (-6.300, 0.900) | -6.70, 6.70 |
|  | | | | | | | | | |
| Leukocytes (10^9/L) (N = 33) | Baseline | 33 | 8.083 (2.6579) | 7.440 (6.700, 8.830) | 4.10, 18.51 |  |  |  |  |
|  | C1D8 | 33 | 8.072 (2.3057) | 6.900 (6.500, 9.980) | 4.20, 12.84 | 33 | -0.011 (2.5886) | -0.010 (-1.030, 1.750) | -6.66, 5.11 |
|  | C2D1 | 32 | 8.390 (2.3495) | 7.945 (6.900, 9.065) | 4.70, 15.97 | 32 | 0.251 (2.6112) | -0.100 (-1.075, 1.805) | -6.75, 6.14 |
|  | C3D1 | 31 | 8.207 (3.8543) | 7.430 (6.100, 9.590) | 4.30, 25.59 | 31 | 0.034 (2.3558) | 0.250 (-1.440, 1.270) | -6.53, 7.08 |
|  | C4D1 | 30 | 7.863 (2.4217) | 7.770 (6.210, 8.610) | 3.73, 15.05 | 30 | -0.289 (2.4806) | -0.275 (-1.000, 0.460) | -6.42, 6.60 |
|  | C5D1 | 28 | 7.781 (1.7362) | 7.420 (6.720, 8.875) | 4.80, 12.90 | 28 | -0.046 (2.0169) | 0.575 (-1.075, 1.335) | -6.26, 3.14 |
|  | C6D1 | 27 | 8.047 (2.0750) | 7.580 (6.870, 9.040) | 4.60, 14.71 | 27 | 0.189 (2.1324) | 0.300 (-0.850, 1.100) | -4.80, 6.13 |
|  | C7D1 | 23 | 7.520 (1.6958) | 7.470 (6.300, 8.030) | 3.90, 11.45 | 23 | -0.108 (2.1279) | -0.300 (-1.500, 1.210) | -4.62, 5.20 |
|  | C8D1 | 15 | 9.047 (2.8056) | 8.250 (7.520, 9.970) | 5.70, 17.36 | 15 | 0.963 (2.7577) | 1.200 (-0.580, 2.390) | -5.01, 7.53 |
|  | C9D1 | 11 | 8.586 (1.9012) | 8.250 (7.060, 9.630) | 6.00, 12.90 | 11 | 0.607 (1.1426) | 0.300 (-0.220, 1.830) | -0.70, 2.58 |
|  | C10D1 | 6 | 11.692 (5.4117) | 10.495 (8.540, 13.520) | 5.70, 21.40 | 6 | 3.532 (4.2045) | 2.310 (0.930, 6.240) | -1.00, 10.40 |
|  | C11D1 | 6 | 8.490 (2.3981) | 8.275 (6.260, 10.830) | 5.70, 11.60 | 6 | 0.330 (1.0636) | 0.800 (-1.000, 1.080) | -1.02, 1.32 |
|  | C12D1 | 5 | 8.870 (2.5130) | 8.020 (7.500, 9.290) | 6.54, 13.00 | 5 | 0.418 (1.1197) | 0.450 (-0.540, 0.920) | -0.74, 2.00 |
|  | C13D1 | 4 | 8.703 (2.3433) | 7.990 (7.305, 10.100) | 6.73, 12.10 | 4 | -0.043 (1.1992) | 0.230 (-0.790, 0.705) | -1.73, 1.10 |
|  | C14D1 | 4 | 9.958 (0.9850) | 9.620 (9.365, 10.550) | 9.19, 11.40 | 4 | 1.213 (1.6638) | 1.185 (-0.120, 2.545) | -0.64, 3.12 |
|  | C15D1 | 3 | 11.713 (3.8662) | 11.460 (7.980, 15.700) | 7.98, 15.70 | 3 | 2.577 (1.8425) | 1.630 (1.400, 4.700) | 1.40, 4.70 |
|  | C16D1 | 2 | 9.340 (2.8991) | 9.340 (7.290, 11.390) | 7.29, 11.39 | 2 | 1.135 (0.6010) | 1.135 (0.710, 1.560) | 0.71, 1.56 |
|  | C17D1 | 2 | 9.175 (2.8496) | 9.175 (7.160, 11.190) | 7.16, 11.19 | 2 | 0.970 (0.5515) | 0.970 (0.580, 1.360) | 0.58, 1.36 |
|  | C18D1 | 1 | 9.100 (NA) | 9.100 (9.100, 9.100) | 9.10, 9.10 | 1 | 2.520 (NA) | 2.520 (2.520, 2.520) | 2.52, 2.52 |
|  | End of Treatment | 4 | 13.583 (6.2916) | 12.205 (8.940, 18.225) | 7.82, 22.10 | 4 | 1.665 (3.7926) | 2.175 (-1.225, 4.555) | -3.21, 5.52 |
|  | | | | | | | | | |
| Neutrophils (10^9/L) (N = 33) | Baseline | 33 | 5.432 (2.1683) | 5.300 (4.200, 6.140) | 2.30, 13.03 |  |  |  |  |
|  | C1D8 | 33 | 5.283 (1.8021) | 4.750 (4.000, 6.370) | 2.82, 9.51 | 33 | -0.149 (2.1651) | -0.300 (-1.200, 1.470) | -6.06, 4.73 |
|  | C2D1 | 32 | 5.481 (1.8936) | 5.200 (4.405, 5.875) | 2.97, 12.99 | 32 | 0.044 (2.4930) | -0.035 (-1.185, 1.235) | -6.60, 6.38 |
|  | C3D1 | 31 | 5.261 (3.3978) | 4.520 (3.390, 5.660) | 2.10, 20.78 | 31 | -0.226 (2.2319) | 0.070 (-1.600, 0.700) | -6.37, 7.75 |
|  | C4D1 | 30 | 5.066 (1.8918) | 4.990 (3.840, 5.640) | 1.85, 10.80 | 30 | -0.399 (2.2521) | -0.410 (-0.850, 0.400) | -6.27, 6.20 |
|  | C5D1 | 28 | 5.106 (1.4175) | 4.920 (4.180, 5.550) | 3.10, 10.10 | 28 | -0.127 (1.7257) | -0.035 (-0.960, 1.050) | -5.63, 2.20 |
|  | C6D1 | 27 | 5.435 (1.9122) | 5.040 (4.300, 6.120) | 2.50, 11.57 | 27 | 0.185 (1.8986) | 0.060 (-0.490, 0.700) | -4.57, 5.80 |
|  | C7D1 | 23 | 4.952 (1.4887) | 4.560 (3.800, 5.630) | 2.50, 8.17 | 23 | -0.078 (1.8994) | -0.060 (-0.970, 0.740) | -4.52, 4.67 |
|  | C8D1 | 15 | 6.351 (2.8442) | 5.720 (4.950, 6.600) | 3.50, 15.38 | 15 | 0.945 (2.7909) | 0.600 (-0.380, 1.700) | -4.62, 8.77 |
|  | C9D1 | 11 | 5.724 (1.7772) | 5.390 (4.780, 6.170) | 3.60, 10.20 | 11 | 0.320 (0.9630) | -0.050 (-0.400, 1.300) | -1.19, 1.91 |
|  | C10D1 | 6 | 8.875 (5.6014) | 7.175 (4.950, 11.250) | 3.70, 19.00 | 6 | 3.428 (3.9094) | 2.210 (0.530, 5.720) | -0.20, 10.10 |
|  | C11D1 | 6 | 5.580 (2.0890) | 4.810 (3.920, 7.640) | 3.70, 8.60 | 6 | 0.133 (0.9642) | 0.200 (-0.300, 1.030) | -1.42, 1.09 |
|  | C12D1 | 5 | 6.062 (2.5392) | 5.200 (4.850, 6.260) | 3.70, 10.30 | 5 | 0.306 (0.8411) | 0.380 (-0.350, 0.780) | -0.68, 1.40 |
|  | C13D1 | 4 | 5.740 (2.5393) | 4.985 (4.135, 7.345) | 3.59, 9.40 | 4 | -0.073 (0.8390) | 0.265 (-0.530, 0.385) | -1.32, 0.50 |
|  | C14D1 | 4 | 6.963 (1.1058) | 6.530 (6.315, 7.610) | 6.19, 8.60 | 4 | 1.150 (1.6234) | 1.015 (-0.235, 2.535) | -0.30, 2.87 |
|  | C15D1 | 3 | 8.660 (4.7154) | 8.400 (4.080, 13.500) | 4.08, 13.50 | 3 | 2.383 (1.9876) | 1.790 (0.760, 4.600) | 0.76, 4.60 |
|  | C16D1 | 2 | 6.085 (2.8779) | 6.085 (4.050, 8.120) | 4.05, 8.12 | 2 | 1.120 (0.5515) | 1.120 (0.730, 1.510) | 0.73, 1.51 |
|  | C17D1 | 2 | 5.960 (2.5597) | 5.960 (4.150, 7.770) | 4.15, 7.77 | 2 | 0.995 (0.2333) | 0.995 (0.830, 1.160) | 0.83, 1.16 |
|  | C18D1 | 1 | 5.510 (NA) | 5.510 (5.510, 5.510) | 5.51, 5.51 | 1 | 2.190 (NA) | 2.190 (2.190, 2.190) | 2.19, 2.19 |
|  | End of Treatment | 4 | 10.263 (4.9681) | 9.155 (6.420, 14.105) | 5.94, 16.80 | 4 | 1.735 (3.5217) | 2.155 (-1.050, 4.520) | -2.64, 5.27 |
|  | | | | | | | | | |
| Eosinophils (10^9/L) (N = 33) | Baseline | 33 | 0.278 (0.3449) | 0.160 (0.090, 0.320) | 0.01, 1.60 |  |  |  |  |
|  | C1D8 | 33 | 0.268 (0.2024) | 0.230 (0.130, 0.400) | 0.00, 0.87 | 33 | -0.011 (0.2554) | 0.040 (-0.010, 0.100) | -1.20, 0.25 |
|  | C2D1 | 32 | 0.420 (0.3365) | 0.350 (0.205, 0.525) | 0.06, 1.53 | 32 | 0.134 (0.3992) | 0.135 (0.010, 0.300) | -1.40, 1.21 |
|  | C3D1 | 31 | 0.387 (0.4138) | 0.290 (0.160, 0.470) | 0.01, 2.16 | 31 | 0.096 (0.5452) | 0.070 (-0.070, 0.210) | -1.33, 1.84 |
|  | C4D1 | 30 | 0.308 (0.2674) | 0.260 (0.130, 0.390) | 0.00, 1.35 | 30 | 0.010 (0.3245) | 0.040 (0.010, 0.140) | -1.35, 0.56 |
|  | C5D1 | 28 | 0.280 (0.1927) | 0.235 (0.130, 0.435) | 0.02, 0.74 | 28 | 0.006 (0.3108) | 0.035 (-0.015, 0.135) | -1.35, 0.42 |
|  | C6D1 | 27 | 0.530 (1.7566) | 0.170 (0.070, 0.310) | 0.01, 9.30 | 27 | 0.253 (1.7185) | 0.000 (-0.100, 0.090) | -1.47, 8.70 |
|  | C7D1 | 23 | 0.229 (0.1787) | 0.160 (0.110, 0.330) | 0.01, 0.80 | 23 | -0.027 (0.3456) | 0.020 (-0.060, 0.150) | -1.49, 0.32 |
|  | C8D1 | 15 | 0.201 (0.1572) | 0.180 (0.090, 0.250) | 0.00, 0.50 | 15 | -0.099 (0.3987) | -0.030 (-0.120, 0.070) | -1.47, 0.31 |
|  | C9D1 | 11 | 0.234 (0.1479) | 0.250 (0.120, 0.290) | 0.01, 0.52 | 11 | 0.010 (0.1472) | 0.000 (-0.140, 0.040) | -0.14, 0.33 |
|  | C10D1 | 6 | 0.152 (0.1416) | 0.125 (0.090, 0.150) | 0.00, 0.42 | 6 | 0.020 (0.0942) | -0.010 (-0.030, 0.000) | -0.04, 0.21 |
|  | C11D1 | 6 | 0.177 (0.1606) | 0.110 (0.080, 0.330) | 0.01, 0.42 | 6 | 0.045 (0.1075) | -0.005 (-0.030, 0.120) | -0.04, 0.23 |
|  | C12D1 | 5 | 0.198 (0.1736) | 0.150 (0.070, 0.370) | 0.01, 0.39 | 5 | 0.068 (0.1035) | 0.000 (0.000, 0.160) | -0.02, 0.20 |
|  | C13D1 | 4 | 0.180 (0.1339) | 0.180 (0.065, 0.295) | 0.05, 0.31 | 4 | 0.020 (0.0898) | 0.015 (-0.055, 0.095) | -0.07, 0.12 |
|  | C14D1 | 4 | 0.215 (0.1323) | 0.235 (0.105, 0.325) | 0.06, 0.33 | 4 | 0.055 (0.0827) | 0.055 (-0.015, 0.125) | -0.03, 0.14 |
|  | C15D1 | 3 | 0.267 (0.1137) | 0.300 (0.140, 0.360) | 0.14, 0.36 | 3 | 0.083 (0.0902) | 0.090 (-0.010, 0.170) | -0.01, 0.17 |
|  | C16D1 | 2 | 0.230 (0.1697) | 0.230 (0.110, 0.350) | 0.11, 0.35 | 2 | 0.050 (0.1273) | 0.050 (-0.040, 0.140) | -0.04, 0.14 |
|  | C17D1 | 2 | 0.230 (0.1556) | 0.230 (0.120, 0.340) | 0.12, 0.34 | 2 | 0.050 (0.1131) | 0.050 (-0.030, 0.130) | -0.03, 0.13 |
|  | C18D1 | 1 | 0.170 (NA) | 0.170 (0.170, 0.170) | 0.17, 0.17 | 1 | 0.020 (NA) | 0.020 (0.020, 0.020) | 0.02, 0.02 |
|  | End of Treatment | 4 | 0.363 (0.2128) | 0.355 (0.225, 0.500) | 0.11, 0.63 | 4 | -0.035 (0.3786) | 0.110 (-0.275, 0.205) | -0.59, 0.23 |
|  | | | | | | | | | |
| Basophils (10^9/L) (N = 33) | Baseline | 33 | 0.035 (0.0258) | 0.030 (0.020, 0.040) | 0.01, 0.11 |  |  |  |  |
|  | C1D8 | 33 | 0.064 (0.0397) | 0.060 (0.040, 0.080) | 0.01, 0.22 | 33 | 0.028 (0.0273) | 0.020 (0.010, 0.040) | -0.01, 0.14 |
|  | C2D1 | 32 | 0.069 (0.0470) | 0.060 (0.030, 0.090) | 0.01, 0.19 | 32 | 0.033 (0.0390) | 0.030 (0.010, 0.050) | -0.05, 0.11 |
|  | C3D1 | 31 | 0.086 (0.1393) | 0.060 (0.030, 0.100) | 0.01, 0.80 | 31 | 0.050 (0.1361) | 0.020 (0.000, 0.050) | -0.02, 0.76 |
|  | C4D1 | 30 | 0.064 (0.0510) | 0.045 (0.030, 0.090) | 0.02, 0.25 | 30 | 0.028 (0.0373) | 0.020 (0.010, 0.030) | -0.02, 0.17 |
|  | C5D1 | 28 | 0.054 (0.0330) | 0.050 (0.025, 0.070) | 0.01, 0.14 | 28 | 0.020 (0.0296) | 0.020 (0.000, 0.040) | -0.03, 0.09 |
|  | C6D1 | 27 | 0.073 (0.0795) | 0.050 (0.030, 0.080) | 0.01, 0.40 | 27 | 0.040 (0.0775) | 0.020 (0.000, 0.040) | -0.01, 0.39 |
|  | C7D1 | 23 | 0.057 (0.0313) | 0.050 (0.030, 0.080) | 0.01, 0.11 | 23 | 0.022 (0.0241) | 0.020 (0.000, 0.040) | -0.01, 0.08 |
|  | C8D1 | 15 | 0.059 (0.0267) | 0.060 (0.040, 0.080) | 0.02, 0.11 | 15 | 0.021 (0.0335) | 0.030 (0.000, 0.040) | -0.06, 0.07 |
|  | C9D1 | 11 | 0.076 (0.0533) | 0.060 (0.040, 0.110) | 0.02, 0.21 | 11 | 0.046 (0.0427) | 0.030 (0.020, 0.090) | -0.01, 0.13 |
|  | C10D1 | 6 | 0.067 (0.0258) | 0.065 (0.050, 0.090) | 0.03, 0.10 | 6 | 0.028 (0.0376) | 0.035 (0.000, 0.060) | -0.03, 0.07 |
|  | C11D1 | 6 | 0.070 (0.0424) | 0.055 (0.050, 0.080) | 0.03, 0.15 | 6 | 0.032 (0.0232) | 0.030 (0.020, 0.040) | 0.00, 0.07 |
|  | C12D1 | 5 | 0.092 (0.0540) | 0.080 (0.060, 0.100) | 0.04, 0.18 | 5 | 0.052 (0.0342) | 0.060 (0.030, 0.060) | 0.01, 0.10 |
|  | C13D1 | 4 | 0.088 (0.0690) | 0.060 (0.050, 0.125) | 0.04, 0.19 | 4 | 0.045 (0.0451) | 0.030 (0.015, 0.075) | 0.01, 0.11 |
|  | C14D1 | 4 | 0.085 (0.0619) | 0.070 (0.040, 0.130) | 0.03, 0.17 | 4 | 0.043 (0.0377) | 0.040 (0.015, 0.070) | 0.00, 0.09 |
|  | C15D1 | 3 | 0.117 (0.1026) | 0.090 (0.030, 0.230) | 0.03, 0.23 | 3 | 0.067 (0.0764) | 0.050 (0.000, 0.150) | 0.00, 0.15 |
|  | C16D1 | 2 | 0.145 (0.1061) | 0.145 (0.070, 0.220) | 0.07, 0.22 | 2 | 0.085 (0.0778) | 0.085 (0.030, 0.140) | 0.03, 0.14 |
|  | C17D1 | 2 | 0.155 (0.0919) | 0.155 (0.090, 0.220) | 0.09, 0.22 | 2 | 0.095 (0.0636) | 0.095 (0.050, 0.140) | 0.05, 0.14 |
|  | C18D1 | 1 | 0.080 (NA) | 0.080 (0.080, 0.080) | 0.08, 0.08 | 1 | 0.040 (NA) | 0.040 (0.040, 0.040) | 0.04, 0.04 |
|  | End of Treatment | 4 | 0.083 (0.0580) | 0.075 (0.045, 0.120) | 0.02, 0.16 | 4 | 0.035 (0.0208) | 0.035 (0.020, 0.050) | 0.01, 0.06 |
|  | | | | | | | | | |
| Lymphocytes (10^9/L) (N = 33) | Baseline | 33 | 1.754 (0.6537) | 1.760 (1.370, 2.010) | 0.29, 3.19 |  |  |  |  |
|  | C1D8 | 33 | 1.842 (0.6894) | 1.900 (1.370, 2.050) | 0.20, 3.31 | 33 | 0.087 (0.4665) | -0.020 (-0.160, 0.410) | -1.30, 1.34 |
|  | C2D1 | 32 | 1.794 (0.5587) | 1.700 (1.365, 2.185) | 1.00, 3.24 | 32 | -0.006 (0.4747) | 0.120 (-0.200, 0.280) | -1.30, 0.74 |
|  | C3D1 | 31 | 1.830 (0.5251) | 1.700 (1.400, 2.300) | 0.90, 3.02 | 31 | 0.042 (0.4829) | 0.150 (-0.300, 0.380) | -1.50, 0.94 |
|  | C4D1 | 30 | 1.796 (0.6176) | 1.600 (1.350, 2.140) | 1.04, 3.49 | 30 | 0.013 (0.4369) | 0.010 (-0.310, 0.360) | -1.16, 0.83 |
|  | C5D1 | 28 | 1.733 (0.4637) | 1.630 (1.400, 2.110) | 0.97, 2.63 | 28 | 0.003 (0.4891) | 0.000 (-0.385, 0.285) | -0.90, 0.98 |
|  | C6D1 | 27 | 1.697 (0.4383) | 1.700 (1.370, 1.990) | 0.90, 2.50 | 27 | -0.052 (0.4227) | 0.000 (-0.330, 0.240) | -1.21, 0.68 |
|  | C7D1 | 23 | 1.679 (0.5709) | 1.610 (1.300, 2.070) | 0.79, 2.90 | 23 | -0.085 (0.3836) | 0.030 (-0.400, 0.230) | -1.00, 0.42 |
|  | C8D1 | 15 | 1.788 (0.5154) | 1.780 (1.500, 2.160) | 0.95, 2.69 | 15 | 0.028 (0.4643) | 0.140 (-0.200, 0.300) | -1.19, 0.70 |
|  | C9D1 | 11 | 1.977 (0.6321) | 2.040 (1.400, 2.550) | 0.85, 2.92 | 11 | 0.218 (0.3209) | 0.190 (-0.010, 0.580) | -0.40, 0.60 |
|  | C10D1 | 6 | 1.762 (0.8140) | 1.525 (1.100, 2.610) | 0.93, 2.88 | 6 | -0.132 (0.4209) | -0.060 (-0.390, 0.170) | -0.80, 0.35 |
|  | C11D1 | 6 | 1.998 (0.6651) | 1.935 (1.400, 2.680) | 1.19, 2.85 | 6 | 0.105 (0.4738) | 0.235 (-0.170, 0.430) | -0.70, 0.60 |
|  | C12D1 | 5 | 1.870 (0.6657) | 1.840 (1.700, 2.300) | 0.88, 2.63 | 5 | 0.018 (0.2853) | 0.100 (-0.230, 0.120) | -0.30, 0.40 |
|  | C13D1 | 4 | 2.085 (0.4414) | 2.025 (1.715, 2.455) | 1.70, 2.59 | 4 | -0.040 (0.3509) | -0.075 (-0.310, 0.230) | -0.41, 0.40 |
|  | C14D1 | 4 | 2.030 (0.3764) | 2.085 (1.730, 2.330) | 1.56, 2.39 | 4 | -0.095 (0.4992) | -0.200 (-0.420, 0.230) | -0.58, 0.60 |
|  | C15D1 | 3 | 1.953 (0.9094) | 1.850 (1.100, 2.910) | 1.10, 2.91 | 3 | -0.037 (0.3636) | -0.200 (-0.290, 0.380) | -0.29, 0.38 |
|  | C16D1 | 2 | 2.125 (0.2899) | 2.125 (1.920, 2.330) | 1.92, 2.33 | 2 | -0.210 (0.0141) | -0.210 (-0.220, -0.200) | -0.22, -0.20 |
|  | C17D1 | 2 | 2.095 (0.1344) | 2.095 (2.000, 2.190) | 2.00, 2.19 | 2 | -0.240 (0.1414) | -0.240 (-0.340, -0.140) | -0.34, -0.14 |
|  | C18D1 | 1 | 2.560 (NA) | 2.560 (2.560, 2.560) | 2.56, 2.56 | 1 | 0.030 (NA) | 0.030 (0.030, 0.030) | 0.03, 0.03 |
|  | End of Treatment | 4 | 1.943 (0.7564) | 1.845 (1.435, 2.450) | 1.13, 2.95 | 4 | -0.275 (0.3181) | -0.150 (-0.480, -0.070) | -0.74, -0.06 |
|  | | | | | | | | | |
| Monocytes (10^9/L) (N = 33) | Baseline | 33 | 0.568 (0.2084) | 0.510 (0.430, 0.660) | 0.30, 1.13 |  |  |  |  |
|  | C1D8 | 33 | 0.614 (0.2646) | 0.590 (0.400, 0.740) | 0.21, 1.24 | 33 | 0.045 (0.2323) | 0.050 (-0.090, 0.200) | -0.44, 0.57 |
|  | C2D1 | 32 | 0.625 (0.2486) | 0.570 (0.455, 0.790) | 0.30, 1.38 | 32 | 0.059 (0.2104) | 0.010 (-0.065, 0.205) | -0.43, 0.59 |
|  | C3D1 | 31 | 0.671 (0.3044) | 0.630 (0.500, 0.710) | 0.27, 1.77 | 31 | 0.115 (0.2147) | 0.140 (-0.040, 0.220) | -0.35, 0.64 |
|  | C4D1 | 30 | 0.633 (0.2437) | 0.600 (0.450, 0.800) | 0.21, 1.15 | 30 | 0.080 (0.1802) | 0.060 (-0.010, 0.180) | -0.35, 0.51 |
|  | C5D1 | 28 | 0.618 (0.2167) | 0.575 (0.485, 0.790) | 0.26, 1.06 | 28 | 0.076 (0.1585) | 0.070 (0.000, 0.175) | -0.38, 0.51 |
|  | C6D1 | 27 | 0.630 (0.2579) | 0.600 (0.460, 0.750) | 0.23, 1.45 | 27 | 0.097 (0.1817) | 0.100 (0.000, 0.170) | -0.19, 0.79 |
|  | C7D1 | 23 | 0.610 (0.2105) | 0.600 (0.480, 0.810) | 0.20, 0.93 | 23 | 0.084 (0.1668) | 0.080 (-0.020, 0.210) | -0.31, 0.35 |
|  | C8D1 | 15 | 0.642 (0.2405) | 0.590 (0.500, 0.950) | 0.33, 1.05 | 15 | 0.096 (0.1718) | 0.100 (0.020, 0.160) | -0.34, 0.46 |
|  | C9D1 | 11 | 0.587 (0.1588) | 0.600 (0.400, 0.750) | 0.36, 0.79 | 11 | 0.029 (0.1011) | 0.030 (0.000, 0.100) | -0.20, 0.20 |
|  | C10D1 | 6 | 0.832 (0.2727) | 0.795 (0.600, 1.000) | 0.53, 1.27 | 6 | 0.200 (0.2071) | 0.200 (0.020, 0.320) | -0.04, 0.50 |
|  | C11D1 | 6 | 0.667 (0.1428) | 0.645 (0.570, 0.740) | 0.50, 0.90 | 6 | 0.035 (0.0822) | 0.030 (-0.050, 0.100) | -0.05, 0.15 |
|  | C12D1 | 5 | 0.654 (0.2012) | 0.640 (0.600, 0.740) | 0.37, 0.92 | 5 | -0.004 (0.2452) | -0.140 (-0.150, 0.100) | -0.21, 0.38 |
|  | C13D1 | 4 | 0.623 (0.0903) | 0.645 (0.555, 0.690) | 0.50, 0.70 | 4 | 0.038 (0.1698) | 0.065 (-0.095, 0.170) | -0.18, 0.20 |
|  | C14D1 | 4 | 0.680 (0.1488) | 0.650 (0.570, 0.790) | 0.54, 0.88 | 4 | 0.095 (0.1812) | 0.065 (-0.030, 0.220) | -0.09, 0.34 |
|  | C15D1 | 3 | 0.747 (0.0611) | 0.760 (0.680, 0.800) | 0.68, 0.80 | 3 | 0.137 (0.2173) | 0.220 (-0.110, 0.300) | -0.11, 0.30 |
|  | C16D1 | 2 | 0.755 (0.0354) | 0.755 (0.730, 0.780) | 0.73, 0.78 | 2 | 0.090 (0.1414) | 0.090 (-0.010, 0.190) | -0.01, 0.19 |
|  | C17D1 | 2 | 0.735 (0.1768) | 0.735 (0.610, 0.860) | 0.61, 0.86 | 2 | 0.070 (0.0000) | 0.070 (0.070, 0.070) | 0.07, 0.07 |
|  | C18D1 | 1 | 0.780 (NA) | 0.780 (0.780, 0.780) | 0.78, 0.78 | 1 | 0.240 (NA) | 0.240 (0.240, 0.240) | 0.24, 0.24 |
|  | End of Treatment | 4 | 0.933 (0.5089) | 0.920 (0.575, 1.290) | 0.33, 1.56 | 4 | 0.205 (0.2549) | 0.245 (-0.005, 0.415) | -0.10, 0.43 |
|  | | | | | | | | | |
| Platelets (10^9/L) (N = 33) | Baseline | 33 | 266.0 (90.12) | 252.0 (218.0, 288.0) | 132, 670 |  |  |  |  |
|  | C1D8 | 33 | 276.1 (87.70) | 284.0 (212.0, 332.0) | 152, 567 | 33 | 10.1 (50.73) | 15.0 (-20.0, 41.0) | -116, 107 |
|  | C2D1 | 32 | 265.2 (62.48) | 256.5 (230.5, 289.0) | 161, 462 | 32 | -0.2 (66.00) | 5.5 (-35.5, 41.5) | -208, 105 |
|  | C3D1 | 31 | 307.7 (120.28) | 286.0 (226.0, 355.0) | 154, 804 | 31 | 41.6 (73.58) | 34.0 (0.0, 73.0) | -114, 221 |
|  | C4D1 | 30 | 284.3 (103.88) | 266.0 (200.0, 303.0) | 177, 567 | 30 | 18.5 (79.35) | 5.5 (-27.0, 52.0) | -118, 290 |
|  | C5D1 | 28 | 280.1 (82.92) | 273.0 (220.0, 317.0) | 159, 455 | 28 | 27.3 (61.75) | 24.5 (-3.5, 67.0) | -129, 133 |
|  | C6D1 | 27 | 271.9 (84.13) | 247.0 (213.0, 296.0) | 167, 473 | 27 | 20.4 (59.54) | 31.0 (-9.0, 49.0) | -144, 140 |
|  | C7D1 | 23 | 267.1 (74.53) | 263.0 (214.0, 324.0) | 154, 430 | 23 | 21.6 (47.03) | 26.0 (-24.0, 64.0) | -75, 101 |
|  | C8D1 | 15 | 266.3 (73.40) | 263.0 (204.0, 338.0) | 150, 401 | 15 | 20.6 (56.20) | 18.0 (-6.0, 56.0) | -69, 156 |
|  | C9D1 | 11 | 251.9 (70.65) | 273.0 (173.0, 300.0) | 132, 358 | 11 | 10.7 (67.63) | 34.0 (-45.0, 68.0) | -135, 88 |
|  | C10D1 | 6 | 263.7 (79.76) | 272.0 (180.0, 306.0) | 173, 379 | 6 | -13.8 (58.00) | -5.5 (-53.0, 36.0) | -94, 39 |
|  | C11D1 | 6 | 265.5 (102.70) | 272.5 (184.0, 340.0) | 128, 396 | 6 | -12.0 (72.82) | 6.5 (-49.0, 50.0) | -139, 53 |
|  | C12D1 | 5 | 257.0 (96.44) | 322.0 (154.0, 325.0) | 149, 335 | 5 | -29.4 (63.20) | -21.0 (-53.0, -10.0) | -118, 55 |
|  | C13D1 | 4 | 315.5 (53.85) | 302.0 (282.0, 349.0) | 266, 392 | 4 | 24.3 (42.78) | 37.5 (-4.5, 53.0) | -37, 59 |
|  | C14D1 | 4 | 310.3 (46.69) | 319.0 (279.5, 341.0) | 246, 357 | 4 | 19.0 (28.99) | 26.5 (-3.0, 41.0) | -20, 43 |
|  | C15D1 | 3 | 310.3 (45.65) | 306.0 (267.0, 358.0) | 267, 358 | 3 | -9.0 (25.53) | -3.0 (-37.0, 13.0) | -37, 13 |
|  | C16D1 | 2 | 280.0 (24.04) | 280.0 (263.0, 297.0) | 263, 297 | 2 | -27.5 (28.99) | -27.5 (-48.0, -7.0) | -48, -7 |
|  | C17D1 | 2 | 364.0 (42.43) | 364.0 (334.0, 394.0) | 334, 394 | 2 | 56.5 (10.61) | 56.5 (49.0, 64.0) | 49, 64 |
|  | C18D1 | 1 | 287.0 (NA) | 287.0 (287.0, 287.0) | 287, 287 | 1 | 17.0 (NA) | 17.0 (17.0, 17.0) | 17, 17 |
|  | End of Treatment | 4 | 458.3 (187.31) | 459.5 (337.0, 579.5) | 228, 686 | 4 | 78.8 (96.59) | 64.5 (1.5, 156.0) | -13, 199 |

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 14.3.5.1.2.2 Summary of Chemistry Results - Phase II part 1 treatment-naive locally-advanced or metastatic NSCLC (Safety Analysis Set)**

|  | | Observed Value | | | | Change from Baseline | | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Parameter | Visit | n | Mean (STD) | Median (Q1, Q3) | Min, Max | n | Mean (STD) | Median (Q1, Q3) | Min, Max |
| Creatinine Clearance (mL/min) (N = 33) | Baseline | 32 | 83.39 (15.763) | 82.65 (72.20, 95.40) | 54.7, 116.4 |  |  |  |  |
|  | C2D1 | 32 | 76.88 (14.330) | 78.90 (66.20, 87.05) | 49.7, 106.0 | 31 | -6.11 (5.936) | -6.90 (-10.40, -1.20) | -18.0, 3.7 |
|  | C3D1 | 31 | 77.05 (14.303) | 74.40 (68.90, 85.40) | 49.9, 106.6 | 30 | -5.98 (8.951) | -6.80 (-11.10, 1.90) | -21.1, 15.5 |
|  | C4D1 | 30 | 76.72 (15.022) | 77.15 (67.00, 85.70) | 49.7, 111.0 | 29 | -6.98 (9.107) | -8.30 (-13.00, -0.30) | -28.1, 11.3 |
|  | C5D1 | 27 | 77.25 (14.464) | 74.20 (68.30, 85.70) | 51.9, 108.5 | 26 | -6.54 (9.524) | -6.60 (-14.90, 2.10) | -22.4, 8.5 |
|  | C6D1 | 27 | 78.37 (18.973) | 76.30 (68.50, 86.20) | 46.4, 123.0 | 26 | -5.35 (11.974) | -4.95 (-14.60, 3.60) | -25.7, 23.3 |
|  | C7D1 | 22 | 77.78 (16.663) | 76.90 (68.90, 83.50) | 48.8, 121.6 | 21 | -6.58 (10.676) | -5.40 (-10.80, 0.00) | -27.8, 21.1 |
|  | C8D1 | 15 | 78.67 (16.773) | 77.70 (66.40, 89.00) | 46.5, 109.1 | 14 | -5.96 (9.557) | -9.20 (-13.70, 1.30) | -14.3, 18.6 |
|  | C9D1 | 11 | 71.72 (12.997) | 70.60 (65.40, 81.60) | 44.4, 90.7 | 10 | -8.08 (8.354) | -10.20 (-12.60, 2.60) | -20.8, 3.3 |
|  | C10D1 | 6 | 76.62 (13.190) | 77.30 (72.00, 89.20) | 54.0, 89.9 | 5 | -5.90 (8.292) | -5.20 (-13.30, -2.30) | -14.4, 5.7 |
|  | C11D1 | 6 | 71.57 (18.349) | 71.20 (62.20, 82.30) | 44.1, 98.4 | 5 | -13.66 (7.850) | -15.10 (-18.00, -12.10) | -21.9, -1.2 |
|  | C12D1 | 5 | 70.56 (15.389) | 77.60 (69.80, 80.00) | 44.2, 81.2 | 5 | -9.30 (4.197) | -10.20 (-10.90, -5.90) | -15.0, -4.5 |
|  | C13D1 | 4 | 74.15 (7.919) | 73.95 (67.45, 80.85) | 66.2, 82.5 | 4 | -10.88 (10.508) | -8.65 (-18.45, -3.30) | -25.2, -1.0 |
|  | C14D1 | 4 | 74.83 (11.159) | 75.30 (68.00, 81.65) | 60.7, 88.0 | 4 | -10.20 (5.878) | -10.90 (-14.85, -5.55) | -16.1, -2.9 |
|  | C15D1 | 3 | 73.97 (9.235) | 74.90 (64.30, 82.70) | 64.3, 82.7 | 3 | -8.93 (0.945) | -8.60 (-10.00, -8.20) | -10.0, -8.2 |
|  | C16D1 | 2 | 63.80 (8.910) | 63.80 (57.50, 70.10) | 57.5, 70.1 | 2 | -15.10 (2.404) | -15.10 (-16.80, -13.40) | -16.8, -13.4 |
|  | C17D1 | 2 | 70.50 (9.758) | 70.50 (63.60, 77.40) | 63.6, 77.4 | 2 | -8.40 (3.253) | -8.40 (-10.70, -6.10) | -10.7, -6.1 |
|  | C18D1 | 1 | 81.30 (NA) | 81.30 (81.30, 81.30) | 81.3, 81.3 | 1 | -2.20 (NA) | -2.20 (-2.20, -2.20) | -2.2, -2.2 |
|  | End of Treatment | 4 | 64.08 (13.643) | 65.95 (52.85, 75.30) | 47.8, 76.6 | 4 | -14.98 (30.773) | -4.10 (-33.15, 3.20) | -60.2, 8.5 |
|  | | | | | | | | | |
| Bilirubin (umol/L) (N = 33) | Baseline | 33 | 10.987 (4.6744) | 9.900 (7.500, 12.600) | 5.10, 25.70 |  |  |  |  |
|  | C1D8 | 33 | 10.423 (4.1059) | 9.400 (7.300, 13.000) | 5.00, 21.30 | 33 | -0.564 (3.8236) | -1.100 (-2.300, 1.500) | -9.60, 13.20 |
|  | C2D1 | 32 | 9.953 (2.8758) | 9.800 (7.400, 12.150) | 5.00, 15.50 | 32 | -1.018 (4.1877) | -0.550 (-2.350, 1.800) | -14.00, 6.00 |
|  | C3D1 | 31 | 10.507 (3.9721) | 9.300 (7.600, 13.500) | 4.50, 19.50 | 31 | -0.324 (4.5480) | 0.500 (-2.200, 2.400) | -12.20, 7.80 |
|  | C4D1 | 30 | 10.983 (6.0961) | 8.800 (6.400, 14.200) | 4.10, 30.50 | 30 | 0.121 (3.9066) | -0.300 (-2.100, 2.100) | -7.90, 11.90 |
|  | C5D1 | 28 | 10.407 (4.4567) | 10.300 (7.150, 12.400) | 3.80, 21.70 | 28 | -0.107 (3.9156) | -0.450 (-2.300, 2.550) | -12.60, 8.50 |
|  | C6D1 | 27 | 10.274 (3.7073) | 9.700 (7.500, 12.800) | 5.10, 17.40 | 27 | -0.441 (4.2060) | 0.000 (-2.400, 1.600) | -11.80, 11.10 |
|  | C7D1 | 23 | 10.574 (3.8363) | 10.400 (7.700, 12.500) | 4.90, 19.60 | 23 | -0.713 (3.6590) | -1.300 (-2.600, 1.400) | -10.90, 6.60 |
|  | C8D1 | 15 | 9.987 (3.4117) | 10.000 (6.700, 14.000) | 5.20, 14.70 | 15 | 0.027 (3.0591) | -0.100 (-3.400, 2.800) | -4.20, 5.20 |
|  | C9D1 | 11 | 9.682 (2.7506) | 10.100 (6.700, 12.200) | 5.90, 13.30 | 11 | -0.191 (2.7552) | -0.400 (-2.500, 2.900) | -3.80, 3.80 |
|  | C10D1 | 6 | 15.933 (4.8123) | 16.050 (11.000, 17.600) | 11.00, 23.90 | 6 | 5.267 (4.2174) | 4.950 (3.700, 5.900) | -0.40, 12.50 |
|  | C11D1 | 6 | 11.700 (3.7008) | 11.050 (9.500, 14.600) | 6.80, 17.20 | 6 | 1.033 (4.0884) | 1.700 (-2.300, 4.600) | -4.60, 5.10 |
|  | C12D1 | 5 | 9.960 (3.5990) | 9.600 (7.200, 10.100) | 7.00, 15.90 | 5 | -0.320 (3.7519) | -2.200 (-2.500, 2.800) | -4.20, 4.50 |
|  | C13D1 | 4 | 10.425 (1.9294) | 10.700 (8.900, 11.950) | 8.00, 12.30 | 4 | 0.425 (2.6924) | 1.300 (-1.450, 2.300) | -3.40, 2.50 |
|  | C14D1 | 4 | 9.075 (1.2764) | 9.450 (8.150, 10.000) | 7.30, 10.10 | 4 | -0.925 (2.3684) | -1.950 (-2.300, 0.450) | -2.40, 2.60 |
|  | C15D1 | 3 | 13.967 (4.0079) | 15.600 (9.400, 16.900) | 9.40, 16.90 | 3 | 3.067 (4.7427) | 3.800 (-2.000, 7.400) | -2.00, 7.40 |
|  | C16D1 | 2 | 8.700 (0.1414) | 8.700 (8.600, 8.800) | 8.60, 8.80 | 2 | -1.750 (1.2021) | -1.750 (-2.600, -0.900) | -2.60, -0.90 |
|  | C17D1 | 2 | 15.150 (3.0406) | 15.150 (13.000, 17.300) | 13.00, 17.30 | 2 | 4.700 (4.3841) | 4.700 (1.600, 7.800) | 1.60, 7.80 |
|  | C18D1 | 1 | 19.400 (NA) | 19.400 (19.400, 19.400) | 19.40, 19.40 | 1 | 9.900 (NA) | 9.900 (9.900, 9.900) | 9.90, 9.90 |
|  | End of Treatment | 4 | 16.008 (10.3510) | 16.010 (7.050, 24.965) | 6.70, 25.31 | 4 | 5.993 (8.3636) | 5.530 (-0.950, 12.935) | -2.50, 15.41 |
|  | | | | | | | | | |
| Direct Bilirubin (umol/L) (N = 33) | Baseline | 33 | 3.902 (1.7047) | 3.700 (2.650, 4.900) | 1.30, 8.90 |  |  |  |  |
|  | C1D8 | 33 | 3.475 (1.8381) | 3.000 (2.200, 4.500) | 0.90, 7.60 | 33 | -0.427 (1.4538) | -0.300 (-1.200, 0.000) | -2.90, 4.30 |
|  | C2D1 | 32 | 3.678 (1.6218) | 3.500 (2.650, 4.850) | 0.60, 7.90 | 32 | -0.167 (1.4574) | -0.200 (-0.850, 0.650) | -3.50, 3.50 |
|  | C3D1 | 31 | 3.936 (2.2816) | 3.600 (2.100, 4.900) | 1.50, 11.40 | 31 | 0.128 (1.9712) | 0.000 (-0.700, 0.900) | -3.30, 7.00 |
|  | C4D1 | 30 | 3.950 (2.8339) | 3.250 (1.900, 4.500) | 1.00, 14.90 | 30 | 0.095 (2.0136) | -0.250 (-0.800, 0.600) | -2.90, 7.50 |
|  | C5D1 | 28 | 3.618 (2.1115) | 3.000 (2.050, 4.850) | 0.80, 9.40 | 28 | -0.179 (1.7218) | -0.200 (-0.850, 0.700) | -4.70, 4.30 |
|  | C6D1 | 27 | 3.396 (1.6890) | 2.800 (2.400, 4.800) | 0.90, 7.50 | 27 | -0.433 (1.5616) | -0.200 (-1.300, 0.300) | -3.60, 4.70 |
|  | C7D1 | 23 | 3.691 (1.5219) | 3.500 (2.800, 4.500) | 1.70, 7.50 | 23 | -0.417 (1.2445) | -0.300 (-0.800, 0.300) | -3.70, 1.50 |
|  | C8D1 | 15 | 3.420 (1.4910) | 3.200 (2.600, 3.400) | 1.30, 6.30 | 15 | -0.307 (1.3107) | -0.200 (-1.200, 0.700) | -2.60, 2.00 |
|  | C9D1 | 11 | 3.291 (1.2645) | 3.100 (2.100, 4.100) | 1.30, 5.60 | 11 | -0.509 (0.6774) | -0.400 (-1.000, 0.000) | -1.90, 0.40 |
|  | C10D1 | 6 | 5.450 (2.8353) | 5.600 (2.900, 7.700) | 1.90, 9.00 | 6 | 1.433 (1.6476) | 1.550 (-0.300, 2.800) | -0.40, 3.40 |
|  | C11D1 | 6 | 4.167 (2.1097) | 4.100 (3.300, 4.600) | 1.20, 7.70 | 6 | 0.150 (1.4516) | -0.200 (-1.000, 0.600) | -1.10, 2.80 |
|  | C12D1 | 5 | 3.880 (2.4672) | 4.000 (1.700, 4.900) | 1.40, 7.40 | 5 | 0.040 (1.4346) | -0.500 (-0.900, 1.300) | -1.50, 1.80 |
|  | C13D1 | 4 | 3.175 (1.4408) | 3.300 (2.050, 4.300) | 1.40, 4.70 | 4 | -0.225 (0.5737) | -0.150 (-0.700, 0.250) | -0.90, 0.30 |
|  | C14D1 | 4 | 2.850 (1.0536) | 2.850 (1.950, 3.750) | 1.80, 3.90 | 4 | -0.550 (0.7506) | -0.550 (-1.150, 0.050) | -1.40, 0.30 |
|  | C15D1 | 3 | 3.533 (2.3029) | 3.400 (1.300, 5.900) | 1.30, 5.90 | 3 | 0.200 (1.2000) | 0.200 (-1.000, 1.400) | -1.00, 1.40 |
|  | C16D1 | 2 | 1.850 (0.0707) | 1.850 (1.800, 1.900) | 1.80, 1.90 | 2 | -0.900 (0.7071) | -0.900 (-1.400, -0.400) | -1.40, -0.40 |
|  | C17D1 | 2 | 2.950 (0.9192) | 2.950 (2.300, 3.600) | 2.30, 3.60 | 2 | 0.200 (0.2828) | 0.200 (0.000, 0.400) | 0.00, 0.40 |
|  | C18D1 | 1 | 4.300 (NA) | 4.300 (4.300, 4.300) | 4.30, 4.30 | 1 | 1.100 (NA) | 1.100 (1.100, 1.100) | 1.10, 1.10 |
|  | End of Treatment | 4 | 5.005 (3.6577) | 4.485 (2.150, 7.860) | 1.40, 9.65 | 4 | 2.543 (3.5838) | 1.610 (-0.250, 5.335) | -0.30, 7.25 |
|  | | | | | | | | | |
| Indirect Bilirubin (umol/L) (N = 33) | Baseline | 30 | 7.190 (3.5569) | 6.250 (4.800, 8.900) | 2.20, 16.80 |  |  |  |  |
|  | C1D8 | 30 | 6.976 (2.9726) | 6.400 (4.600, 9.100) | 2.70, 13.70 | 30 | -0.214 (2.7863) | -0.700 (-1.800, 1.700) | -7.30, 8.90 |
|  | C2D1 | 30 | 6.380 (2.3732) | 5.850 (4.400, 8.100) | 2.60, 10.50 | 30 | -0.810 (3.3566) | -0.050 (-2.200, 1.400) | -10.50, 3.90 |
|  | C3D1 | 29 | 6.676 (3.0238) | 6.500 (4.700, 7.500) | 2.80, 14.90 | 29 | -0.407 (3.7184) | 0.600 (-1.300, 1.500) | -11.90, 6.00 |
|  | C4D1 | 28 | 6.971 (3.8924) | 5.050 (3.800, 9.250) | 2.60, 15.60 | 28 | -0.097 (2.6499) | -0.250 (-1.300, 1.150) | -5.00, 9.80 |
|  | C5D1 | 26 | 6.931 (2.9525) | 6.600 (5.100, 9.000) | 2.10, 12.30 | 26 | 0.169 (2.6997) | 0.050 (-0.800, 1.800) | -7.90, 4.40 |
|  | C6D1 | 25 | 6.624 (2.6013) | 6.100 (4.500, 8.100) | 2.60, 11.60 | 25 | -0.320 (2.8702) | 0.600 (-1.700, 1.400) | -10.30, 3.20 |
|  | C7D1 | 22 | 6.868 (3.0724) | 6.100 (4.400, 9.600) | 2.10, 12.10 | 22 | -0.236 (2.8374) | -0.400 (-1.900, 1.900) | -7.20, 5.20 |
|  | C8D1 | 15 | 6.567 (2.9073) | 6.700 (4.300, 8.400) | 2.00, 11.30 | 15 | 0.333 (2.0934) | 0.100 (-1.600, 2.000) | -2.90, 5.00 |
|  | C9D1 | 11 | 6.391 (2.4878) | 6.300 (4.400, 8.100) | 2.90, 10.40 | 11 | 0.318 (2.2816) | 0.300 (-1.600, 2.700) | -2.80, 4.10 |
|  | C10D1 | 6 | 10.483 (2.8999) | 9.900 (9.000, 12.500) | 6.70, 14.90 | 6 | 3.833 (3.3267) | 3.200 (1.300, 6.200) | 0.00, 9.10 |
|  | C11D1 | 6 | 7.533 (2.3619) | 6.650 (5.600, 9.500) | 5.50, 11.30 | 6 | 0.883 (3.1865) | 1.100 (-1.800, 3.400) | -3.50, 5.00 |
|  | C12D1 | 5 | 6.080 (1.3737) | 5.600 (5.300, 5.800) | 5.20, 8.50 | 5 | -0.360 (2.4327) | -1.000 (-1.700, 1.500) | -3.30, 2.70 |
|  | C13D1 | 4 | 7.250 (1.3026) | 7.100 (6.250, 8.250) | 5.90, 8.90 | 4 | 0.650 (2.3274) | 1.250 (-1.100, 2.400) | -2.50, 2.60 |
|  | C14D1 | 4 | 6.000 (0.4082) | 6.000 (5.750, 6.250) | 5.50, 6.50 | 4 | -0.600 (2.2166) | -0.800 (-1.950, 0.750) | -3.10, 2.30 |
|  | C15D1 | 3 | 10.433 (2.7737) | 9.700 (8.100, 13.500) | 8.10, 13.50 | 3 | 2.867 (4.1199) | 2.400 (-1.000, 7.200) | -1.00, 7.20 |
|  | C16D1 | 2 | 6.850 (0.0707) | 6.850 (6.800, 6.900) | 6.80, 6.90 | 2 | -0.850 (1.9092) | -0.850 (-2.200, 0.500) | -2.20, 0.50 |
|  | C17D1 | 2 | 12.200 (2.1213) | 12.200 (10.700, 13.700) | 10.70, 13.70 | 2 | 4.500 (4.1012) | 4.500 (1.600, 7.400) | 1.60, 7.40 |
|  | C18D1 | 1 | 15.100 (NA) | 15.100 (15.100, 15.100) | 15.10, 15.10 | 1 | 8.800 (NA) | 8.800 (8.800, 8.800) | 8.80, 8.80 |
|  | End of Treatment | 4 | 11.003 (7.2009) | 10.830 (4.900, 17.105) | 3.80, 18.55 | 4 | 3.450 (4.9671) | 3.920 (-0.700, 7.600) | -2.20, 8.16 |
|  | | | | | | | | | |
| Alanine Aminotransferase (IU/L) (N = 33) | Baseline | 33 | 19.97 (14.095) | 16.00 (13.70, 21.00) | 4.0, 81.0 |  |  |  |  |
|  | C1D8 | 33 | 28.38 (38.565) | 17.00 (12.00, 28.00) | 3.0, 222.0 | 33 | 8.41 (27.196) | 1.00 (-2.00, 12.00) | -25.0, 141.0 |
|  | C2D1 | 32 | 33.80 (31.157) | 25.50 (12.50, 42.50) | 6.0, 149.9 | 32 | 14.45 (31.838) | 4.50 (0.50, 20.00) | -27.0, 135.5 |
|  | C3D1 | 31 | 29.44 (21.816) | 23.00 (13.00, 40.00) | 6.0, 115.0 | 31 | 9.91 (22.796) | 6.00 (-3.00, 20.00) | -25.0, 98.0 |
|  | C4D1 | 30 | 23.35 (13.770) | 20.75 (14.00, 35.00) | 4.0, 69.0 | 30 | 4.18 (15.870) | 2.50 (-3.00, 8.00) | -39.0, 52.0 |
|  | C5D1 | 28 | 21.90 (11.413) | 19.00 (13.00, 31.00) | 7.0, 52.0 | 28 | 2.11 (15.644) | 1.00 (-5.00, 9.00) | -49.0, 35.0 |
|  | C6D1 | 27 | 20.39 (11.865) | 17.00 (13.00, 25.00) | 7.0, 62.0 | 27 | 0.39 (14.112) | 0.00 (-6.00, 6.00) | -42.0, 37.0 |
|  | C7D1 | 23 | 18.68 (6.026) | 18.00 (15.00, 23.00) | 8.0, 37.0 | 23 | -2.20 (14.997) | 1.00 (-6.00, 7.00) | -58.0, 20.0 |
|  | C8D1 | 15 | 18.00 (5.657) | 19.00 (13.00, 22.00) | 10.0, 30.0 | 15 | -5.93 (19.084) | -1.00 (-8.00, 6.00) | -62.0, 13.0 |
|  | C9D1 | 11 | 19.00 (6.928) | 17.00 (14.00, 25.00) | 9.0, 30.0 | 11 | -2.18 (10.666) | 0.00 (-9.00, 5.00) | -22.0, 13.0 |
|  | C10D1 | 6 | 17.50 (5.683) | 16.50 (12.00, 23.00) | 12.0, 25.0 | 6 | -5.17 (12.416) | -3.50 (-7.00, 3.00) | -28.0, 8.0 |
|  | C11D1 | 6 | 17.83 (4.535) | 17.50 (14.00, 23.00) | 12.0, 23.0 | 6 | -4.83 (10.870) | -2.50 (-7.00, 2.00) | -25.0, 6.0 |
|  | C12D1 | 5 | 14.80 (3.962) | 14.00 (14.00, 18.00) | 9.0, 19.0 | 5 | -7.00 (12.728) | -1.00 (-10.00, 2.00) | -28.0, 2.0 |
|  | C13D1 | 4 | 13.50 (3.109) | 12.50 (11.50, 15.50) | 11.0, 18.0 | 4 | -9.00 (13.540) | -4.00 (-16.50, -1.50) | -29.0, 1.0 |
|  | C14D1 | 4 | 11.75 (2.986) | 12.00 (9.50, 14.00) | 8.0, 15.0 | 4 | -10.75 (12.339) | -6.00 (-18.00, -3.50) | -29.0, -2.0 |
|  | C15D1 | 3 | 14.67 (4.163) | 16.00 (10.00, 18.00) | 10.0, 18.0 | 3 | -10.00 (12.288) | -5.00 (-24.00, -1.00) | -24.0, -1.0 |
|  | C16D1 | 2 | 16.50 (3.536) | 16.50 (14.00, 19.00) | 14.0, 19.0 | 2 | -13.00 (21.213) | -13.00 (-28.00, 2.00) | -28.0, 2.0 |
|  | C17D1 | 2 | 17.00 (7.071) | 17.00 (12.00, 22.00) | 12.0, 22.0 | 2 | -12.50 (24.749) | -12.50 (-30.00, 5.00) | -30.0, 5.0 |
|  | C18D1 | 1 | 17.00 (NA) | 17.00 (17.00, 17.00) | 17.0, 17.0 | 1 | 0.00 (NA) | 0.00 (0.00, 0.00) | 0.0, 0.0 |
|  | End of Treatment | 4 | 11.30 (7.212) | 8.00 (7.55, 15.05) | 7.1, 22.1 | 4 | -7.78 (11.711) | -6.50 (-15.60, 0.05) | -23.2, 5.1 |
|  | | | | | | | | | |
| Aspartate Aminotransferase (IU/L) (N = 33) | Baseline | 33 | 21.67 (8.960) | 19.00 (16.00, 23.00) | 10.0, 52.0 |  |  |  |  |
|  | C1D8 | 33 | 30.04 (21.017) | 23.80 (19.00, 30.70) | 12.0, 120.0 | 33 | 8.37 (16.396) | 5.00 (-1.00, 12.00) | -14.0, 68.0 |
|  | C2D1 | 32 | 30.86 (18.553) | 27.00 (19.70, 32.00) | 14.0, 102.7 | 32 | 9.70 (19.865) | 6.30 (-1.00, 12.50) | -19.3, 82.8 |
|  | C3D1 | 31 | 32.70 (20.707) | 28.00 (20.00, 38.00) | 15.0, 115.4 | 31 | 11.57 (21.661) | 5.40 (2.00, 17.00) | -23.0, 95.5 |
|  | C4D1 | 30 | 26.82 (10.435) | 24.40 (19.00, 32.00) | 14.0, 59.0 | 30 | 6.25 (10.857) | 5.50 (2.00, 10.00) | -25.0, 36.0 |
|  | C5D1 | 28 | 26.23 (8.391) | 25.50 (21.00, 29.50) | 14.0, 50.0 | 28 | 5.28 (11.118) | 5.00 (-0.50, 12.00) | -26.0, 29.0 |
|  | C6D1 | 27 | 24.03 (9.683) | 22.00 (18.80, 29.00) | 9.0, 56.0 | 27 | 2.93 (10.835) | 2.00 (-3.00, 8.00) | -23.0, 35.0 |
|  | C7D1 | 23 | 23.13 (5.463) | 22.00 (20.00, 24.00) | 17.0, 42.0 | 23 | 1.40 (9.674) | 3.00 (0.00, 6.00) | -28.0, 19.0 |
|  | C8D1 | 15 | 24.00 (6.279) | 23.00 (19.00, 30.00) | 17.0, 35.0 | 15 | -0.27 (13.483) | 3.00 (-7.00, 10.00) | -34.0, 16.0 |
|  | C9D1 | 11 | 24.45 (6.699) | 23.00 (19.00, 31.00) | 16.0, 37.0 | 11 | 1.64 (9.146) | 3.00 (-4.00, 8.00) | -19.0, 14.0 |
|  | C10D1 | 6 | 22.83 (5.492) | 22.50 (18.00, 27.00) | 17.0, 30.0 | 6 | -1.83 (9.109) | 2.50 (-9.00, 4.00) | -17.0, 6.0 |
|  | C11D1 | 6 | 22.67 (5.538) | 23.00 (17.00, 28.00) | 16.0, 29.0 | 6 | -2.00 (10.119) | 3.50 (-10.00, 5.00) | -19.0, 5.0 |
|  | C12D1 | 5 | 19.80 (3.564) | 21.00 (16.00, 23.00) | 16.0, 23.0 | 5 | -5.00 (10.000) | 0.00 (-12.00, 2.00) | -19.0, 4.0 |
|  | C13D1 | 4 | 22.25 (4.425) | 22.00 (18.50, 26.00) | 18.0, 27.0 | 4 | 0.00 (6.733) | 3.00 (-4.00, 4.00) | -10.0, 4.0 |
|  | C14D1 | 4 | 18.50 (3.697) | 18.00 (15.50, 21.50) | 15.0, 23.0 | 4 | -3.75 (7.544) | -0.50 (-8.00, 0.50) | -15.0, 1.0 |
|  | C15D1 | 3 | 21.00 (5.196) | 24.00 (15.00, 24.00) | 15.0, 24.0 | 3 | -3.00 (6.928) | 1.00 (-11.00, 1.00) | -11.0, 1.0 |
|  | C16D1 | 2 | 26.00 (2.828) | 26.00 (24.00, 28.00) | 24.0, 28.0 | 2 | -3.00 (11.314) | -3.00 (-11.00, 5.00) | -11.0, 5.0 |
|  | C17D1 | 2 | 25.50 (4.950) | 25.50 (22.00, 29.00) | 22.0, 29.0 | 2 | -3.50 (13.435) | -3.50 (-13.00, 6.00) | -13.0, 6.0 |
|  | C18D1 | 1 | 30.00 (NA) | 30.00 (30.00, 30.00) | 30.0, 30.0 | 1 | 7.00 (NA) | 7.00 (7.00, 7.00) | 7.0, 7.0 |
|  | End of Treatment | 4 | 19.40 (4.280) | 19.60 (16.50, 22.30) | 14.0, 24.4 | 4 | -2.93 (7.175) | -0.50 (-7.65, 1.80) | -13.3, 2.6 |
|  | | | | | | | | | |
| Gamma Glutamyl Transferase (IU/L) (N = 33) | Baseline | 33 | 48.09 (70.745) | 26.00 (20.00, 33.90) | 9.0, 327.0 |  |  |  |  |
|  | C1D8 | 33 | 48.48 (69.366) | 24.00 (17.00, 35.00) | 7.0, 336.0 | 33 | 0.39 (34.985) | -2.00 (-4.00, 2.00) | -115.0, 148.3 |
|  | C2D1 | 32 | 55.03 (66.780) | 32.00 (21.00, 55.50) | 8.0, 352.1 | 32 | 10.00 (79.485) | 0.45 (-3.50, 16.00) | -234.0, 323.2 |
|  | C3D1 | 31 | 45.58 (49.496) | 28.00 (23.00, 56.00) | 8.0, 283.7 | 31 | -0.06 (79.989) | 2.00 (-4.00, 14.00) | -279.0, 254.8 |
|  | C4D1 | 30 | 42.29 (41.305) | 25.00 (19.00, 42.00) | 7.0, 171.1 | 30 | 6.03 (57.537) | -1.50 (-7.00, 6.00) | -215.0, 142.2 |
|  | C5D1 | 28 | 41.70 (34.909) | 27.25 (18.00, 51.00) | 9.0, 143.0 | 28 | 5.32 (58.558) | -0.50 (-5.00, 12.50) | -235.0, 124.0 |
|  | C6D1 | 27 | 42.30 (42.947) | 28.00 (19.00, 53.00) | 11.0, 208.0 | 27 | 5.53 (60.511) | 1.00 (-6.00, 10.00) | -204.0, 189.0 |
|  | C7D1 | 23 | 44.13 (33.717) | 26.00 (20.00, 59.00) | 9.0, 124.0 | 23 | 5.70 (61.001) | 1.00 (-7.00, 17.00) | -226.0, 105.0 |
|  | C8D1 | 15 | 30.00 (21.132) | 21.00 (17.00, 33.00) | 8.0, 87.0 | 15 | -13.67 (62.340) | -1.00 (-6.00, 2.00) | -230.0, 58.0 |
|  | C9D1 | 11 | 33.00 (20.620) | 25.00 (18.00, 51.00) | 16.0, 80.0 | 11 | 3.45 (11.776) | 2.00 (-6.00, 11.00) | -9.0, 28.0 |
|  | C10D1 | 6 | 28.17 (10.572) | 25.50 (22.00, 37.00) | 15.0, 44.0 | 6 | -3.00 (7.211) | -4.50 (-6.00, 2.00) | -13.0, 8.0 |
|  | C11D1 | 6 | 28.17 (11.990) | 25.00 (21.00, 32.00) | 16.0, 50.0 | 6 | -3.00 (4.050) | -4.50 (-6.00, 1.00) | -7.0, 3.0 |
|  | C12D1 | 5 | 28.20 (10.426) | 28.00 (23.00, 32.00) | 15.0, 43.0 | 5 | -5.20 (6.017) | -5.00 (-5.00, -5.00) | -14.0, 3.0 |
|  | C13D1 | 4 | 28.50 (12.871) | 29.50 (19.50, 37.50) | 12.0, 43.0 | 4 | -6.25 (7.042) | -7.00 (-11.00, -1.50) | -14.0, 3.0 |
|  | C14D1 | 4 | 30.00 (13.904) | 30.00 (21.00, 39.00) | 13.0, 47.0 | 4 | -4.75 (5.123) | -5.50 (-8.50, -1.00) | -10.0, 2.0 |
|  | C15D1 | 3 | 35.00 (10.000) | 35.00 (25.00, 45.00) | 25.0, 45.0 | 3 | -4.67 (9.452) | -8.00 (-12.00, 6.00) | -12.0, 6.0 |
|  | C16D1 | 2 | 37.50 (10.607) | 37.50 (30.00, 45.00) | 30.0, 45.0 | 2 | -5.50 (9.192) | -5.50 (-12.00, 1.00) | -12.0, 1.0 |
|  | C17D1 | 2 | 33.00 (0.000) | 33.00 (33.00, 33.00) | 33.0, 33.0 | 2 | -10.00 (19.799) | -10.00 (-24.00, 4.00) | -24.0, 4.0 |
|  | C18D1 | 1 | 33.00 (NA) | 33.00 (33.00, 33.00) | 33.0, 33.0 | 1 | 4.00 (NA) | 4.00 (4.00, 4.00) | 4.0, 4.0 |
|  | End of Treatment | 4 | 29.45 (10.935) | 30.25 (21.00, 37.90) | 16.0, 41.3 | 4 | -76.08 (144.645) | -10.40 (-154.25, 2.10) | -292.5, 9.0 |
|  | | | | | | | | | |
| Alkaline Phosphatase (IU/L) (N = 33) | Baseline | 33 | 103.833 (43.5207) | 100.000 (79.000, 108.000) | 38.90, 246.00 |  |  |  |  |
|  | C1D8 | 33 | 98.933 (38.2063) | 96.000 (71.000, 115.000) | 50.00, 220.00 | 33 | -4.900 (14.8740) | -6.000 (-14.000, 2.000) | -36.00, 35.00 |
|  | C2D1 | 32 | 102.781 (46.0301) | 92.000 (75.000, 111.000) | 39.80, 286.20 | 32 | 1.859 (53.7349) | -5.000 (-18.000, 13.000) | -98.00, 215.60 |
|  | C3D1 | 31 | 92.487 (30.6834) | 89.000 (70.000, 102.000) | 39.90, 187.20 | 31 | -7.981 (39.3485) | -4.000 (-15.000, 2.000) | -118.00, 116.60 |
|  | C4D1 | 30 | 87.097 (23.2071) | 85.500 (73.000, 106.000) | 34.70, 130.00 | 30 | -8.520 (29.9325) | -1.500 (-16.000, 3.000) | -125.00, 52.60 |
|  | C5D1 | 28 | 90.357 (26.1916) | 87.550 (71.000, 108.000) | 39.90, 146.00 | 28 | -6.625 (29.8715) | -1.500 (-9.000, 5.500) | -126.00, 44.00 |
|  | C6D1 | 27 | 92.237 (26.5334) | 90.000 (71.000, 107.000) | 39.30, 152.00 | 27 | -3.819 (27.5644) | 0.000 (-13.000, 9.000) | -114.00, 41.00 |
|  | C7D1 | 23 | 98.261 (38.7512) | 82.000 (73.000, 118.000) | 65.00, 232.00 | 23 | -0.722 (37.0528) | 1.000 (-16.000, 13.000) | -116.00, 96.00 |
|  | C8D1 | 15 | 95.867 (26.5757) | 94.000 (74.000, 119.000) | 59.00, 138.00 | 15 | -3.933 (36.3681) | -5.000 (-18.000, 24.000) | -111.00, 38.00 |
|  | C9D1 | 11 | 102.364 (28.1079) | 95.000 (82.000, 129.000) | 67.00, 158.00 | 11 | 7.273 (20.8954) | 4.000 (-8.000, 23.000) | -21.00, 50.00 |
|  | C10D1 | 6 | 106.000 (33.1723) | 102.500 (84.000, 139.000) | 60.00, 148.00 | 6 | 9.667 (25.4611) | 4.000 (-4.000, 39.000) | -25.00, 40.00 |
|  | C11D1 | 6 | 106.500 (33.1406) | 114.500 (69.000, 121.000) | 67.00, 153.00 | 6 | 10.167 (24.7501) | 16.000 (-16.000, 21.000) | -21.00, 45.00 |
|  | C12D1 | 5 | 93.800 (24.0146) | 106.000 (73.000, 113.000) | 63.00, 114.00 | 5 | -0.200 (17.7257) | 6.000 (-12.000, 14.000) | -25.00, 16.00 |
|  | C13D1 | 4 | 100.000 (35.3553) | 99.000 (69.500, 130.500) | 68.00, 134.00 | 4 | 7.500 (28.6880) | 6.500 (-17.000, 32.000) | -20.00, 37.00 |
|  | C14D1 | 4 | 100.000 (31.1876) | 100.500 (73.000, 127.000) | 72.00, 127.00 | 4 | 7.500 (24.3653) | 8.000 (-13.500, 28.500) | -16.00, 30.00 |
|  | C15D1 | 3 | 85.000 (30.3150) | 68.000 (67.000, 120.000) | 67.00, 120.00 | 3 | -5.000 (24.2693) | -18.000 (-20.000, 23.000) | -20.00, 23.00 |
|  | C16D1 | 2 | 97.500 (28.9914) | 97.500 (77.000, 118.000) | 77.00, 118.00 | 2 | 6.500 (20.5061) | 6.500 (-8.000, 21.000) | -8.00, 21.00 |
|  | C17D1 | 2 | 92.500 (19.0919) | 92.500 (79.000, 106.000) | 79.00, 106.00 | 2 | 1.500 (10.6066) | 1.500 (-6.000, 9.000) | -6.00, 9.00 |
|  | C18D1 | 1 | 73.000 (NA) | 73.000 (73.000, 73.000) | 73.00, 73.00 | 1 | -12.000 (NA) | -12.000 (-12.000, -12.000) | -12.00, -12.00 |
|  | End of Treatment | 4 | 105.250 (27.6933) | 100.000 (83.000, 127.500) | 81.00, 140.00 | 4 | -12.750 (65.5560) | 10.000 (-58.500, 33.000) | -106.00, 35.00 |
|  | | | | | | | | | |
| Lactate Dehydrogenase (IU/L) (N = 33) | Baseline | 33 | 227.91 (54.021) | 229.00 (180.00, 248.60) | 152.0, 358.0 |  |  |  |  |
|  | C1D8 | 33 | 246.33 (88.354) | 232.00 (200.00, 266.00) | 137.0, 497.0 | 33 | 18.42 (74.975) | 2.00 (-16.00, 17.00) | -86.0, 266.0 |
|  | C2D1 | 32 | 204.10 (39.396) | 209.00 (188.70, 229.00) | 104.6, 272.0 | 32 | -20.09 (56.894) | -4.00 (-44.00, 15.00) | -177.0, 74.0 |
|  | C3D1 | 31 | 207.14 (41.569) | 211.00 (185.00, 227.00) | 101.5, 300.9 | 31 | -16.25 (59.960) | -15.00 (-51.00, 24.00) | -161.0, 73.0 |
|  | C4D1 | 30 | 208.29 (36.830) | 219.00 (173.00, 232.00) | 140.0, 273.0 | 30 | -16.67 (53.633) | -6.00 (-39.00, 22.00) | -168.0, 58.0 |
|  | C5D1 | 28 | 212.89 (57.332) | 210.50 (174.50, 238.00) | 132.0, 385.0 | 28 | -11.50 (54.403) | -4.50 (-35.00, 11.00) | -159.0, 123.0 |
|  | C6D1 | 27 | 214.19 (65.704) | 202.00 (175.00, 226.00) | 136.0, 473.0 | 27 | -8.81 (55.570) | -2.00 (-40.00, 16.00) | -155.0, 115.0 |
|  | C7D1 | 23 | 220.17 (69.548) | 214.00 (194.00, 239.00) | 138.0, 500.0 | 23 | -2.48 (55.002) | -4.00 (-24.00, 17.00) | -161.0, 142.0 |
|  | C8D1 | 15 | 216.67 (38.537) | 220.00 (204.00, 229.00) | 151.0, 313.0 | 15 | -10.00 (59.161) | -4.00 (-33.00, 17.00) | -158.0, 87.0 |
|  | C9D1 | 11 | 222.09 (34.428) | 228.00 (201.00, 247.00) | 148.0, 280.0 | 11 | -4.55 (26.901) | -4.00 (-30.00, 16.00) | -50.0, 35.0 |
|  | C10D1 | 6 | 232.67 (26.051) | 225.00 (211.00, 252.00) | 208.0, 275.0 | 6 | -15.33 (10.596) | -12.50 (-18.00, -9.00) | -35.0, -5.0 |
|  | C11D1 | 6 | 226.67 (26.197) | 225.00 (209.00, 240.00) | 194.0, 267.0 | 6 | -21.33 (22.704) | -24.00 (-40.00, -17.00) | -43.0, 20.0 |
|  | C12D1 | 5 | 241.40 (25.026) | 228.00 (227.00, 251.00) | 220.0, 281.0 | 5 | -9.20 (29.710) | -6.00 (-7.00, 8.00) | -59.0, 18.0 |
|  | C13D1 | 4 | 250.25 (28.640) | 253.00 (230.50, 270.00) | 213.0, 282.0 | 4 | 14.50 (36.300) | 8.50 (-13.00, 42.00) | -21.0, 62.0 |
|  | C14D1 | 4 | 240.75 (41.452) | 234.00 (208.50, 273.00) | 201.0, 294.0 | 4 | 5.00 (30.735) | 6.50 (-21.50, 31.50) | -25.0, 32.0 |
|  | C15D1 | 3 | 228.33 (10.693) | 234.00 (216.00, 235.00) | 216.0, 235.0 | 3 | 1.67 (17.388) | 8.00 (-18.00, 15.00) | -18.0, 15.0 |
|  | C16D1 | 2 | 251.50 (75.660) | 251.50 (198.00, 305.00) | 198.0, 305.0 | 2 | 28.50 (79.903) | 28.50 (-28.00, 85.00) | -28.0, 85.0 |
|  | C17D1 | 2 | 246.50 (27.577) | 246.50 (227.00, 266.00) | 227.0, 266.0 | 2 | 23.50 (31.820) | 23.50 (1.00, 46.00) | 1.0, 46.0 |
|  | C18D1 | 1 | 244.00 (NA) | 244.00 (244.00, 244.00) | 244.0, 244.0 | 1 | 24.00 (NA) | 24.00 (24.00, 24.00) | 24.0, 24.0 |
|  | End of Treatment | 4 | 224.53 (122.698) | 192.10 (132.45, 316.60) | 122.9, 391.0 | 4 | -7.30 (96.188) | -25.10 (-77.30, 62.70) | -101.0, 122.0 |
|  | | | | | | | | | |
| Protein (g/L) (N = 33) | Baseline | 33 | 72.185 (5.2067) | 71.700 (69.100, 75.200) | 59.60, 84.80 |  |  |  |  |
|  | C1D8 | 33 | 69.585 (4.5262) | 69.900 (66.000, 72.300) | 61.70, 78.70 | 33 | -2.600 (4.9275) | -2.100 (-6.100, -0.200) | -11.20, 8.10 |
|  | C2D1 | 32 | 68.006 (5.1899) | 68.100 (65.650, 72.000) | 55.00, 77.40 | 32 | -4.016 (4.3076) | -4.400 (-6.850, -2.650) | -12.80, 6.60 |
|  | C3D1 | 31 | 67.232 (4.8721) | 66.100 (64.100, 70.100) | 60.10, 79.60 | 31 | -4.687 (4.5537) | -5.700 (-7.400, -2.300) | -14.30, 6.60 |
|  | C4D1 | 30 | 66.693 (4.1269) | 66.500 (64.000, 69.900) | 56.60, 76.20 | 30 | -4.797 (5.5870) | -5.200 (-9.000, -0.600) | -16.50, 7.10 |
|  | C5D1 | 28 | 67.275 (4.4423) | 67.400 (64.500, 70.300) | 56.60, 74.00 | 28 | -4.061 (5.8002) | -4.400 (-9.050, -0.100) | -14.70, 7.40 |
|  | C6D1 | 27 | 67.941 (4.3961) | 67.700 (63.800, 72.200) | 59.30, 74.50 | 27 | -3.400 (5.7193) | -2.600 (-7.200, 0.100) | -13.80, 7.50 |
|  | C7D1 | 23 | 67.174 (5.1527) | 67.500 (63.700, 71.700) | 52.20, 74.60 | 23 | -4.222 (5.6839) | -3.200 (-8.200, 0.400) | -20.90, 2.90 |
|  | C8D1 | 15 | 66.267 (3.4467) | 65.700 (62.600, 69.400) | 60.80, 72.20 | 15 | -4.660 (4.4858) | -4.600 (-8.800, -1.300) | -12.10, 3.90 |
|  | C9D1 | 11 | 68.782 (3.2704) | 69.000 (65.400, 71.900) | 63.80, 72.80 | 11 | -1.564 (3.5984) | -1.300 (-2.900, 1.700) | -8.00, 4.20 |
|  | C10D1 | 6 | 67.650 (4.2548) | 67.550 (64.400, 70.400) | 62.00, 74.00 | 6 | -3.633 (5.7733) | -5.000 (-8.100, 2.400) | -10.10, 4.00 |
|  | C11D1 | 6 | 69.050 (4.4325) | 69.350 (68.000, 71.600) | 61.40, 74.60 | 6 | -2.233 (4.0981) | -2.350 (-5.900, 1.600) | -6.20, 1.80 |
|  | C12D1 | 5 | 66.220 (3.8022) | 66.200 (63.500, 68.500) | 61.70, 71.20 | 5 | -3.160 (4.6645) | -2.900 (-7.400, 0.700) | -8.30, 2.10 |
|  | C13D1 | 4 | 69.475 (3.2715) | 70.350 (67.050, 71.900) | 65.00, 72.20 | 4 | -2.350 (3.2970) | -1.850 (-4.550, -0.150) | -6.80, 1.10 |
|  | C14D1 | 4 | 68.575 (2.7011) | 68.900 (66.550, 70.600) | 65.10, 71.40 | 4 | -3.250 (2.7343) | -2.900 (-5.500, -1.000) | -6.50, -0.70 |
|  | C15D1 | 3 | 68.933 (0.9238) | 68.400 (68.400, 70.000) | 68.40, 70.00 | 3 | -3.333 (4.6199) | -5.900 (-6.100, 2.000) | -6.10, 2.00 |
|  | C16D1 | 2 | 68.300 (1.4142) | 68.300 (67.300, 69.300) | 67.30, 69.30 | 2 | -6.900 (2.4042) | -6.900 (-8.600, -5.200) | -8.60, -5.20 |
|  | C17D1 | 2 | 69.600 (1.5556) | 69.600 (68.500, 70.700) | 68.50, 70.70 | 2 | -5.600 (2.5456) | -5.600 (-7.400, -3.800) | -7.40, -3.80 |
|  | C18D1 | 1 | 69.100 (NA) | 69.100 (69.100, 69.100) | 69.10, 69.10 | 1 | -5.400 (NA) | -5.400 (-5.400, -5.400) | -5.40, -5.40 |
|  | End of Treatment | 4 | 70.400 (2.9269) | 70.050 (68.600, 72.200) | 67.20, 74.30 | 4 | -7.800 (3.9404) | -7.800 (-11.150, -4.450) | -11.80, -3.80 |
|  | | | | | | | | | |
| Albumin (g/L) (N = 33) | Baseline | 33 | 41.597 (3.8495) | 41.200 (38.900, 45.400) | 32.60, 46.90 |  |  |  |  |
|  | C1D8 | 33 | 39.352 (3.4846) | 39.200 (37.500, 40.600) | 32.30, 45.30 | 33 | -2.245 (2.6597) | -2.200 (-4.500, -0.300) | -8.60, 2.70 |
|  | C2D1 | 32 | 38.688 (3.5733) | 39.400 (36.800, 41.100) | 30.30, 43.80 | 32 | -3.191 (2.7126) | -2.650 (-4.400, -1.100) | -9.40, 1.30 |
|  | C3D1 | 31 | 37.826 (3.4393) | 38.300 (36.100, 40.100) | 27.70, 43.20 | 31 | -4.145 (2.9894) | -3.900 (-6.500, -1.800) | -11.10, 0.60 |
|  | C4D1 | 30 | 38.153 (2.9864) | 38.100 (37.100, 40.300) | 27.40, 42.70 | 30 | -4.077 (3.4126) | -3.750 (-6.500, -2.000) | -10.40, 2.80 |
|  | C5D1 | 28 | 38.582 (3.1742) | 38.550 (36.200, 41.100) | 33.10, 45.20 | 28 | -3.668 (4.3154) | -2.700 (-5.700, -1.150) | -12.10, 4.10 |
|  | C6D1 | 27 | 39.489 (3.6103) | 39.100 (37.100, 41.800) | 32.00, 49.30 | 27 | -2.885 (3.4677) | -3.300 (-5.100, 0.100) | -10.10, 3.80 |
|  | C7D1 | 23 | 40.030 (3.9944) | 40.300 (38.200, 42.300) | 28.60, 46.70 | 23 | -2.974 (4.7822) | -3.700 (-5.700, 0.000) | -17.80, 5.60 |
|  | C8D1 | 15 | 39.507 (3.3663) | 39.900 (37.300, 42.000) | 32.30, 45.00 | 15 | -2.633 (3.4834) | -1.900 (-5.400, -0.200) | -7.80, 3.90 |
|  | C9D1 | 11 | 39.918 (2.7520) | 39.500 (37.300, 43.300) | 36.30, 43.50 | 11 | -1.718 (2.2640) | -2.100 (-3.000, -0.100) | -5.00, 2.40 |
|  | C10D1 | 6 | 39.217 (0.6969) | 39.350 (39.000, 39.500) | 38.00, 40.10 | 6 | -2.283 (3.8285) | -3.350 (-5.600, 1.200) | -5.80, 3.20 |
|  | C11D1 | 6 | 39.067 (2.8535) | 38.400 (37.300, 42.300) | 35.40, 42.60 | 6 | -2.433 (3.4581) | -2.400 (-4.300, 0.500) | -7.80, 1.80 |
|  | C12D1 | 5 | 39.600 (2.9257) | 39.500 (38.500, 40.600) | 35.70, 43.70 | 5 | -1.180 (2.7941) | -0.300 (-2.600, -0.200) | -5.10, 2.30 |
|  | C13D1 | 4 | 40.050 (3.6928) | 40.000 (36.900, 43.200) | 36.40, 43.80 | 4 | -1.875 (0.3686) | -1.900 (-2.100, -1.650) | -2.30, -1.40 |
|  | C14D1 | 4 | 40.500 (1.9408) | 40.900 (39.050, 41.950) | 37.90, 42.30 | 4 | -1.425 (2.4784) | -1.750 (-2.950, 0.100) | -4.10, 1.90 |
|  | C15D1 | 3 | 39.433 (1.3796) | 38.900 (38.400, 41.000) | 38.40, 41.00 | 3 | -1.800 (2.5515) | -0.800 (-4.700, 0.100) | -4.70, 0.10 |
|  | C16D1 | 2 | 39.700 (2.6870) | 39.700 (37.800, 41.600) | 37.80, 41.60 | 2 | -3.000 (1.5556) | -3.000 (-4.100, -1.900) | -4.10, -1.90 |
|  | C17D1 | 2 | 39.700 (3.5355) | 39.700 (37.200, 42.200) | 37.20, 42.20 | 2 | -3.000 (0.7071) | -3.000 (-3.500, -2.500) | -3.50, -2.50 |
|  | C18D1 | 1 | 43.000 (NA) | 43.000 (43.000, 43.000) | 43.00, 43.00 | 1 | -2.700 (NA) | -2.700 (-2.700, -2.700) | -2.70, -2.70 |
|  | End of Treatment | 4 | 32.400 (5.2656) | 33.550 (28.250, 36.550) | 25.60, 36.90 | 4 | -4.900 (2.9922) | -4.600 (-7.250, -2.550) | -8.60, -1.80 |
|  | | | | | | | | | |
| Triglycerides (mmol/L) (N = 33) | Baseline | 33 | 1.194 (0.6300) | 1.040 (0.820, 1.290) | 0.53, 3.10 |  |  |  |  |
|  | C1D8 | 33 | 1.618 (0.6755) | 1.390 (1.040, 1.870) | 0.74, 3.27 | 33 | 0.423 (0.4516) | 0.310 (0.140, 0.600) | -0.18, 1.82 |
|  | C2D1 | 32 | 1.648 (0.6905) | 1.405 (1.170, 2.005) | 0.75, 3.38 | 32 | 0.433 (0.4990) | 0.375 (0.150, 0.670) | -0.34, 1.93 |
|  | C3D1 | 31 | 1.581 (0.7324) | 1.360 (1.190, 1.570) | 0.59, 3.64 | 31 | 0.356 (0.5601) | 0.420 (0.150, 0.610) | -1.91, 1.32 |
|  | C4D1 | 30 | 1.763 (0.8671) | 1.470 (1.180, 2.090) | 0.81, 4.23 | 30 | 0.521 (0.4562) | 0.415 (0.260, 0.700) | -0.16, 1.87 |
|  | C5D1 | 28 | 1.741 (0.7187) | 1.585 (1.210, 1.965) | 0.93, 3.83 | 28 | 0.548 (0.4195) | 0.495 (0.290, 0.630) | 0.03, 1.92 |
|  | C6D1 | 27 | 1.648 (0.5803) | 1.590 (1.240, 1.880) | 0.85, 3.51 | 27 | 0.442 (0.5389) | 0.450 (0.010, 0.810) | -0.83, 1.47 |
|  | C7D1 | 23 | 1.782 (0.8399) | 1.500 (1.260, 2.210) | 0.89, 4.71 | 23 | 0.580 (0.6054) | 0.550 (0.140, 0.860) | -0.80, 1.92 |
|  | C8D1 | 15 | 1.473 (0.4879) | 1.460 (1.260, 1.600) | 0.75, 2.54 | 15 | 0.459 (0.4924) | 0.500 (0.130, 0.790) | -0.45, 1.38 |
|  | C9D1 | 11 | 1.528 (0.4467) | 1.510 (1.190, 1.840) | 0.75, 2.31 | 11 | 0.508 (0.4369) | 0.430 (0.100, 0.950) | 0.03, 1.19 |
|  | C10D1 | 6 | 1.642 (0.5560) | 1.700 (1.090, 1.980) | 0.95, 2.43 | 6 | 0.493 (0.5872) | 0.240 (0.040, 1.160) | -0.03, 1.31 |
|  | C11D1 | 6 | 1.432 (0.4024) | 1.415 (1.190, 1.470) | 0.95, 2.15 | 6 | 0.283 (0.4288) | 0.065 (0.040, 0.570) | -0.07, 1.03 |
|  | C12D1 | 5 | 1.598 (0.3517) | 1.720 (1.660, 1.810) | 0.98, 1.82 | 5 | 0.444 (0.3236) | 0.400 (0.210, 0.700) | 0.07, 0.84 |
|  | C13D1 | 4 | 1.478 (0.3600) | 1.600 (1.265, 1.690) | 0.95, 1.76 | 4 | 0.240 (0.2226) | 0.210 (0.055, 0.425) | 0.04, 0.50 |
|  | C14D1 | 4 | 1.353 (0.2838) | 1.395 (1.120, 1.585) | 1.01, 1.61 | 4 | 0.115 (0.3152) | 0.125 (-0.090, 0.320) | -0.28, 0.49 |
|  | C15D1 | 3 | 1.463 (0.5879) | 1.670 (0.800, 1.920) | 0.80, 1.92 | 3 | 0.283 (0.3478) | 0.410 (-0.110, 0.550) | -0.11, 0.55 |
|  | C16D1 | 2 | 1.175 (0.0919) | 1.175 (1.110, 1.240) | 1.11, 1.24 | 2 | -0.140 (0.1838) | -0.140 (-0.270, -0.010) | -0.27, -0.01 |
|  | C17D1 | 2 | 1.605 (0.1626) | 1.605 (1.490, 1.720) | 1.49, 1.72 | 2 | 0.290 (0.4384) | 0.290 (-0.020, 0.600) | -0.02, 0.60 |
|  | C18D1 | 1 | 2.070 (NA) | 2.070 (2.070, 2.070) | 2.07, 2.07 | 1 | 0.560 (NA) | 0.560 (0.560, 0.560) | 0.56, 0.56 |
|  | End of Treatment | 4 | 1.545 (0.7935) | 1.210 (1.065, 2.025) | 1.04, 2.72 | 4 | 0.223 (0.4554) | 0.275 (-0.080, 0.525) | -0.38, 0.72 |
|  | | | | | | | | | |
| Cholesterol (mmol/L) (N = 33) | Baseline | 32 | 4.628 (1.0205) | 4.825 (3.730, 5.405) | 2.30, 6.45 |  |  |  |  |
|  | C1D8 | 33 | 5.248 (1.0137) | 5.360 (4.760, 5.860) | 3.28, 7.09 | 32 | 0.624 (0.5845) | 0.565 (0.165, 0.995) | -0.38, 2.42 |
|  | C2D1 | 32 | 5.125 (1.0768) | 5.230 (4.240, 6.050) | 2.45, 6.93 | 31 | 0.435 (0.7717) | 0.580 (0.090, 0.810) | -1.36, 2.02 |
|  | C3D1 | 31 | 5.074 (1.1202) | 5.070 (4.350, 5.830) | 2.96, 7.76 | 30 | 0.345 (0.8291) | 0.410 (0.040, 0.800) | -2.13, 2.33 |
|  | C4D1 | 30 | 5.123 (0.9326) | 4.795 (4.380, 5.940) | 3.67, 7.22 | 29 | 0.490 (0.8657) | 0.610 (0.030, 0.990) | -1.71, 2.00 |
|  | C5D1 | 28 | 5.108 (0.7898) | 4.980 (4.540, 5.695) | 3.49, 6.74 | 27 | 0.532 (0.8408) | 0.600 (0.120, 1.090) | -1.89, 1.80 |
|  | C6D1 | 27 | 5.080 (0.9896) | 5.360 (4.450, 5.780) | 3.09, 7.14 | 26 | 0.483 (1.0739) | 0.605 (-0.220, 1.110) | -1.91, 2.83 |
|  | C7D1 | 23 | 4.912 (0.8054) | 5.120 (4.290, 5.480) | 3.34, 6.46 | 22 | 0.330 (0.8677) | 0.465 (0.110, 0.560) | -1.97, 1.89 |
|  | C8D1 | 15 | 4.701 (0.8209) | 4.500 (4.130, 5.020) | 3.60, 6.60 | 14 | 0.453 (1.0809) | 0.715 (-0.220, 1.250) | -1.41, 2.07 |
|  | C9D1 | 11 | 4.986 (0.9049) | 5.010 (3.870, 5.650) | 3.78, 6.31 | 10 | 0.800 (0.7760) | 0.900 (0.330, 1.480) | -0.84, 1.65 |
|  | C10D1 | 6 | 4.728 (0.9715) | 4.715 (4.010, 5.410) | 3.52, 6.00 | 5 | 0.388 (1.1737) | 0.520 (0.430, 1.220) | -1.58, 1.35 |
|  | C11D1 | 6 | 4.575 (0.7967) | 4.690 (4.440, 5.140) | 3.13, 5.36 | 5 | 0.278 (0.8456) | 0.710 (0.160, 0.830) | -1.15, 0.84 |
|  | C12D1 | 5 | 4.714 (0.7678) | 4.880 (4.620, 4.940) | 3.51, 5.62 | 4 | 0.618 (1.0659) | 1.090 (0.000, 1.235) | -0.97, 1.26 |
|  | C13D1 | 4 | 5.128 (0.6902) | 5.395 (4.705, 5.550) | 4.11, 5.61 | 3 | 0.450 (0.4115) | 0.490 (0.020, 0.840) | 0.02, 0.84 |
|  | C14D1 | 4 | 4.943 (0.6496) | 5.240 (4.595, 5.290) | 3.97, 5.32 | 3 | 0.230 (0.4521) | 0.350 (-0.270, 0.610) | -0.27, 0.61 |
|  | C15D1 | 3 | 5.037 (0.7190) | 5.270 (4.230, 5.610) | 4.23, 5.61 | 2 | 0.615 (0.0071) | 0.615 (0.610, 0.620) | 0.61, 0.62 |
|  | C16D1 | 2 | 4.565 (0.6718) | 4.565 (4.090, 5.040) | 4.09, 5.04 | 1 | 0.470 (NA) | 0.470 (0.470, 0.470) | 0.47, 0.47 |
|  | C17D1 | 2 | 4.680 (1.2587) | 4.680 (3.790, 5.570) | 3.79, 5.57 | 1 | 0.170 (NA) | 0.170 (0.170, 0.170) | 0.17, 0.17 |
|  | C18D1 | 1 | 5.360 (NA) | 5.360 (5.360, 5.360) | 5.36, 5.36 | 0 |  |  |  |
|  | End of Treatment | 4 | 5.380 (1.0539) | 5.595 (4.540, 6.220) | 4.04, 6.29 | 4 | 0.190 (1.1196) | -0.125 (-0.540, 0.920) | -0.78, 1.79 |
|  | | | | | | | | | |
| Sodium (mmol/L) (N = 33) | Baseline | 33 | 139.382 (3.0937) | 139.800 (138.000, 141.000) | 130.20, 144.40 |  |  |  |  |
|  | C1D8 | 33 | 139.033 (3.7067) | 140.000 (138.000, 141.800) | 124.10, 144.00 | 33 | -0.348 (2.8272) | -0.100 (-2.000, 2.000) | -8.30, 3.60 |
|  | C2D1 | 32 | 140.113 (2.1354) | 140.150 (139.000, 141.500) | 135.00, 145.00 | 32 | 0.513 (3.1924) | 1.000 (-2.000, 2.000) | -4.00, 10.30 |
|  | C3D1 | 31 | 140.265 (2.3635) | 140.500 (138.000, 142.000) | 136.00, 144.00 | 31 | 0.626 (3.0427) | 1.000 (-1.300, 1.600) | -7.00, 11.60 |
|  | C4D1 | 30 | 140.763 (2.3367) | 140.850 (139.200, 142.000) | 136.00, 146.40 | 30 | 1.013 (2.7439) | 0.450 (-1.000, 3.000) | -4.40, 7.00 |
|  | C5D1 | 28 | 139.986 (2.3103) | 140.000 (139.000, 141.350) | 135.00, 146.00 | 28 | 0.389 (2.8477) | 1.000 (-1.000, 2.000) | -5.00, 7.50 |
|  | C6D1 | 27 | 139.496 (2.6832) | 139.000 (138.000, 142.000) | 134.00, 143.30 | 27 | -0.085 (2.9299) | 0.000 (-2.000, 1.900) | -5.00, 8.40 |
|  | C7D1 | 23 | 139.713 (2.3038) | 140.000 (138.000, 141.300) | 133.00, 143.00 | 23 | -0.070 (3.0933) | 0.000 (-3.000, 2.600) | -6.00, 7.50 |
|  | C8D1 | 15 | 139.460 (2.4477) | 139.000 (137.500, 141.200) | 136.00, 144.20 | 15 | 0.107 (3.2334) | 0.000 (-2.000, 2.000) | -5.00, 7.40 |
|  | C9D1 | 11 | 139.709 (2.8119) | 140.000 (138.000, 140.000) | 135.00, 145.00 | 11 | 0.673 (3.3350) | 1.000 (-2.000, 2.000) | -4.40, 8.00 |
|  | C10D1 | 6 | 138.133 (2.3036) | 138.400 (136.000, 140.000) | 135.00, 141.00 | 6 | -0.433 (5.5648) | -2.700 (-3.800, 4.000) | -6.00, 8.60 |
|  | C11D1 | 6 | 140.067 (4.6233) | 139.150 (137.100, 140.000) | 136.00, 149.00 | 6 | 1.500 (5.1178) | 1.000 (-2.700, 5.000) | -4.40, 9.10 |
|  | C12D1 | 5 | 138.100 (1.4422) | 138.000 (137.100, 139.000) | 136.40, 140.00 | 5 | 0.620 (5.0845) | 1.000 (-3.400, 4.000) | -5.40, 6.90 |
|  | C13D1 | 4 | 138.225 (2.9398) | 138.500 (135.850, 140.600) | 134.70, 141.20 | 4 | -1.075 (3.9844) | -1.600 (-4.150, 2.000) | -5.10, 4.00 |
|  | C14D1 | 4 | 139.125 (2.0966) | 138.750 (137.750, 140.500) | 137.00, 142.00 | 4 | -0.175 (2.3329) | -0.650 (-1.850, 1.500) | -2.40, 3.00 |
|  | C15D1 | 3 | 136.800 (2.5534) | 137.400 (134.000, 139.000) | 134.00, 139.00 | 3 | -0.800 (3.3045) | -2.400 (-3.000, 3.000) | -3.00, 3.00 |
|  | C16D1 | 2 | 137.900 (1.5556) | 137.900 (136.800, 139.000) | 136.80, 139.00 | 2 | 0.000 (4.2426) | 0.000 (-3.000, 3.000) | -3.00, 3.00 |
|  | C17D1 | 2 | 137.800 (1.1314) | 137.800 (137.000, 138.600) | 137.00, 138.60 | 2 | -0.100 (1.5556) | -0.100 (-1.200, 1.000) | -1.20, 1.00 |
|  | C18D1 | 1 | 138.000 (NA) | 138.000 (138.000, 138.000) | 138.00, 138.00 | 1 | -1.800 (NA) | -1.800 (-1.800, -1.800) | -1.80, -1.80 |
|  | End of Treatment | 4 | 136.525 (3.6945) | 138.200 (134.500, 138.550) | 131.00, 138.70 | 4 | -1.000 (3.3427) | -0.700 (-3.700, 1.700) | -5.00, 2.40 |
|  | | | | | | | | | |
| Potassium (mmol/L) (N = 33) | Baseline | 33 | 4.2242 (0.3788) | 4.2000 (3.9800, 4.5000) | 3.380, 4.970 |  |  |  |  |
|  | C1D8 | 33 | 4.1172 (0.4917) | 4.1300 (3.9000, 4.3300) | 2.990, 5.560 | 33 | -0.1071 (0.4559) | -0.1600 (-0.3400, 0.0700) | -0.910, 1.360 |
|  | C2D1 | 32 | 4.2797 (0.4232) | 4.3550 (4.0200, 4.5650) | 3.150, 4.990 | 32 | 0.0366 (0.4491) | -0.0200 (-0.2750, 0.4500) | -0.760, 0.790 |
|  | C3D1 | 31 | 4.1465 (0.4066) | 4.1600 (3.9200, 4.4300) | 3.270, 4.920 | 31 | -0.1013 (0.3776) | -0.1100 (-0.3400, 0.2200) | -1.100, 0.520 |
|  | C4D1 | 30 | 4.2263 (0.4600) | 4.2600 (3.9900, 4.5900) | 3.220, 5.030 | 30 | -0.0217 (0.4174) | 0.0200 (-0.2600, 0.2100) | -0.980, 0.830 |
|  | C5D1 | 28 | 4.1982 (0.4895) | 4.2000 (3.9300, 4.5300) | 3.190, 5.360 | 28 | -0.0571 (0.5287) | 0.0000 (-0.3500, 0.2900) | -1.720, 1.080 |
|  | C6D1 | 27 | 4.2344 (0.4580) | 4.2700 (3.9400, 4.5900) | 3.080, 4.930 | 27 | -0.0285 (0.4014) | -0.1100 (-0.2500, 0.1800) | -0.760, 1.080 |
|  | C7D1 | 23 | 4.2230 (0.3712) | 4.2100 (4.0500, 4.4600) | 3.060, 4.820 | 23 | -0.0326 (0.3940) | 0.0200 (-0.3100, 0.2200) | -0.950, 0.590 |
|  | C8D1 | 15 | 4.1727 (0.3892) | 4.2000 (3.7900, 4.5500) | 3.430, 4.670 | 15 | -0.0987 (0.5641) | -0.0700 (-0.5000, 0.3500) | -1.270, 0.890 |
|  | C9D1 | 11 | 4.1864 (0.3231) | 4.2400 (4.0800, 4.3600) | 3.650, 4.810 | 11 | 0.0264 (0.4179) | 0.0700 (-0.3500, 0.4300) | -0.630, 0.630 |
|  | C10D1 | 6 | 4.0217 (0.4750) | 4.0850 (3.6600, 4.1500) | 3.380, 4.770 | 6 | -0.0550 (0.5929) | -0.3050 (-0.4800, 0.3000) | -0.530, 0.990 |
|  | C11D1 | 6 | 4.0100 (0.3581) | 4.0950 (3.8600, 4.3200) | 3.370, 4.320 | 6 | -0.0667 (0.4550) | -0.0550 (-0.2700, 0.2100) | -0.770, 0.540 |
|  | C12D1 | 5 | 4.2860 (0.3820) | 4.2000 (4.1500, 4.3400) | 3.850, 4.890 | 5 | 0.2220 (0.5563) | 0.1000 (-0.0100, 0.3000) | -0.390, 1.110 |
|  | C13D1 | 4 | 4.3675 (0.1438) | 4.3500 (4.2500, 4.4850) | 4.230, 4.540 | 4 | 0.2250 (0.4440) | 0.1500 (-0.1400, 0.5900) | -0.160, 0.760 |
|  | C14D1 | 4 | 4.5025 (0.4824) | 4.4250 (4.2000, 4.8050) | 4.000, 5.160 | 4 | 0.3600 (0.4738) | 0.5850 (0.1100, 0.6100) | -0.350, 0.620 |
|  | C15D1 | 3 | 4.1800 (0.0520) | 4.2100 (4.1200, 4.2100) | 4.120, 4.210 | 3 | -0.0600 (0.4553) | -0.1400 (-0.4700, 0.4300) | -0.470, 0.430 |
|  | C16D1 | 2 | 4.5650 (0.0212) | 4.5650 (4.5500, 4.5800) | 4.550, 4.580 | 2 | 0.0950 (0.1909) | 0.0950 (-0.0400, 0.2300) | -0.040, 0.230 |
|  | C17D1 | 2 | 4.3100 (0.0283) | 4.3100 (4.2900, 4.3300) | 4.290, 4.330 | 2 | -0.1600 (0.1980) | -0.1600 (-0.3000, -0.0200) | -0.300, -0.020 |
|  | C18D1 | 1 | 3.9400 (NA) | 3.9400 (3.9400, 3.9400) | 3.940, 3.940 | 1 | -0.4100 (NA) | -0.4100 (-0.4100, -0.4100) | -0.410, -0.410 |
|  | End of Treatment | 4 | 4.5550 (0.6500) | 4.6200 (4.0100, 5.1000) | 3.820, 5.160 | 4 | 0.0775 (0.5212) | 0.0350 (-0.3600, 0.5150) | -0.420, 0.660 |
|  | | | | | | | | | |
| Magnesium (mmol/L) (N = 33) | Baseline | 33 | 0.882 (0.0804) | 0.890 (0.830, 0.930) | 0.69, 1.06 |  |  |  |  |
|  | C1D8 | 33 | 0.858 (0.0720) | 0.860 (0.810, 0.900) | 0.66, 0.99 | 33 | -0.024 (0.0795) | -0.040 (-0.080, 0.050) | -0.16, 0.15 |
|  | C2D1 | 32 | 0.846 (0.0835) | 0.850 (0.810, 0.905) | 0.64, 1.00 | 32 | -0.038 (0.0889) | -0.040 (-0.095, 0.010) | -0.21, 0.15 |
|  | C3D1 | 31 | 0.839 (0.0782) | 0.850 (0.790, 0.890) | 0.69, 0.98 | 31 | -0.046 (0.0787) | -0.040 (-0.100, 0.000) | -0.19, 0.19 |
|  | C4D1 | 30 | 0.837 (0.0808) | 0.850 (0.800, 0.870) | 0.67, 1.04 | 30 | -0.049 (0.0513) | -0.045 (-0.090, -0.020) | -0.14, 0.10 |
|  | C5D1 | 28 | 0.853 (0.0669) | 0.855 (0.820, 0.890) | 0.71, 1.05 | 28 | -0.041 (0.0716) | -0.045 (-0.085, -0.005) | -0.18, 0.14 |
|  | C6D1 | 27 | 0.864 (0.0876) | 0.870 (0.810, 0.900) | 0.69, 1.08 | 27 | -0.031 (0.0874) | -0.040 (-0.100, 0.020) | -0.17, 0.17 |
|  | C7D1 | 23 | 0.869 (0.0701) | 0.880 (0.830, 0.910) | 0.70, 0.99 | 23 | -0.027 (0.0676) | -0.040 (-0.070, 0.010) | -0.12, 0.15 |
|  | C8D1 | 15 | 0.837 (0.0505) | 0.840 (0.790, 0.880) | 0.74, 0.91 | 15 | -0.057 (0.0527) | -0.050 (-0.110, -0.020) | -0.14, 0.05 |
|  | C9D1 | 11 | 0.847 (0.0600) | 0.850 (0.800, 0.880) | 0.74, 0.94 | 11 | -0.047 (0.0704) | -0.070 (-0.100, 0.040) | -0.15, 0.06 |
|  | C10D1 | 5 | 0.798 (0.0858) | 0.850 (0.720, 0.860) | 0.69, 0.87 | 5 | -0.062 (0.0614) | -0.070 (-0.080, -0.050) | -0.14, 0.03 |
|  | C11D1 | 6 | 0.833 (0.0671) | 0.835 (0.770, 0.900) | 0.75, 0.91 | 6 | -0.020 (0.0851) | -0.035 (-0.080, 0.080) | -0.13, 0.08 |
|  | C12D1 | 5 | 0.830 (0.0949) | 0.870 (0.750, 0.890) | 0.71, 0.93 | 5 | -0.006 (0.0559) | 0.020 (-0.050, 0.030) | -0.08, 0.05 |
|  | C13D1 | 4 | 0.820 (0.0688) | 0.845 (0.775, 0.865) | 0.72, 0.87 | 4 | -0.020 (0.0440) | -0.020 (-0.055, 0.015) | -0.07, 0.03 |
|  | C14D1 | 4 | 0.838 (0.1109) | 0.850 (0.745, 0.930) | 0.71, 0.94 | 4 | -0.003 (0.0403) | 0.000 (-0.035, 0.030) | -0.05, 0.04 |
|  | C15D1 | 3 | 0.783 (0.0651) | 0.780 (0.720, 0.850) | 0.72, 0.85 | 3 | -0.023 (0.0462) | -0.050 (-0.050, 0.030) | -0.05, 0.03 |
|  | C16D1 | 1 | 0.690 (NA) | 0.690 (0.690, 0.690) | 0.69, 0.69 | 1 | 0.000 (NA) | 0.000 (0.000, 0.000) | 0.00, 0.00 |
|  | C17D1 | 2 | 0.725 (0.1202) | 0.725 (0.640, 0.810) | 0.64, 0.81 | 2 | -0.035 (0.0212) | -0.035 (-0.050, -0.020) | -0.05, -0.02 |
|  | C18D1 | 1 | 0.790 (NA) | 0.790 (0.790, 0.790) | 0.79, 0.79 | 1 | -0.040 (NA) | -0.040 (-0.040, -0.040) | -0.04, -0.04 |
|  | End of Treatment | 4 | 0.790 (0.0730) | 0.790 (0.730, 0.850) | 0.71, 0.87 | 4 | -0.088 (0.0618) | -0.105 (-0.130, -0.045) | -0.14, 0.00 |
|  | | | | | | | | | |
| Chloride (mmol/L) (N = 33) | Baseline | 33 | 101.409 (3.2977) | 101.600 (99.800, 104.000) | 91.70, 106.70 |  |  |  |  |
|  | C1D8 | 33 | 101.140 (4.9537) | 102.000 (100.000, 104.000) | 84.60, 109.00 | 33 | -0.269 (3.9861) | 0.000 (-2.100, 2.300) | -8.80, 6.00 |
|  | C2D1 | 32 | 102.672 (2.6145) | 102.650 (101.000, 104.500) | 97.00, 110.00 | 32 | 0.959 (3.5403) | 0.950 (-1.350, 3.150) | -7.00, 10.20 |
|  | C3D1 | 31 | 103.223 (2.3493) | 103.200 (101.300, 105.000) | 99.00, 108.00 | 31 | 1.574 (3.0061) | 2.000 (-0.500, 3.900) | -5.00, 6.50 |
|  | C4D1 | 30 | 103.230 (2.3074) | 103.050 (101.000, 105.000) | 99.00, 107.00 | 30 | 1.513 (3.0248) | 1.600 (-1.000, 3.400) | -3.70, 9.00 |
|  | C5D1 | 28 | 102.418 (2.8193) | 102.900 (100.000, 104.550) | 96.00, 107.00 | 28 | 0.811 (3.4382) | 1.200 (-1.000, 3.000) | -8.00, 6.50 |
|  | C6D1 | 27 | 101.807 (3.0539) | 102.000 (100.000, 104.500) | 95.00, 107.00 | 27 | 0.289 (2.5840) | 0.300 (-2.000, 2.800) | -4.00, 4.00 |
|  | C7D1 | 23 | 102.504 (2.8283) | 103.000 (101.600, 104.000) | 95.40, 107.00 | 23 | 0.570 (2.5209) | 0.500 (-1.700, 2.500) | -6.00, 6.00 |
|  | C8D1 | 15 | 102.013 (2.1784) | 101.100 (100.300, 104.000) | 98.00, 105.60 | 15 | -0.347 (2.8317) | -0.900 (-2.700, 0.300) | -3.40, 6.00 |
|  | C9D1 | 11 | 102.991 (2.7991) | 103.100 (100.000, 105.000) | 98.90, 107.20 | 11 | 0.664 (2.5109) | 0.500 (-1.000, 3.000) | -4.30, 5.00 |
|  | C10D1 | 6 | 101.800 (2.1251) | 102.150 (100.000, 102.400) | 99.00, 105.10 | 6 | -0.650 (2.0859) | -0.900 (-1.000, 0.600) | -4.00, 2.30 |
|  | C11D1 | 6 | 102.683 (2.8875) | 101.350 (100.800, 105.600) | 100.00, 107.00 | 6 | 0.233 (3.7739) | -0.400 (-1.500, 3.000) | -5.10, 5.80 |
|  | C12D1 | 5 | 102.180 (1.7513) | 101.100 (101.000, 103.000) | 100.90, 104.90 | 5 | 0.040 (3.2462) | -0.500 (-2.300, 1.000) | -3.10, 5.10 |
|  | C13D1 | 4 | 101.175 (0.9032) | 101.250 (100.600, 101.750) | 100.00, 102.20 | 4 | -1.550 (2.4352) | -1.000 (-3.400, 0.300) | -4.80, 0.60 |
|  | C14D1 | 4 | 102.825 (1.4660) | 103.050 (101.650, 104.000) | 101.00, 104.20 | 4 | 0.100 (1.3441) | 0.650 (-0.650, 0.850) | -1.90, 1.00 |
|  | C15D1 | 3 | 99.600 (2.8213) | 99.200 (97.000, 102.600) | 97.00, 102.60 | 3 | -2.000 (1.2490) | -2.400 (-3.000, -0.600) | -3.00, -0.60 |
|  | C16D1 | 2 | 101.800 (0.4243) | 101.800 (101.500, 102.100) | 101.50, 102.10 | 2 | -0.600 (0.7071) | -0.600 (-1.100, -0.100) | -1.10, -0.10 |
|  | C17D1 | 2 | 100.350 (3.6062) | 100.350 (97.800, 102.900) | 97.80, 102.90 | 2 | -2.050 (2.4749) | -2.050 (-3.800, -0.300) | -3.80, -0.30 |
|  | C18D1 | 1 | 103.400 (NA) | 103.400 (103.400, 103.400) | 103.40, 103.40 | 1 | 0.200 (NA) | 0.200 (0.200, 0.200) | 0.20, 0.20 |
|  | End of Treatment | 4 | 97.325 (3.0358) | 98.150 (95.150, 99.500) | 93.10, 99.90 | 4 | -2.450 (2.9950) | -1.900 (-4.800, -0.100) | -6.30, 0.30 |
|  | | | | | | | | | |
| Calcium (mmol/L) (N = 33) | Baseline | 33 | 2.338 (0.1179) | 2.330 (2.260, 2.420) | 2.06, 2.58 |  |  |  |  |
|  | C1D8 | 33 | 2.302 (0.1295) | 2.310 (2.260, 2.340) | 1.88, 2.61 | 33 | -0.035 (0.1317) | -0.030 (-0.090, 0.050) | -0.53, 0.15 |
|  | C2D1 | 32 | 2.331 (0.1309) | 2.330 (2.265, 2.425) | 2.04, 2.63 | 32 | -0.004 (0.1052) | 0.000 (-0.065, 0.070) | -0.22, 0.25 |
|  | C3D1 | 31 | 2.337 (0.1021) | 2.320 (2.270, 2.400) | 2.10, 2.58 | 31 | 0.004 (0.1010) | -0.010 (-0.060, 0.060) | -0.27, 0.20 |
|  | C4D1 | 30 | 2.330 (0.1222) | 2.335 (2.270, 2.440) | 2.05, 2.49 | 30 | 0.001 (0.1279) | -0.020 (-0.110, 0.080) | -0.20, 0.23 |
|  | C5D1 | 28 | 2.342 (0.1250) | 2.345 (2.270, 2.415) | 1.99, 2.62 | 28 | 0.005 (0.1373) | -0.010 (-0.110, 0.075) | -0.23, 0.25 |
|  | C6D1 | 27 | 2.344 (0.1399) | 2.340 (2.260, 2.420) | 2.00, 2.70 | 27 | 0.004 (0.1434) | 0.000 (-0.090, 0.100) | -0.25, 0.34 |
|  | C7D1 | 23 | 2.306 (0.1570) | 2.330 (2.260, 2.380) | 1.68, 2.49 | 23 | -0.034 (0.1942) | 0.020 (-0.100, 0.080) | -0.77, 0.19 |
|  | C8D1 | 15 | 2.338 (0.1103) | 2.310 (2.280, 2.430) | 2.14, 2.52 | 15 | 0.014 (0.1111) | 0.000 (-0.080, 0.080) | -0.16, 0.23 |
|  | C9D1 | 11 | 2.314 (0.0963) | 2.290 (2.250, 2.400) | 2.18, 2.47 | 11 | 0.009 (0.0784) | 0.010 (-0.070, 0.070) | -0.11, 0.15 |
|  | C10D1 | 6 | 2.357 (0.0776) | 2.365 (2.280, 2.430) | 2.26, 2.44 | 6 | 0.023 (0.1442) | 0.010 (-0.010, 0.120) | -0.21, 0.22 |
|  | C11D1 | 6 | 2.273 (0.1184) | 2.320 (2.140, 2.360) | 2.11, 2.39 | 6 | -0.060 (0.0925) | -0.040 (-0.120, 0.000) | -0.21, 0.05 |
|  | C12D1 | 5 | 2.328 (0.1242) | 2.370 (2.270, 2.370) | 2.15, 2.48 | 5 | 0.006 (0.1397) | 0.010 (-0.060, 0.040) | -0.17, 0.21 |
|  | C13D1 | 4 | 2.345 (0.1287) | 2.385 (2.260, 2.430) | 2.16, 2.45 | 4 | -0.043 (0.0946) | -0.005 (-0.105, 0.020) | -0.18, 0.02 |
|  | C14D1 | 4 | 2.305 (0.1515) | 2.315 (2.210, 2.400) | 2.11, 2.48 | 4 | -0.083 (0.1127) | -0.075 (-0.170, 0.005) | -0.22, 0.04 |
|  | C15D1 | 3 | 2.343 (0.0896) | 2.390 (2.240, 2.400) | 2.24, 2.40 | 3 | -0.030 (0.1212) | -0.050 (-0.140, 0.100) | -0.14, 0.10 |
|  | C16D1 | 2 | 2.410 (0.0424) | 2.410 (2.380, 2.440) | 2.38, 2.44 | 2 | -0.080 (0.0283) | -0.080 (-0.100, -0.060) | -0.10, -0.06 |
|  | C17D1 | 2 | 2.260 (0.1697) | 2.260 (2.140, 2.380) | 2.14, 2.38 | 2 | -0.230 (0.0990) | -0.230 (-0.300, -0.160) | -0.30, -0.16 |
|  | C18D1 | 1 | 2.330 (NA) | 2.330 (2.330, 2.330) | 2.33, 2.33 | 1 | -0.210 (NA) | -0.210 (-0.210, -0.210) | -0.21, -0.21 |
|  | End of Treatment | 4 | 2.415 (0.2317) | 2.470 (2.260, 2.570) | 2.09, 2.63 | 4 | 0.130 (0.2031) | 0.185 (0.000, 0.260) | -0.16, 0.31 |
|  | | | | | | | | | |
| Phosphorus (mmol/L) (N = 33) | Baseline | 33 | 1.100 (0.1640) | 1.100 (1.010, 1.210) | 0.68, 1.46 |  |  |  |  |
|  | C1D8 | 33 | 1.138 (0.1939) | 1.180 (1.020, 1.250) | 0.47, 1.51 | 33 | 0.038 (0.1554) | 0.040 (-0.060, 0.210) | -0.22, 0.27 |
|  | C2D1 | 32 | 1.284 (0.1881) | 1.300 (1.160, 1.415) | 0.83, 1.70 | 32 | 0.171 (0.1627) | 0.205 (0.085, 0.275) | -0.19, 0.49 |
|  | C3D1 | 31 | 1.309 (0.1671) | 1.300 (1.250, 1.430) | 0.96, 1.70 | 31 | 0.186 (0.1769) | 0.180 (0.090, 0.290) | -0.19, 0.65 |
|  | C4D1 | 30 | 1.314 (0.1270) | 1.280 (1.200, 1.400) | 1.12, 1.56 | 30 | 0.195 (0.1688) | 0.175 (0.090, 0.290) | -0.18, 0.53 |
|  | C5D1 | 28 | 1.355 (0.1362) | 1.360 (1.275, 1.405) | 1.07, 1.68 | 28 | 0.239 (0.1772) | 0.215 (0.105, 0.350) | -0.05, 0.63 |
|  | C6D1 | 27 | 1.297 (0.1652) | 1.340 (1.230, 1.390) | 0.87, 1.57 | 27 | 0.173 (0.1965) | 0.220 (0.070, 0.320) | -0.42, 0.48 |
|  | C7D1 | 23 | 1.274 (0.2011) | 1.320 (1.230, 1.370) | 0.46, 1.47 | 23 | 0.157 (0.2480) | 0.230 (0.040, 0.310) | -0.73, 0.46 |
|  | C8D1 | 15 | 1.264 (0.1080) | 1.290 (1.180, 1.370) | 1.07, 1.41 | 15 | 0.147 (0.1749) | 0.170 (0.110, 0.250) | -0.25, 0.44 |
|  | C9D1 | 11 | 1.240 (0.1332) | 1.310 (1.140, 1.330) | 0.94, 1.36 | 11 | 0.125 (0.2044) | 0.140 (-0.070, 0.300) | -0.20, 0.47 |
|  | C10D1 | 5 | 1.186 (0.1369) | 1.230 (1.100, 1.250) | 1.00, 1.35 | 5 | 0.052 (0.1866) | 0.070 (-0.050, 0.220) | -0.21, 0.23 |
|  | C11D1 | 6 | 1.213 (0.1763) | 1.300 (1.090, 1.320) | 0.91, 1.36 | 6 | 0.125 (0.2846) | 0.165 (-0.170, 0.300) | -0.21, 0.50 |
|  | C12D1 | 5 | 1.224 (0.0956) | 1.220 (1.180, 1.240) | 1.11, 1.37 | 5 | 0.120 (0.2847) | 0.100 (0.060, 0.210) | -0.28, 0.51 |
|  | C13D1 | 4 | 1.233 (0.0624) | 1.245 (1.185, 1.280) | 1.15, 1.29 | 4 | 0.068 (0.1626) | 0.125 (-0.035, 0.170) | -0.17, 0.19 |
|  | C14D1 | 4 | 1.155 (0.0370) | 1.160 (1.125, 1.185) | 1.11, 1.19 | 4 | -0.010 (0.2120) | 0.060 (-0.130, 0.110) | -0.32, 0.16 |
|  | C15D1 | 3 | 1.263 (0.1563) | 1.240 (1.120, 1.430) | 1.12, 1.43 | 3 | 0.083 (0.3102) | 0.070 (-0.220, 0.400) | -0.22, 0.40 |
|  | C16D1 | 1 | 1.370 (NA) | 1.370 (1.370, 1.370) | 1.37, 1.37 | 1 | -0.090 (NA) | -0.090 (-0.090, -0.090) | -0.09, -0.09 |
|  | C17D1 | 2 | 1.150 (0.0849) | 1.150 (1.090, 1.210) | 1.09, 1.21 | 2 | -0.095 (0.2192) | -0.095 (-0.250, 0.060) | -0.25, 0.06 |
|  | C18D1 | 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 |
|  | End of Treatment | 4 | 1.370 (0.2952) | 1.325 (1.135, 1.605) | 1.09, 1.74 | 4 | 0.148 (0.3872) | 0.175 (-0.175, 0.470) | -0.29, 0.53 |
|  | | | | | | | | | |
| Urea (mmol/L) (N = 33) | Baseline | 30 | 5.020 (1.3958) | 4.940 (3.760, 5.900) | 2.60, 8.52 |  |  |  |  |
|  | C1D8 | 30 | 5.198 (1.2063) | 4.870 (4.500, 5.800) | 3.20, 8.03 | 30 | 0.178 (1.2620) | 0.255 (-0.700, 1.110) | -2.58, 2.61 |
|  | C2D1 | 29 | 5.416 (1.3364) | 5.200 (4.400, 5.890) | 3.57, 8.75 | 29 | 0.480 (1.5099) | 0.410 (-0.800, 1.220) | -2.18, 4.20 |
|  | C3D1 | 28 | 5.117 (1.4886) | 4.750 (4.480, 5.650) | 2.40, 8.34 | 28 | 0.138 (1.3560) | -0.045 (-0.750, 0.740) | -1.90, 3.96 |
|  | C4D1 | 27 | 5.046 (1.4507) | 4.850 (4.080, 5.840) | 2.36, 7.91 | 27 | 0.086 (1.3353) | -0.040 (-0.900, 0.890) | -2.24, 3.33 |
|  | C5D1 | 25 | 5.433 (1.3676) | 5.230 (4.740, 6.210) | 2.50, 8.88 | 25 | 0.435 (1.4388) | 0.500 (-0.400, 1.300) | -2.00, 4.50 |
|  | C6D1 | 24 | 5.501 (1.3095) | 5.350 (4.520, 6.130) | 3.10, 8.19 | 24 | 0.561 (1.0544) | 0.450 (-0.280, 1.150) | -0.93, 3.30 |
|  | C7D1 | 21 | 5.270 (1.2356) | 5.600 (4.400, 5.920) | 2.30, 7.50 | 21 | 0.334 (1.3053) | 0.020 (-0.300, 1.200) | -2.65, 3.10 |
|  | C8D1 | 13 | 6.005 (1.9599) | 6.050 (4.500, 6.600) | 4.00, 11.25 | 13 | 0.815 (2.1449) | 0.350 (-0.600, 1.310) | -1.45, 6.87 |
|  | C9D1 | 10 | 6.416 (2.1528) | 6.325 (5.100, 7.100) | 3.34, 11.29 | 10 | 0.831 (2.3643) | 0.500 (-0.320, 0.710) | -1.87, 6.91 |
|  | C10D1 | 6 | 5.418 (2.1675) | 4.855 (3.700, 7.090) | 3.30, 8.71 | 6 | 0.367 (2.1079) | 0.075 (-0.700, 0.320) | -1.90, 4.33 |
|  | C11D1 | 6 | 6.338 (1.3656) | 6.400 (6.000, 6.800) | 4.12, 8.31 | 6 | 1.287 (1.6856) | 1.030 (0.200, 2.300) | -0.77, 3.93 |
|  | C12D1 | 5 | 5.846 (1.6694) | 5.200 (5.100, 6.100) | 4.24, 8.59 | 5 | 1.138 (1.9349) | 0.580 (-0.100, 1.700) | -0.70, 4.21 |
|  | C13D1 | 4 | 5.005 (1.0312) | 4.700 (4.320, 5.690) | 4.14, 6.48 | 4 | 0.220 (1.4067) | -0.110 (-0.850, 1.290) | -1.00, 2.10 |
|  | C14D1 | 4 | 5.663 (1.8945) | 5.050 (4.385, 6.940) | 4.17, 8.38 | 4 | 0.878 (2.1370) | 0.055 (-0.500, 2.255) | -0.60, 4.00 |
|  | C15D1 | 3 | 6.400 (1.7643) | 6.000 (4.870, 8.330) | 4.87, 8.33 | 3 | 1.753 (1.9817) | 1.210 (0.100, 3.950) | 0.10, 3.95 |
|  | C16D1 | 2 | 7.760 (0.0566) | 7.760 (7.720, 7.800) | 7.72, 7.80 | 2 | 2.620 (1.0182) | 2.620 (1.900, 3.340) | 1.90, 3.34 |
|  | C17D1 | 2 | 5.255 (1.2092) | 5.255 (4.400, 6.110) | 4.40, 6.11 | 2 | 0.115 (2.2840) | 0.115 (-1.500, 1.730) | -1.50, 1.73 |
|  | C18D1 | 1 | 4.900 (NA) | 4.900 (4.900, 4.900) | 4.90, 4.90 | 1 | -1.000 (NA) | -1.000 (-1.000, -1.000) | -1.00, -1.00 |
|  | End of Treatment | 3 | 5.190 (0.9344) | 4.880 (4.450, 6.240) | 4.45, 6.24 | 3 | 0.537 (1.7884) | 0.170 (-1.040, 2.480) | -1.04, 2.48 |
|  | | | | | | | | | |
| Urea Nitrogen (mmol/L) (N = 33) | Baseline | 3 | 6.433 (2.5794) | 5.700 (4.300, 9.300) | 4.30, 9.30 |  |  |  |  |
|  | C1D8 | 3 | 7.000 (1.6462) | 6.100 (6.000, 8.900) | 6.00, 8.90 | 3 | 0.567 (1.1240) | 0.300 (-0.400, 1.800) | -0.40, 1.80 |
|  | C2D1 | 3 | 6.300 (1.9698) | 5.700 (4.700, 8.500) | 4.70, 8.50 | 3 | -0.133 (0.6110) | 0.000 (-0.800, 0.400) | -0.80, 0.40 |
|  | C3D1 | 3 | 5.267 (2.4111) | 5.000 (3.000, 7.800) | 3.00, 7.80 | 3 | -1.167 (1.7243) | -1.500 (-2.700, 0.700) | -2.70, 0.70 |
|  | C4D1 | 3 | 6.817 (4.4923) | 4.400 (4.050, 12.000) | 4.05, 12.00 | 3 | 0.383 (2.0738) | -0.250 (-1.300, 2.700) | -1.30, 2.70 |
|  | C5D1 | 3 | 7.867 (4.0216) | 9.000 (3.400, 11.200) | 3.40, 11.20 | 3 | 1.433 (2.1385) | 1.900 (-0.900, 3.300) | -0.90, 3.30 |
|  | C6D1 | 3 | 8.967 (2.6083) | 10.000 (6.000, 10.900) | 6.00, 10.90 | 3 | 2.533 (2.3629) | 1.700 (0.700, 5.200) | 0.70, 5.20 |
|  | C7D1 | 2 | 6.450 (1.6263) | 6.450 (5.300, 7.600) | 5.30, 7.60 | 2 | -0.350 (1.9092) | -0.350 (-1.700, 1.000) | -1.70, 1.00 |
|  | C8D1 | 2 | 7.000 (2.5456) | 7.000 (5.200, 8.800) | 5.20, 8.80 | 2 | 0.200 (0.9899) | 0.200 (-0.500, 0.900) | -0.50, 0.90 |
|  | C9D1 | 1 | 8.200 (NA) | 8.200 (8.200, 8.200) | 8.20, 8.20 | 1 | -1.100 (NA) | -1.100 (-1.100, -1.100) | -1.10, -1.10 |
|  | End of Treatment | 1 | 10.500 (NA) | 10.500 (10.500, 10.500) | 10.50, 10.50 | 1 | 4.800 (NA) | 4.800 (4.800, 4.800) | 4.80, 4.80 |
|  | | | | | | | | | |
| Creatinine (umol/L) (N = 33) | Baseline | 33 | 66.64 (11.538) | 63.00 (61.00, 72.30) | 49.6, 103.6 |  |  |  |  |
|  | C1D8 | 33 | 69.86 (16.926) | 64.00 (59.00, 78.00) | 41.0, 122.9 | 33 | 3.22 (7.106) | 2.00 (-1.50, 7.90) | -9.1, 19.3 |
|  | C2D1 | 32 | 72.45 (13.581) | 68.15 (64.00, 75.50) | 57.2, 115.0 | 32 | 5.29 (5.082) | 5.00 (1.90, 9.50) | -3.0, 20.0 |
|  | C3D1 | 31 | 72.94 (15.015) | 72.50 (60.00, 81.00) | 52.1, 110.3 | 31 | 5.61 (8.098) | 6.00 (0.00, 12.00) | -10.9, 25.0 |
|  | C4D1 | 30 | 73.68 (15.166) | 72.65 (62.50, 81.00) | 48.4, 106.5 | 30 | 6.47 (8.218) | 6.00 (2.00, 12.00) | -8.4, 21.8 |
|  | C5D1 | 28 | 74.05 (16.142) | 73.25 (63.05, 83.00) | 45.5, 115.0 | 28 | 6.13 (9.395) | 7.65 (-0.45, 11.00) | -9.5, 31.0 |
|  | C6D1 | 27 | 73.30 (19.125) | 71.00 (59.10, 85.00) | 46.6, 141.8 | 27 | 5.98 (12.087) | 2.50 (-2.00, 13.00) | -12.0, 38.2 |
|  | C7D1 | 23 | 70.17 (12.295) | 70.30 (59.70, 80.00) | 48.7, 90.0 | 23 | 4.51 (9.207) | 4.10 (-2.00, 11.90) | -15.5, 21.0 |
|  | C8D1 | 15 | 73.10 (12.485) | 74.00 (68.00, 83.00) | 51.1, 97.0 | 15 | 5.57 (7.940) | 5.00 (-2.90, 11.00) | -8.0, 22.0 |
|  | C9D1 | 11 | 78.79 (11.631) | 80.00 (68.10, 90.00) | 62.0, 94.0 | 11 | 9.19 (8.874) | 9.40 (1.00, 14.00) | -4.2, 26.0 |
|  | C10D1 | 6 | 74.32 (7.853) | 73.50 (69.70, 76.00) | 65.2, 88.0 | 6 | 4.45 (9.491) | 7.50 (-7.00, 12.80) | -7.1, 13.0 |
|  | C11D1 | 6 | 79.77 (13.978) | 81.00 (70.10, 88.00) | 59.5, 99.0 | 6 | 9.90 (14.149) | 14.10 (-1.00, 20.00) | -12.8, 25.0 |
|  | C12D1 | 5 | 79.22 (9.222) | 84.00 (73.00, 86.00) | 66.1, 87.0 | 5 | 9.84 (7.722) | 8.00 (6.00, 9.20) | 3.0, 23.0 |
|  | C13D1 | 4 | 80.83 (10.142) | 83.00 (73.15, 88.50) | 67.3, 90.0 | 4 | 9.85 (10.879) | 6.70 (2.00, 17.70) | 1.0, 25.0 |
|  | C14D1 | 4 | 79.88 (15.046) | 81.00 (69.75, 90.00) | 60.5, 97.0 | 4 | 8.90 (5.358) | 9.00 (4.30, 13.50) | 3.6, 14.0 |
|  | C15D1 | 3 | 81.67 (14.742) | 87.00 (65.00, 93.00) | 65.0, 93.0 | 3 | 8.70 (0.520) | 9.00 (8.10, 9.00) | 8.1, 9.0 |
|  | C16D1 | 2 | 98.50 (7.778) | 98.50 (93.00, 104.00) | 93.0, 104.0 | 2 | 17.50 (3.536) | 17.50 (15.00, 20.00) | 15.0, 20.0 |
|  | C17D1 | 2 | 88.50 (7.778) | 88.50 (83.00, 94.00) | 83.0, 94.0 | 2 | 7.50 (3.536) | 7.50 (5.00, 10.00) | 5.0, 10.0 |
|  | C18D1 | 1 | 79.00 (NA) | 79.00 (79.00, 79.00) | 79.0, 79.0 | 1 | 1.00 (NA) | 1.00 (1.00, 1.00) | 1.0, 1.0 |
|  | End of Treatment | 4 | 87.00 (32.371) | 74.50 (67.15, 106.85) | 64.3, 134.7 | 4 | 17.53 (35.224) | 3.50 (-3.30, 38.35) | -6.6, 69.7 |
|  | | | | | | | | | |
| Urate (umol/L) (N = 33) | Baseline | 33 | 313.59 (110.755) | 294.00 (259.00, 370.00) | 3.2, 601.0 |  |  |  |  |
|  | C1D8 | 33 | 312.42 (79.686) | 305.00 (258.00, 348.00) | 177.0, 565.0 | 33 | -1.17 (75.865) | -7.00 (-32.00, 28.00) | -254.0, 256.8 |
|  | C2D1 | 32 | 309.94 (71.968) | 297.00 (262.00, 344.00) | 157.0, 472.0 | 32 | -5.04 (91.832) | -8.00 (-35.50, 33.00) | -343.0, 286.8 |
|  | C3D1 | 31 | 316.46 (84.733) | 307.00 (270.00, 356.00) | 203.0, 635.0 | 31 | 0.28 (89.036) | -11.20 (-37.00, 44.00) | -214.8, 214.8 |
|  | C4D1 | 30 | 334.52 (79.335) | 324.50 (273.00, 383.00) | 187.0, 610.0 | 30 | 25.70 (102.565) | 2.00 (-25.00, 111.00) | -215.0, 247.8 |
|  | C5D1 | 28 | 335.14 (81.745) | 334.00 (280.00, 363.00) | 226.0, 590.0 | 28 | 28.24 (98.345) | 36.50 (-17.00, 93.00) | -262.0, 222.8 |
|  | C6D1 | 27 | 340.07 (75.949) | 341.00 (300.00, 379.00) | 198.0, 518.0 | 27 | 33.99 (99.110) | 36.00 (-16.00, 94.00) | -260.0, 225.8 |
|  | C7D1 | 22 | 317.68 (70.999) | 319.00 (291.00, 357.00) | 168.0, 513.0 | 22 | 10.58 (104.350) | 22.50 (-12.00, 51.00) | -319.0, 200.8 |
|  | C8D1 | 15 | 345.27 (84.031) | 320.00 (298.00, 383.00) | 237.0, 599.0 | 15 | 40.60 (67.077) | 46.00 (-2.00, 82.00) | -100.0, 178.0 |
|  | C9D1 | 11 | 369.91 (104.498) | 350.00 (305.00, 412.00) | 243.0, 623.0 | 11 | 60.73 (55.238) | 60.00 (21.00, 110.00) | -41.0, 141.0 |
|  | C10D1 | 6 | 337.50 (121.401) | 315.50 (266.00, 360.00) | 212.0, 556.0 | 6 | 17.50 (50.599) | 15.50 (-31.00, 70.00) | -39.0, 74.0 |
|  | C11D1 | 6 | 377.00 (117.107) | 357.00 (294.00, 408.00) | 261.0, 585.0 | 6 | 57.00 (58.145) | 33.50 (20.00, 103.00) | 0.0, 152.0 |
|  | C12D1 | 5 | 362.40 (152.726) | 296.00 (276.00, 392.00) | 233.0, 615.0 | 5 | 57.80 (83.092) | 64.00 (22.00, 133.00) | -64.0, 134.0 |
|  | C13D1 | 4 | 391.75 (146.197) | 346.00 (298.00, 485.50) | 272.0, 603.0 | 4 | 46.50 (70.911) | 45.00 (-13.50, 106.50) | -25.0, 121.0 |
|  | C14D1 | 4 | 393.50 (179.936) | 333.00 (282.00, 505.00) | 252.0, 656.0 | 4 | 48.25 (99.406) | 32.00 (-30.50, 127.00) | -45.0, 174.0 |
|  | C15D1 | 3 | 397.33 (117.070) | 402.00 (278.00, 512.00) | 278.0, 512.0 | 3 | 36.00 (8.718) | 32.00 (30.00, 46.00) | 30.0, 46.0 |
|  | C16D1 | 2 | 504.00 (130.108) | 504.00 (412.00, 596.00) | 412.0, 596.0 | 2 | 78.00 (50.912) | 78.00 (42.00, 114.00) | 42.0, 114.0 |
|  | C17D1 | 2 | 413.50 (74.246) | 413.50 (361.00, 466.00) | 361.0, 466.0 | 2 | -12.50 (4.950) | -12.50 (-16.00, -9.00) | -16.0, -9.0 |
|  | C18D1 | 1 | 360.00 (NA) | 360.00 (360.00, 360.00) | 360.0, 360.0 | 1 | -10.00 (NA) | -10.00 (-10.00, -10.00) | -10.0, -10.0 |
|  | End of Treatment | 4 | 394.15 (87.562) | 376.85 (335.35, 452.95) | 308.0, 514.9 | 4 | 20.35 (141.525) | 55.85 (-82.65, 123.35) | -174.3, 144.0 |
|  | | | | | | | | | |
| Glucose (mmol/L) (N = 33) | Baseline | 33 | 5.428 (1.1536) | 5.130 (4.750, 5.610) | 3.49, 10.24 |  |  |  |  |
|  | C1D8 | 33 | 5.228 (1.2666) | 4.860 (4.630, 5.500) | 3.61, 10.29 | 33 | -0.201 (1.0362) | -0.250 (-0.580, 0.140) | -2.60, 4.00 |
|  | C2D1 | 32 | 5.093 (0.7547) | 5.035 (4.585, 5.595) | 3.77, 7.03 | 32 | -0.308 (0.7903) | -0.230 (-0.605, 0.145) | -3.49, 0.96 |
|  | C3D1 | 31 | 5.097 (0.7441) | 4.830 (4.600, 5.530) | 3.88, 7.46 | 31 | -0.305 (0.7603) | -0.140 (-0.640, 0.080) | -2.78, 1.32 |
|  | C4D1 | 30 | 5.021 (0.7180) | 4.820 (4.610, 5.250) | 3.97, 7.42 | 30 | -0.414 (0.8606) | -0.275 (-0.710, 0.130) | -3.44, 0.83 |
|  | C5D1 | 28 | 5.016 (0.8207) | 4.950 (4.575, 5.270) | 3.53, 8.13 | 28 | -0.393 (0.8579) | -0.145 (-0.685, 0.030) | -3.29, 0.72 |
|  | C6D1 | 27 | 5.077 (0.6980) | 4.900 (4.560, 5.420) | 4.17, 6.78 | 27 | -0.344 (0.9979) | -0.330 (-0.810, 0.240) | -3.98, 1.72 |
|  | C7D1 | 23 | 5.061 (0.8041) | 5.020 (4.560, 5.290) | 4.06, 8.01 | 23 | -0.340 (0.7420) | -0.220 (-0.720, 0.130) | -2.23, 0.96 |
|  | C8D1 | 15 | 4.859 (0.6199) | 4.630 (4.350, 5.160) | 4.15, 6.19 | 15 | -0.088 (0.6501) | -0.040 (-0.540, 0.440) | -1.15, 1.06 |
|  | C9D1 | 11 | 4.783 (0.4591) | 4.780 (4.640, 4.970) | 3.83, 5.43 | 11 | -0.036 (0.4960) | -0.030 (-0.590, 0.310) | -0.71, 0.95 |
|  | C10D1 | 6 | 4.902 (0.4740) | 4.855 (4.750, 4.930) | 4.28, 5.74 | 6 | 0.238 (0.6570) | 0.130 (-0.290, 0.400) | -0.38, 1.44 |
|  | C11D1 | 6 | 4.707 (0.5434) | 4.820 (4.440, 5.100) | 3.80, 5.26 | 6 | 0.043 (0.2783) | -0.030 (-0.130, 0.310) | -0.30, 0.44 |
|  | C12D1 | 5 | 4.788 (0.6585) | 4.420 (4.420, 5.080) | 4.21, 5.81 | 5 | 0.106 (0.4716) | -0.050 (-0.210, 0.470) | -0.40, 0.72 |
|  | C13D1 | 4 | 4.628 (0.5343) | 4.700 (4.285, 4.970) | 3.91, 5.20 | 4 | 0.110 (0.2162) | 0.050 (-0.025, 0.245) | -0.08, 0.42 |
|  | C14D1 | 4 | 4.625 (0.7245) | 4.475 (4.040, 5.210) | 4.02, 5.53 | 4 | 0.108 (0.5887) | 0.330 (-0.250, 0.465) | -0.76, 0.53 |
|  | C15D1 | 3 | 4.627 (0.3009) | 4.780 (4.280, 4.820) | 4.28, 4.82 | 3 | 0.210 (0.5703) | 0.190 (-0.350, 0.790) | -0.35, 0.79 |
|  | C16D1 | 2 | 4.520 (0.1414) | 4.520 (4.420, 4.620) | 4.42, 4.62 | 2 | -0.360 (0.2121) | -0.360 (-0.510, -0.210) | -0.51, -0.21 |
|  | C17D1 | 2 | 4.735 (0.0919) | 4.735 (4.670, 4.800) | 4.67, 4.80 | 2 | -0.145 (0.2616) | -0.145 (-0.330, 0.040) | -0.33, 0.04 |
|  | C18D1 | 1 | 4.560 (NA) | 4.560 (4.560, 4.560) | 4.56, 4.56 | 1 | -0.070 (NA) | -0.070 (-0.070, -0.070) | -0.07, -0.07 |
|  | End of Treatment | 4 | 5.813 (1.5835) | 5.175 (4.795, 6.830) | 4.77, 8.13 | 4 | 0.070 (0.9515) | -0.145 (-0.690, 0.830) | -0.71, 1.28 |
|  | | | | | | | | | |
| Amylase (IU/L) (N = 33) | Baseline | 22 | 76.811 (61.2144) | 61.500 (42.000, 96.000) | 22.00, 309.00 |  |  |  |  |
|  | C1D8 | 21 | 70.365 (30.3059) | 67.000 (49.000, 87.000) | 30.00, 152.50 | 21 | -8.818 (56.2773) | 6.000 (-4.000, 9.000) | -242.00, 48.80 |
|  | C2D1 | 21 | 64.440 (19.4689) | 58.470 (55.000, 70.000) | 34.00, 114.44 | 21 | -14.743 (57.8995) | -1.000 (-9.290, 10.000) | -247.00, 26.00 |
|  | C3D1 | 20 | 64.062 (24.3781) | 59.615 (48.500, 79.000) | 26.00, 115.00 | 20 | -12.837 (52.6338) | 0.000 (-10.500, 6.400) | -230.00, 19.00 |
|  | C4D1 | 19 | 66.274 (23.6385) | 58.000 (44.000, 86.000) | 36.00, 109.00 | 19 | -11.105 (53.1409) | -1.000 (-8.000, 11.000) | -223.00, 26.00 |
|  | C5D1 | 17 | 66.276 (26.9600) | 58.000 (46.000, 80.000) | 32.00, 113.00 | 17 | -12.147 (59.8078) | 1.000 (-4.400, 9.000) | -240.00, 18.00 |
|  | C6D1 | 17 | 66.347 (26.6582) | 62.000 (50.000, 72.000) | 30.00, 126.00 | 17 | -12.076 (59.6180) | 4.400 (-4.000, 12.000) | -237.00, 15.00 |
|  | C7D1 | 13 | 59.777 (22.0571) | 55.000 (47.000, 73.000) | 30.00, 109.10 | 13 | -18.262 (70.5000) | 8.000 (-4.000, 10.000) | -245.00, 12.00 |
|  | C8D1 | 9 | 55.667 (13.3604) | 53.000 (47.000, 66.000) | 37.00, 77.00 | 9 | -29.222 (81.1384) | 1.000 (-3.000, 12.000) | -232.00, 14.00 |
|  | C9D1 | 6 | 68.167 (27.2427) | 62.000 (47.000, 81.000) | 43.00, 114.00 | 6 | -40.500 (93.0306) | -3.500 (-29.000, 9.000) | -228.00, 12.00 |
|  | C10D1 | 3 | 66.333 (27.3922) | 61.000 (42.000, 96.000) | 42.00, 96.00 | 3 | -16.000 (26.8514) | -1.000 (-47.000, 0.000) | -47.00, 0.00 |
|  | C11D1 | 3 | 80.000 (33.1512) | 90.000 (43.000, 107.000) | 43.00, 107.00 | 3 | -2.333 (32.1299) | 1.000 (-36.000, 28.000) | -36.00, 28.00 |
|  | C12D1 | 2 | 91.500 (26.1630) | 91.500 (73.000, 110.000) | 73.00, 110.00 | 2 | -11.000 (31.1127) | -11.000 (-33.000, 11.000) | -33.00, 11.00 |
|  | C13D1 | 2 | 93.000 (26.8701) | 93.000 (74.000, 112.000) | 74.00, 112.00 | 2 | -9.500 (30.4056) | -9.500 (-31.000, 12.000) | -31.00, 12.00 |
|  | C14D1 | 2 | 97.000 (31.1127) | 97.000 (75.000, 119.000) | 75.00, 119.00 | 2 | -5.500 (26.1630) | -5.500 (-24.000, 13.000) | -24.00, 13.00 |
|  | C15D1 | 2 | 84.000 (19.7990) | 84.000 (70.000, 98.000) | 70.00, 98.00 | 2 | -18.500 (37.4767) | -18.500 (-45.000, 8.000) | -45.00, 8.00 |
|  | C16D1 | 1 | 103.000 (NA) | 103.000 (103.000, 103.000) | 103.00, 103.00 | 1 | -40.000 (NA) | -40.000 (-40.000, -40.000) | -40.00, -40.00 |
|  | C17D1 | 1 | 85.000 (NA) | 85.000 (85.000, 85.000) | 85.00, 85.00 | 1 | -58.000 (NA) | -58.000 (-58.000, -58.000) | -58.00, -58.00 |
|  | End of Treatment | 4 | 60.750 (38.6383) | 44.500 (37.500, 84.000) | 36.00, 118.00 | 4 | -5.440 (22.3333) | -6.000 (-21.380, 10.500) | -31.76, 22.00 |
|  | | | | | | | | | |
| Lipase (IU/L) (N = 33) | Baseline | 19 | 61.949 (139.6805) | 24.500 (18.520, 37.200) | 6.00, 627.30 |  |  |  |  |
|  | C1D8 | 19 | 29.711 (16.2605) | 24.000 (18.700, 42.000) | 2.60, 61.40 | 19 | -32.239 (131.4412) | 1.700 (-2.800, 5.000) | -565.90, 25.00 |
|  | C2D1 | 19 | 36.597 (34.0699) | 25.800 (20.670, 36.100) | 7.00, 153.70 | 19 | -25.352 (144.4482) | 1.300 (-4.800, 7.900) | -595.00, 127.58 |
|  | C3D1 | 18 | 29.411 (14.4120) | 27.450 (21.750, 35.000) | 5.00, 58.00 | 18 | -34.952 (141.0378) | -1.000 (-5.000, 4.600) | -593.00, 37.00 |
|  | C4D1 | 17 | 31.347 (15.7643) | 29.100 (22.900, 41.000) | 7.00, 67.00 | 17 | -33.489 (144.2480) | 2.600 (0.000, 7.000) | -588.20, 20.00 |
|  | C5D1 | 15 | 26.900 (16.4558) | 25.000 (15.500, 34.700) | 7.00, 62.00 | 15 | -43.207 (155.8738) | 1.000 (-7.400, 5.500) | -601.80, 17.00 |
|  | C6D1 | 15 | 32.247 (14.6001) | 32.700 (22.300, 43.800) | 5.00, 62.00 | 15 | -37.860 (155.0233) | 5.000 (-3.200, 19.600) | -592.10, 24.30 |
|  | C7D1 | 12 | 25.167 (10.8502) | 26.350 (18.700, 30.850) | 4.00, 45.70 | 12 | -55.533 (174.5807) | -0.200 (-7.250, 8.800) | -601.10, 21.40 |
|  | C8D1 | 9 | 23.600 (11.3982) | 24.000 (20.300, 29.000) | 4.00, 40.30 | 9 | -77.511 (198.9654) | -2.000 (-7.700, 0.100) | -598.30, 16.00 |
|  | C9D1 | 6 | 31.233 (19.3559) | 25.950 (18.600, 54.000) | 8.00, 54.90 | 6 | -107.967 (242.6146) | -4.300 (-81.000, 2.000) | -596.90, 36.70 |
|  | C10D1 | 3 | 28.367 (6.6935) | 25.600 (23.500, 36.000) | 23.50, 36.00 | 3 | -32.867 (57.2732) | 0.100 (-99.000, 0.300) | -99.00, 0.30 |
|  | C11D1 | 3 | 34.700 (13.4235) | 29.200 (24.900, 50.000) | 24.90, 50.00 | 3 | -26.533 (50.6478) | 1.500 (-85.000, 3.900) | -85.00, 3.90 |
|  | C12D1 | 2 | 38.100 (21.0718) | 38.100 (23.200, 53.000) | 23.20, 53.00 | 2 | -41.100 (57.8413) | -41.100 (-82.000, -0.200) | -82.00, -0.20 |
|  | C13D1 | 2 | 37.150 (19.5869) | 37.150 (23.300, 51.000) | 23.30, 51.00 | 2 | -42.050 (59.3263) | -42.050 (-84.000, -0.100) | -84.00, -0.10 |
|  | C14D1 | 2 | 38.250 (10.9602) | 38.250 (30.500, 46.000) | 30.50, 46.00 | 2 | -40.950 (67.9530) | -40.950 (-89.000, 7.100) | -89.00, 7.10 |
|  | C15D1 | 2 | 33.150 (6.8589) | 33.150 (28.300, 38.000) | 28.30, 38.00 | 2 | -46.050 (72.0542) | -46.050 (-97.000, 4.900) | -97.00, 4.90 |
|  | C16D1 | 1 | 40.000 (NA) | 40.000 (40.000, 40.000) | 40.00, 40.00 | 1 | -95.000 (NA) | -95.000 (-95.000, -95.000) | -95.00, -95.00 |
|  | C17D1 | 1 | 40.000 (NA) | 40.000 (40.000, 40.000) | 40.00, 40.00 | 1 | -95.000 (NA) | -95.000 (-95.000, -95.000) | -95.00, -95.00 |
|  | End of Treatment | 4 | 28.168 (20.7173) | 29.535 (11.285, 45.050) | 4.00, 49.60 | 4 | -3.238 (24.1259) | 5.200 (-19.865, 13.390) | -37.73, 14.38 |
|  | | | | | | | | | |
| Creatine Kinase (IU/L) (N = 33) | Baseline | 22 | 72.54 (60.706) | 52.50 (40.00, 91.00) | 27.0, 307.0 |  |  |  |  |
|  | C1D8 | 22 | 85.69 (68.838) | 56.50 (46.00, 96.00) | 29.0, 286.0 | 22 | 13.15 (41.589) | 7.00 (-4.00, 15.00) | -78.2, 156.0 |
|  | C2D1 | 21 | 72.97 (42.830) | 61.00 (43.00, 85.00) | 24.0, 204.0 | 21 | -1.65 (30.771) | 7.00 (-16.00, 20.00) | -103.0, 31.0 |
|  | C3D1 | 20 | 102.97 (105.311) | 61.50 (45.65, 94.00) | 25.0, 454.0 | 20 | 31.00 (85.173) | 11.50 (-4.00, 21.50) | -74.0, 350.0 |
|  | C4D1 | 19 | 98.30 (90.872) | 63.00 (41.70, 116.00) | 31.0, 351.0 | 19 | 24.03 (72.141) | 3.00 (-10.00, 25.00) | -38.0, 289.0 |
|  | C5D1 | 17 | 100.53 (95.237) | 65.00 (54.00, 100.00) | 31.0, 412.0 | 17 | 22.71 (77.664) | 4.00 (-2.00, 21.00) | -74.0, 295.0 |
|  | C6D1 | 17 | 85.53 (62.819) | 57.00 (49.00, 80.00) | 37.0, 268.0 | 17 | 7.71 (51.214) | 8.00 (-5.00, 17.00) | -115.0, 151.0 |
|  | C7D1 | 13 | 83.46 (39.811) | 68.00 (49.00, 115.00) | 42.0, 155.0 | 13 | 0.85 (55.613) | 15.00 (-14.00, 25.00) | -152.0, 75.0 |
|  | C8D1 | 9 | 86.11 (36.730) | 84.00 (56.00, 93.00) | 43.0, 147.0 | 9 | -4.22 (85.860) | 27.00 (-1.00, 30.00) | -223.0, 56.0 |
|  | C9D1 | 6 | 111.83 (67.892) | 82.00 (61.00, 166.00) | 56.0, 224.0 | 6 | 6.33 (52.550) | 19.50 (-21.00, 47.00) | -83.0, 56.0 |
|  | C10D1 | 4 | 111.25 (62.388) | 85.50 (72.00, 150.50) | 71.0, 203.0 | 3 | -27.33 (69.945) | -11.00 (-104.00, 33.00) | -104.0, 33.0 |
|  | C11D1 | 3 | 97.33 (71.501) | 67.00 (46.00, 179.00) | 46.0, 179.0 | 3 | -45.67 (72.072) | -15.00 (-128.00, 6.00) | -128.0, 6.0 |
|  | C12D1 | 2 | 127.50 (99.702) | 127.50 (57.00, 198.00) | 57.0, 198.0 | 2 | -46.00 (89.095) | -46.00 (-109.00, 17.00) | -109.0, 17.0 |
|  | C13D1 | 2 | 152.00 (135.765) | 152.00 (56.00, 248.00) | 56.0, 248.0 | 2 | -21.50 (53.033) | -21.50 (-59.00, 16.00) | -59.0, 16.0 |
|  | C14D1 | 2 | 108.00 (74.953) | 108.00 (55.00, 161.00) | 55.0, 161.0 | 2 | -65.50 (113.844) | -65.50 (-146.00, 15.00) | -146.0, 15.0 |
|  | C15D1 | 2 | 132.00 (107.480) | 132.00 (56.00, 208.00) | 56.0, 208.0 | 2 | -41.50 (81.317) | -41.50 (-99.00, 16.00) | -99.0, 16.0 |
|  | C16D1 | 1 | 160.00 (NA) | 160.00 (160.00, 160.00) | 160.0, 160.0 | 1 | -147.00 (NA) | -147.00 (-147.00, -147.00) | -147.0, -147.0 |
|  | C17D1 | 1 | 183.00 (NA) | 183.00 (183.00, 183.00) | 183.0, 183.0 | 1 | -124.00 (NA) | -124.00 (-124.00, -124.00) | -124.0, -124.0 |
|  | End of Treatment | 4 | 36.63 (15.126) | 30.80 (27.75, 45.50) | 25.9, 59.0 | 4 | -5.98 (7.794) | -2.65 (-10.30, -1.65) | -17.6, -1.0 |

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 14.3.5.1.3.2 Summary of Urinalysis Results - Phase II part 1 treatment-naive locally-advanced or metastatic NSCLC (Safety Analysis Set)**

|  | | Observed Value | | | | Change from Baseline | | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Parameter | Visit | n | Mean (STD) | Median (Q1, Q3) | Min, Max | n | Mean (STD) | Median (Q1, Q3) | Min, Max |
| pH, Quantitative (N = 33) | Baseline | 33 | 6.20 (0.661) | 6.00 (6.00, 6.50) | 5.0, 7.5 |  |  |  |  |
|  | C1D8 | 33 | 5.95 (0.550) | 6.00 (5.50, 6.00) | 5.0, 7.0 | 33 | -0.24 (0.639) | -0.50 (-1.00, 0.50) | -1.0, 1.0 |
|  | C2D1 | 32 | 5.78 (0.595) | 5.75 (5.50, 6.00) | 5.0, 7.0 | 32 | -0.41 (0.723) | -0.50 (-1.00, 0.00) | -1.5, 1.5 |
|  | C3D1 | 31 | 5.82 (0.626) | 6.00 (5.50, 6.50) | 5.0, 7.5 | 31 | -0.37 (0.718) | -0.50 (-1.00, 0.00) | -1.5, 1.0 |
|  | C4D1 | 30 | 5.87 (0.669) | 5.75 (5.50, 6.50) | 5.0, 7.0 | 30 | -0.33 (0.791) | -0.25 (-1.00, 0.00) | -1.5, 1.5 |
|  | C5D1 | 28 | 5.89 (0.672) | 5.75 (5.50, 6.25) | 5.0, 7.5 | 28 | -0.34 (0.734) | -0.50 (-1.00, 0.00) | -1.5, 1.0 |
|  | C6D1 | 27 | 5.59 (0.572) | 5.50 (5.00, 6.00) | 5.0, 7.5 | 27 | -0.69 (0.638) | -0.50 (-1.00, 0.00) | -2.0, 0.5 |
|  | C7D1 | 23 | 5.80 (0.579) | 5.50 (5.50, 6.50) | 5.0, 7.0 | 23 | -0.48 (0.648) | -0.50 (-1.00, 0.00) | -2.0, 0.5 |
|  | C8D1 | 15 | 5.63 (0.516) | 5.50 (5.00, 6.00) | 5.0, 6.5 | 15 | -0.57 (0.884) | -0.50 (-1.50, 0.00) | -2.0, 1.0 |
|  | C9D1 | 11 | 5.73 (0.607) | 5.50 (5.50, 6.00) | 5.0, 7.0 | 11 | -0.50 (0.775) | -1.00 (-1.00, 0.00) | -1.5, 1.0 |
|  | C10D1 | 6 | 5.83 (0.516) | 6.00 (5.50, 6.00) | 5.0, 6.5 | 6 | -0.50 (1.000) | -0.50 (-1.50, 0.00) | -1.5, 1.0 |
|  | C11D1 | 6 | 5.58 (0.801) | 5.25 (5.00, 6.00) | 5.0, 7.0 | 6 | -0.75 (0.822) | -0.50 (-1.50, 0.00) | -2.0, 0.0 |
|  | C12D1 | 5 | 5.60 (0.418) | 5.50 (5.50, 6.00) | 5.0, 6.0 | 5 | -1.00 (0.707) | -1.50 (-1.50, -0.50) | -1.5, 0.0 |
|  | C13D1 | 4 | 5.63 (0.250) | 5.50 (5.50, 5.75) | 5.5, 6.0 | 4 | -0.75 (1.041) | -0.75 (-1.50, 0.00) | -2.0, 0.5 |
|  | C14D1 | 4 | 5.75 (0.645) | 5.75 (5.25, 6.25) | 5.0, 6.5 | 4 | -0.63 (0.750) | -0.50 (-1.25, 0.00) | -1.5, 0.0 |
|  | C15D1 | 3 | 6.83 (1.155) | 7.50 (5.50, 7.50) | 5.5, 7.5 | 3 | 0.00 (1.500) | 0.00 (-1.50, 1.50) | -1.5, 1.5 |
|  | C16D1 | 2 | 6.25 (1.061) | 6.25 (5.50, 7.00) | 5.5, 7.0 | 2 | -1.00 (0.707) | -1.00 (-1.50, -0.50) | -1.5, -0.5 |
|  | C17D1 | 2 | 6.25 (0.354) | 6.25 (6.00, 6.50) | 6.0, 6.5 | 2 | -1.00 (0.000) | -1.00 (-1.00, -1.00) | -1.0, -1.0 |
|  | C18D1 | 1 | 6.00 (NA) | 6.00 (6.00, 6.00) | 6.0, 6.0 | 1 | -1.00 (NA) | -1.00 (-1.00, -1.00) | -1.0, -1.0 |
|  | End of Treatment | 4 | 5.75 (0.500) | 6.00 (5.50, 6.00) | 5.0, 6.0 | 4 | -0.63 (0.946) | -0.25 (-1.25, 0.00) | -2.0, 0.0 |
|  | | | | | | | | | |
| Specific Gravity, Quantitative (N = 33) | Baseline | 33 | 1.0205 (0.0075) | 1.0200 (1.0150, 1.0250) | 1.004, 1.045 |  |  |  |  |
|  | C1D8 | 33 | 1.0197 (0.0062) | 1.0200 (1.0150, 1.0250) | 1.006, 1.030 | 33 | -0.0008 (0.0096) | -0.0010 (-0.0050, 0.0050) | -0.025, 0.015 |
|  | C2D1 | 32 | 1.0193 (0.0064) | 1.0190 (1.0150, 1.0225) | 1.005, 1.031 | 32 | -0.0012 (0.0083) | -0.0010 (-0.0060, 0.0055) | -0.022, 0.014 |
|  | C3D1 | 31 | 1.0244 (0.0111) | 1.0220 (1.0170, 1.0260) | 1.011, 1.050 | 31 | 0.0042 (0.0113) | 0.0000 (-0.0040, 0.0100) | -0.011, 0.039 |
|  | C4D1 | 30 | 1.0179 (0.0072) | 1.0180 (1.0150, 1.0230) | 1.000, 1.032 | 30 | -0.0021 (0.0097) | -0.0030 (-0.0070, 0.0040) | -0.025, 0.017 |
|  | C5D1 | 27 | 1.0183 (0.0050) | 1.0180 (1.0150, 1.0210) | 1.009, 1.030 | 27 | -0.0017 (0.0087) | 0.0000 (-0.0090, 0.0030) | -0.026, 0.015 |
|  | C6D1 | 27 | 1.0179 (0.0065) | 1.0180 (1.0150, 1.0230) | 1.004, 1.032 | 27 | -0.0022 (0.0086) | -0.0010 (-0.0060, 0.0030) | -0.026, 0.017 |
|  | C7D1 | 23 | 1.0193 (0.0107) | 1.0170 (1.0100, 1.0250) | 1.005, 1.045 | 23 | -0.0011 (0.0088) | -0.0010 (-0.0080, 0.0050) | -0.015, 0.021 |
|  | C8D1 | 15 | 1.0185 (0.0057) | 1.0180 (1.0160, 1.0230) | 1.010, 1.029 | 15 | -0.0047 (0.0096) | -0.0040 (-0.0090, -0.0010) | -0.027, 0.011 |
|  | C9D1 | 11 | 1.0223 (0.0061) | 1.0220 (1.0180, 1.0250) | 1.015, 1.037 | 11 | 0.0003 (0.0065) | 0.0010 (-0.0020, 0.0060) | -0.015, 0.008 |
|  | C10D1 | 6 | 1.0197 (0.0053) | 1.0200 (1.0160, 1.0230) | 1.012, 1.027 | 6 | -0.0002 (0.0073) | 0.0000 (-0.0070, 0.0020) | -0.008, 0.012 |
|  | C11D1 | 6 | 1.0193 (0.0051) | 1.0205 (1.0180, 1.0230) | 1.010, 1.024 | 6 | -0.0005 (0.0045) | 0.0000 (-0.0050, 0.0020) | -0.006, 0.006 |
|  | C12D1 | 5 | 1.0242 (0.0090) | 1.0210 (1.0190, 1.0230) | 1.018, 1.040 | 5 | 0.0060 (0.0093) | 0.0020 (0.0010, 0.0060) | -0.001, 0.022 |
|  | C13D1 | 4 | 1.0203 (0.0036) | 1.0215 (1.0180, 1.0225) | 1.015, 1.023 | 4 | 0.0020 (0.0037) | 0.0015 (-0.0005, 0.0045) | -0.002, 0.007 |
|  | C14D1 | 4 | 1.0195 (0.0075) | 1.0170 (1.0140, 1.0250) | 1.014, 1.030 | 4 | 0.0013 (0.0069) | 0.0010 (-0.0045, 0.0070) | -0.006, 0.009 |
|  | C15D1 | 3 | 1.0227 (0.0093) | 1.0200 (1.0150, 1.0330) | 1.015, 1.033 | 3 | 0.0050 (0.0070) | 0.0050 (-0.0020, 0.0120) | -0.002, 0.012 |
|  | C16D1 | 2 | 1.0135 (0.0035) | 1.0135 (1.0110, 1.0160) | 1.011, 1.016 | 2 | -0.0025 (0.0021) | -0.0025 (-0.0040, -0.0010) | -0.004, -0.001 |
|  | C17D1 | 2 | 1.0125 (0.0021) | 1.0125 (1.0110, 1.0140) | 1.011, 1.014 | 2 | -0.0035 (0.0007) | -0.0035 (-0.0040, -0.0030) | -0.004, -0.003 |
|  | C18D1 | 1 | 1.0170 (NA) | 1.0170 (1.0170, 1.0170) | 1.017, 1.017 | 1 | 0.0020 (NA) | 0.0020 (0.0020, 0.0020) | 0.002, 0.002 |
|  | End of Treatment | 4 | 1.0213 (0.0085) | 1.0225 (1.0150, 1.0275) | 1.010, 1.030 | 4 | 0.0008 (0.0072) | 0.0040 (-0.0035, 0.0050) | -0.010, 0.005 |
|  | | | | | | | | | |
| Urine Erythrocytes (/uL), Quantitative (N = 33) | Baseline | 33 | 10.482 (12.8181) | 6.400 (3.300, 13.700) | 0.00, 66.00 |  |  |  |  |
|  | C1D8 | 32 | 59.617 (112.9632) | 10.550 (2.500, 56.650) | 0.00, 523.80 | 32 | 48.988 (105.0203) | 6.000 (-0.800, 45.150) | -18.00, 457.80 |
|  | C2D1 | 32 | 55.773 (124.8154) | 14.400 (4.600, 38.250) | 0.00, 663.20 | 32 | 45.133 (115.5781) | 7.200 (0.220, 32.650) | -26.00, 597.20 |
|  | C3D1 | 31 | 57.015 (145.1902) | 10.000 (3.600, 38.700) | 0.00, 778.60 | 31 | 46.256 (135.1952) | 4.050 (-3.500, 27.500) | -12.00, 712.60 |
|  | C4D1 | 30 | 29.968 (44.9620) | 12.110 (5.000, 44.900) | 0.00, 225.80 | 30 | 19.018 (36.5422) | 5.400 (0.000, 23.300) | -22.00, 159.80 |
|  | C5D1 | 28 | 31.298 (54.9013) | 13.950 (6.050, 25.400) | 0.00, 271.50 | 28 | 20.748 (43.9039) | 7.850 (0.650, 17.100) | -12.00, 205.50 |
|  | C6D1 | 27 | 225.772 (1021.2193) | 13.100 (4.000, 29.000) | 0.00, 5324.50 | 27 | 215.498 (1021.2018) | 5.000 (-0.700, 24.000) | -15.70, 5317.50 |
|  | C7D1 | 23 | 42.162 (79.2640) | 15.900 (4.000, 44.700) | 1.00, 385.80 | 23 | 31.357 (79.4539) | 10.000 (1.600, 28.700) | -33.00, 374.40 |
|  | C8D1 | 15 | 35.580 (30.6658) | 30.000 (13.000, 46.000) | 4.00, 99.20 | 15 | 24.747 (33.1907) | 16.000 (2.000, 34.000) | -22.00, 90.10 |
|  | C9D1 | 11 | 43.518 (28.4292) | 37.200 (26.000, 62.200) | 3.00, 96.50 | 11 | 36.573 (26.1408) | 36.200 (12.000, 58.900) | 1.00, 85.10 |
|  | C10D1 | 6 | 138.733 (130.3830) | 100.250 (55.700, 194.800) | 9.00, 372.40 | 6 | 131.400 (129.4147) | 92.600 (44.100, 184.100) | 9.00, 366.00 |
|  | C11D1 | 6 | 154.383 (270.2983) | 48.750 (14.300, 114.600) | 1.00, 698.90 | 6 | 147.050 (270.6021) | 41.100 (3.600, 103.000) | 1.00, 692.50 |
|  | C12D1 | 5 | 118.600 (164.1260) | 65.500 (20.000, 104.400) | 0.00, 403.10 | 5 | 110.460 (164.2593) | 53.500 (9.300, 92.800) | 0.00, 396.70 |
|  | C13D1 | 4 | 68.425 (66.6917) | 55.850 (19.600, 117.250) | 4.00, 158.00 | 4 | 59.850 (62.9322) | 44.500 (14.250, 105.450) | 4.00, 146.40 |
|  | C14D1 | 4 | 72.575 (57.8557) | 54.250 (38.350, 106.800) | 25.00, 156.80 | 4 | 64.000 (55.3813) | 42.450 (32.550, 95.450) | 25.00, 146.10 |
|  | C15D1 | 3 | 116.533 (53.9543) | 106.500 (68.300, 174.800) | 68.30, 174.80 | 3 | 105.100 (54.6190) | 94.900 (56.300, 164.100) | 56.30, 164.10 |
|  | C16D1 | 2 | 53.150 (38.9616) | 53.150 (25.600, 80.700) | 25.60, 80.70 | 2 | 41.350 (39.2444) | 41.350 (13.600, 69.100) | 13.60, 69.10 |
|  | C17D1 | 2 | 107.200 (75.8018) | 107.200 (53.600, 160.800) | 53.60, 160.80 | 2 | 95.400 (76.0847) | 95.400 (41.600, 149.200) | 41.60, 149.20 |
|  | C18D1 | 1 | 126.300 (NA) | 126.300 (126.300, 126.300) | 126.30, 126.30 | 1 | 114.300 (NA) | 114.300 (114.300, 114.300) | 114.30, 114.30 |
|  | End of Treatment | 4 | 25.250 (28.3828) | 17.000 (7.000, 43.500) | 1.00, 66.00 | 4 | 15.325 (33.7494) | 7.650 (-8.350, 39.000) | -16.00, 62.00 |
|  | | | | | | | | | |
| Urine Leukocytes (/uL), Quantitative (N = 33) | Baseline | 32 | 62.303 (237.8929) | 3.000 (0.800, 4.600) | 0.00, 1246.00 |  |  |  |  |
|  | C1D8 | 32 | 85.022 (331.1992) | 4.250 (2.300, 7.900) | 0.00, 1766.70 | 32 | 22.719 (235.4562) | 1.215 (0.000, 4.350) | -536.00, 1201.60 |
|  | C2D1 | 32 | 40.287 (119.6862) | 4.650 (2.550, 8.400) | 0.00, 584.50 | 31 | -22.668 (166.0087) | 1.900 (-1.200, 7.000) | -907.00, 126.00 |
|  | C3D1 | 31 | 45.000 (167.5278) | 3.000 (1.000, 8.000) | 0.00, 882.50 | 31 | -19.255 (172.9825) | 0.000 (-1.200, 3.200) | -897.00, 317.40 |
|  | C4D1 | 30 | 71.355 (362.9501) | 2.850 (1.000, 7.440) | 0.00, 1992.70 | 30 | 5.091 (351.7696) | 0.000 (-1.700, 3.200) | -1244.00, 1427.60 |
|  | C5D1 | 28 | 22.846 (85.8028) | 2.650 (1.050, 4.350) | 0.00, 452.00 | 28 | -45.621 (171.9820) | 0.000 (-2.400, 1.950) | -794.00, 7.20 |
|  | C6D1 | 27 | 12.067 (28.8325) | 1.800 (0.700, 5.800) | 0.00, 132.70 | 27 | -12.789 (84.7513) | 0.200 (-2.000, 2.500) | -432.40, 61.80 |
|  | C7D1 | 23 | 86.791 (401.4649) | 3.000 (1.000, 5.200) | 0.00, 1928.40 | 23 | 58.070 (284.6531) | 0.300 (-0.800, 2.300) | -38.00, 1363.30 |
|  | C8D1 | 15 | 5.073 (4.4770) | 3.900 (1.800, 7.200) | 0.00, 16.90 | 15 | -37.380 (145.2516) | 0.600 (-2.000, 3.900) | -560.80, 14.40 |
|  | C9D1 | 11 | 3.118 (2.3697) | 2.300 (1.200, 5.000) | 0.00, 7.00 | 11 | 1.391 (1.7615) | 1.000 (0.000, 2.300) | -0.60, 5.00 |
|  | C10D1 | 6 | 4.617 (1.9343) | 4.350 (3.000, 6.300) | 2.30, 7.40 | 6 | 2.983 (2.2140) | 1.950 (1.700, 3.400) | 1.60, 7.30 |
|  | C11D1 | 6 | 4.383 (3.2480) | 3.900 (1.700, 7.000) | 0.70, 9.10 | 6 | 2.750 (2.2519) | 2.250 (0.800, 4.000) | 0.60, 6.60 |
|  | C12D1 | 5 | 3.440 (1.8609) | 3.000 (3.000, 4.100) | 1.00, 6.10 | 5 | 2.400 (1.5379) | 2.300 (2.000, 3.600) | 0.10, 4.00 |
|  | C13D1 | 4 | 3.050 (0.7047) | 2.950 (2.600, 3.500) | 2.30, 4.00 | 4 | 2.375 (0.8421) | 2.400 (1.700, 3.050) | 1.40, 3.30 |
|  | C14D1 | 4 | 4.250 (2.5357) | 4.050 (2.100, 6.400) | 1.90, 7.00 | 4 | 3.575 (2.2485) | 3.550 (1.700, 5.450) | 1.20, 6.00 |
|  | C15D1 | 3 | 3.367 (1.0017) | 3.300 (2.400, 4.400) | 2.40, 4.40 | 3 | 2.800 (1.4107) | 2.600 (1.500, 4.300) | 1.50, 4.30 |
|  | C16D1 | 2 | 1.050 (0.0707) | 1.050 (1.000, 1.100) | 1.00, 1.10 | 2 | 0.650 (0.3536) | 0.650 (0.400, 0.900) | 0.40, 0.90 |
|  | C17D1 | 2 | 3.350 (1.7678) | 3.350 (2.100, 4.600) | 2.10, 4.60 | 2 | 2.950 (1.3435) | 2.950 (2.000, 3.900) | 2.00, 3.90 |
|  | C18D1 | 1 | 9.400 (NA) | 9.400 (9.400, 9.400) | 9.40, 9.40 | 1 | 9.300 (NA) | 9.300 (9.300, 9.300) | 9.30, 9.30 |
|  | End of Treatment | 4 | 19.350 (14.4392) | 17.500 (7.700, 31.000) | 5.40, 37.00 | 4 | -0.125 (30.9472) | 3.250 (-20.250, 20.000) | -41.00, 34.00 |
|  | | | | | | | | | |
| Urine Creatinine (g/L), Quantitative (N = 33) | Baseline | 9 | 1.28 (0.755) | 1.00 (1.00, 1.00) | 0.5, 3.0 |  |  |  |  |
|  | C1D8 | 9 | 1.50 (0.791) | 1.00 (1.00, 2.00) | 0.5, 3.0 | 9 | 0.22 (0.972) | 0.00 (0.00, 1.00) | -1.0, 2.0 |
|  | C2D1 | 8 | 1.25 (0.655) | 1.00 (0.75, 2.00) | 0.5, 2.0 | 8 | -0.13 (0.791) | -0.25 (-0.75, 0.50) | -1.0, 1.0 |
|  | C3D1 | 7 | 1.29 (0.488) | 1.00 (1.00, 2.00) | 1.0, 2.0 | 7 | -0.14 (0.900) | 0.00 (0.00, 0.00) | -2.0, 1.0 |
|  | C4D1 | 8 | 1.44 (0.821) | 1.00 (1.00, 2.00) | 0.5, 3.0 | 8 | 0.06 (1.016) | 0.00 (-0.75, 0.50) | -1.0, 2.0 |
|  | C5D1 | 7 | 1.00 (0.500) | 1.00 (0.50, 1.00) | 0.5, 2.0 | 7 | -0.14 (0.748) | 0.00 (-0.50, 0.00) | -1.5, 1.0 |
|  | C6D1 | 6 | 0.85 (0.660) | 0.75 (0.50, 1.00) | 0.1, 2.0 | 6 | -0.32 (0.736) | -0.50 (-0.90, 0.00) | -1.0, 1.0 |
|  | C7D1 | 6 | 1.25 (0.612) | 1.00 (1.00, 2.00) | 0.5, 2.0 | 6 | 0.08 (0.492) | 0.00 (0.00, 0.00) | -0.5, 1.0 |
|  | C8D1 | 5 | 1.00 (0.612) | 1.00 (0.50, 1.00) | 0.5, 2.0 | 5 | -0.20 (0.274) | 0.00 (-0.50, 0.00) | -0.5, 0.0 |
|  | C9D1 | 3 | 1.33 (0.577) | 1.00 (1.00, 2.00) | 1.0, 2.0 | 3 | 0.00 (1.000) | 0.00 (-1.00, 1.00) | -1.0, 1.0 |
|  | C10D1 | 2 | 1.00 (0.000) | 1.00 (1.00, 1.00) | 1.0, 1.0 | 2 | -0.50 (0.707) | -0.50 (-1.00, 0.00) | -1.0, 0.0 |
|  | C11D1 | 2 | 1.50 (0.707) | 1.50 (1.00, 2.00) | 1.0, 2.0 | 2 | 0.00 (1.414) | 0.00 (-1.00, 1.00) | -1.0, 1.0 |
|  | C12D1 | 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 |
|  | C13D1 | 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 |
|  | C14D1 | 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 |
|  | C15D1 | 1 | 2.00 (NA) | 2.00 (2.00, 2.00) | 2.0, 2.0 | 1 | 1.00 (NA) | 1.00 (1.00, 1.00) | 1.0, 1.0 |
|  | | | | | | | | | |
| Urine Creatinine, Quantitative (N = 33) | C6D1 | 1 | 1.00 (NA) | 1.00 (1.00, 1.00) | 1.0, 1.0 | 0 |  |  |  |
|  | C7D1 | 1 | 1.00 (NA) | 1.00 (1.00, 1.00) | 1.0, 1.0 | 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

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

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

**Table 14.3.5.1.4.2 Summary of Coagulation Function Results - Phase II part 1 treatment-naive locally-advanced or metastatic NSCLC (Safety Analysis Set)**

|  | | Observed Value | | | | Change from Baseline | | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Parameter | Visit | n | Mean (STD) | Median (Q1, Q3) | Min, Max | n | Mean (STD) | Median (Q1, Q3) | Min, Max |
| Activated Partial Thromboplastin Time (s) (N = 33) | Baseline | 33 | 30.139 (4.7009) | 28.700 (27.000, 32.500) | 24.40, 43.30 |  |  |  |  |
|  | C1D8 | 32 | 29.533 (3.5969) | 28.850 (26.900, 31.535) | 24.40, 39.00 | 32 | -0.210 (3.4676) | 0.250 (-0.800, 1.100) | -16.20, 6.50 |
|  | C2D1 | 32 | 31.322 (5.6280) | 30.200 (27.300, 34.550) | 24.60, 50.00 | 32 | 1.084 (5.8393) | 0.500 (-1.250, 2.600) | -18.00, 17.50 |
|  | C3D1 | 31 | 31.903 (6.0957) | 30.100 (27.600, 35.300) | 23.90, 48.20 | 31 | 1.903 (4.3257) | 1.300 (-0.100, 3.400) | -3.60, 20.30 |
|  | C4D1 | 30 | 30.677 (4.8325) | 28.650 (27.200, 33.400) | 24.50, 41.90 | 30 | 0.607 (4.0957) | 0.400 (-0.900, 2.000) | -13.00, 9.30 |
|  | C5D1 | 28 | 31.046 (5.0134) | 30.400 (26.900, 33.650) | 23.90, 45.20 | 28 | 0.964 (2.9693) | 0.900 (-1.050, 2.350) | -4.80, 7.70 |
|  | C6D1 | 27 | 31.370 (4.9242) | 30.100 (27.800, 34.900) | 23.90, 43.70 | 27 | 1.178 (2.6292) | 0.900 (-0.100, 1.900) | -2.80, 9.10 |
|  | C7D1 | 23 | 30.522 (4.8761) | 28.700 (26.300, 33.900) | 25.50, 39.40 | 23 | 1.452 (3.1785) | 0.500 (-0.300, 2.700) | -4.90, 8.70 |
|  | C8D1 | 15 | 32.107 (5.4488) | 29.900 (28.000, 37.500) | 25.40, 43.80 | 15 | 2.087 (3.9544) | 0.600 (-0.900, 3.500) | -2.00, 11.30 |
|  | C9D1 | 11 | 31.636 (4.9852) | 33.000 (26.700, 35.700) | 24.80, 39.10 | 11 | 1.927 (3.6409) | 1.500 (-0.600, 3.200) | -2.30, 10.40 |
|  | C10D1 | 6 | 29.983 (5.3143) | 29.050 (25.700, 33.100) | 24.30, 38.70 | 6 | 1.667 (3.0356) | 1.350 (-0.500, 3.800) | -2.20, 6.20 |
|  | C11D1 | 6 | 30.283 (5.4249) | 28.450 (27.900, 34.600) | 23.60, 38.70 | 6 | 1.967 (3.3393) | 1.250 (0.700, 5.300) | -2.90, 6.20 |
|  | C12D1 | 5 | 29.960 (4.6074) | 28.600 (27.400, 29.200) | 26.60, 38.00 | 5 | 1.840 (2.2434) | 1.000 (0.200, 2.400) | 0.10, 5.50 |
|  | C13D1 | 4 | 32.250 (4.8198) | 30.650 (29.050, 35.450) | 28.50, 39.20 | 4 | 3.725 (2.7861) | 3.450 (1.350, 6.100) | 1.30, 6.70 |
|  | C14D1 | 4 | 30.250 (3.8820) | 28.950 (27.800, 32.700) | 27.20, 35.90 | 4 | 1.725 (1.4361) | 1.750 (0.650, 2.800) | 0.00, 3.40 |
|  | C15D1 | 3 | 33.033 (5.9214) | 30.500 (28.800, 39.800) | 28.80, 39.80 | 3 | 4.067 (2.8042) | 2.600 (2.300, 7.300) | 2.30, 7.30 |
|  | C16D1 | 2 | 30.650 (10.1116) | 30.650 (23.500, 37.800) | 23.50, 37.80 | 2 | 1.300 (5.6569) | 1.300 (-2.700, 5.300) | -2.70, 5.30 |
|  | C17D1 | 2 | 36.350 (10.9602) | 36.350 (28.600, 44.100) | 28.60, 44.10 | 2 | 7.000 (6.5054) | 7.000 (2.400, 11.600) | 2.40, 11.60 |
|  | C18D1 | 1 | 29.600 (NA) | 29.600 (29.600, 29.600) | 29.60, 29.60 | 1 | 3.400 (NA) | 3.400 (3.400, 3.400) | 3.40, 3.40 |
|  | End of Treatment | 4 | 41.725 (1.1500) | 41.700 (40.850, 42.600) | 40.40, 43.10 | 4 | 4.975 (6.7539) | 3.850 (-0.450, 10.400) | -1.20, 13.40 |
|  | | | | | | | | | |
| Prothrombin Time (s) (N = 33) | Baseline | 32 | 11.938 (1.0019) | 12.000 (11.050, 12.650) | 10.20, 14.10 |  |  |  |  |
|  | C1D8 | 32 | 11.438 (1.0083) | 11.400 (10.700, 12.200) | 9.60, 13.30 | 32 | -0.500 (0.7080) | -0.600 (-0.900, -0.100) | -1.80, 1.50 |
|  | C2D1 | 32 | 11.647 (1.3373) | 11.550 (10.600, 12.550) | 9.80, 16.00 | 31 | -0.416 (0.8680) | -0.400 (-0.900, 0.100) | -2.10, 1.50 |
|  | C3D1 | 31 | 11.671 (1.1674) | 11.500 (11.000, 12.600) | 9.80, 13.90 | 30 | -0.273 (0.9086) | -0.300 (-0.800, 0.500) | -1.90, 1.40 |
|  | C4D1 | 30 | 11.417 (1.2029) | 11.200 (10.700, 12.400) | 9.80, 14.90 | 29 | -0.586 (0.7415) | -0.500 (-1.100, -0.100) | -1.90, 0.90 |
|  | C5D1 | 28 | 11.407 (1.1415) | 11.200 (10.500, 12.050) | 9.40, 13.80 | 27 | -0.448 (0.7708) | -0.500 (-1.100, 0.100) | -1.50, 1.40 |
|  | C6D1 | 27 | 11.404 (1.0991) | 11.500 (10.900, 12.400) | 9.40, 13.80 | 26 | -0.392 (0.7266) | -0.300 (-1.100, 0.000) | -1.70, 1.20 |
|  | C7D1 | 23 | 11.339 (1.0924) | 11.200 (10.800, 11.900) | 9.60, 13.60 | 22 | -0.477 (0.9149) | -0.250 (-0.900, 0.200) | -2.20, 1.20 |
|  | C8D1 | 15 | 11.527 (1.1100) | 11.500 (10.300, 12.100) | 10.00, 13.80 | 14 | -0.264 (1.0667) | -0.200 (-1.100, 0.900) | -1.90, 1.40 |
|  | C9D1 | 11 | 11.445 (1.3830) | 11.900 (10.100, 12.400) | 9.40, 13.50 | 10 | -0.290 (0.6691) | -0.400 (-0.900, 0.000) | -1.20, 0.80 |
|  | C10D1 | 6 | 11.167 (0.9585) | 11.100 (10.500, 12.000) | 9.90, 12.40 | 5 | -0.300 (0.6442) | -0.500 (-0.500, -0.400) | -0.90, 0.80 |
|  | C11D1 | 6 | 11.517 (1.3674) | 11.550 (10.200, 11.900) | 10.10, 13.80 | 5 | 0.080 (0.8701) | 0.100 (-0.600, 0.300) | -0.80, 1.40 |
|  | C12D1 | 5 | 11.260 (1.0065) | 11.300 (10.400, 12.200) | 10.10, 12.30 | 4 | 0.000 (0.5715) | -0.050 (-0.450, 0.450) | -0.60, 0.70 |
|  | C13D1 | 4 | 11.100 (1.2832) | 11.000 (10.050, 12.150) | 9.80, 12.60 | 3 | 0.300 (0.8888) | 0.600 (-0.700, 1.000) | -0.70, 1.00 |
|  | C14D1 | 4 | 10.950 (1.0247) | 11.000 (10.100, 11.800) | 9.80, 12.00 | 3 | 0.100 (0.6083) | 0.400 (-0.600, 0.500) | -0.60, 0.50 |
|  | C15D1 | 3 | 11.333 (1.3650) | 11.100 (10.100, 12.800) | 10.10, 12.80 | 2 | 0.600 (0.8485) | 0.600 (0.000, 1.200) | 0.00, 1.20 |
|  | C16D1 | 2 | 11.400 (1.1314) | 11.400 (10.600, 12.200) | 10.60, 12.20 | 2 | 0.050 (0.7778) | 0.050 (-0.500, 0.600) | -0.50, 0.60 |
|  | C17D1 | 2 | 11.900 (1.1314) | 11.900 (11.100, 12.700) | 11.10, 12.70 | 2 | 0.550 (0.7778) | 0.550 (0.000, 1.100) | 0.00, 1.10 |
|  | C18D1 | 1 | 11.400 (NA) | 11.400 (11.400, 11.400) | 11.40, 11.40 | 1 | 0.300 (NA) | 0.300 (0.300, 0.300) | 0.30, 0.30 |
|  | End of Treatment | 4 | 13.425 (0.7848) | 13.500 (12.900, 13.950) | 12.40, 14.30 | 4 | 0.425 (1.2738) | 0.000 (-0.500, 1.350) | -0.50, 2.20 |
|  | | | | | | | | | |
| Prothrombin Intl. Normalized Ratio (N = 33) | Baseline | 33 | 1.023 (0.0767) | 1.020 (0.960, 1.060) | 0.88, 1.20 |  |  |  |  |
|  | C1D8 | 33 | 0.972 (0.0735) | 0.980 (0.920, 1.030) | 0.81, 1.11 | 33 | -0.051 (0.0574) | -0.050 (-0.080, -0.010) | -0.17, 0.05 |
|  | C2D1 | 32 | 0.988 (0.1003) | 0.985 (0.925, 1.015) | 0.85, 1.40 | 32 | -0.034 (0.1076) | -0.030 (-0.085, -0.005) | -0.21, 0.41 |
|  | C3D1 | 31 | 0.990 (0.0803) | 1.000 (0.950, 1.010) | 0.85, 1.21 | 31 | -0.033 (0.0841) | -0.050 (-0.090, 0.030) | -0.17, 0.17 |
|  | C4D1 | 30 | 0.974 (0.0928) | 0.965 (0.920, 1.020) | 0.82, 1.30 | 30 | -0.047 (0.0945) | -0.055 (-0.110, -0.010) | -0.18, 0.31 |
|  | C5D1 | 28 | 0.976 (0.0929) | 0.960 (0.925, 1.020) | 0.81, 1.21 | 28 | -0.049 (0.0681) | -0.060 (-0.100, 0.000) | -0.15, 0.13 |
|  | C6D1 | 27 | 0.973 (0.0809) | 0.980 (0.940, 1.020) | 0.81, 1.15 | 27 | -0.048 (0.0591) | -0.050 (-0.100, 0.000) | -0.16, 0.06 |
|  | C7D1 | 23 | 0.967 (0.0867) | 0.960 (0.900, 1.010) | 0.83, 1.20 | 23 | -0.053 (0.0767) | -0.040 (-0.120, 0.000) | -0.20, 0.06 |
|  | C8D1 | 15 | 0.967 (0.0960) | 0.970 (0.900, 1.000) | 0.80, 1.21 | 15 | -0.052 (0.0895) | -0.050 (-0.110, -0.010) | -0.19, 0.13 |
|  | C9D1 | 11 | 0.967 (0.0939) | 0.980 (0.910, 1.030) | 0.82, 1.15 | 11 | -0.065 (0.0686) | -0.060 (-0.120, -0.030) | -0.17, 0.07 |
|  | C10D1 | 6 | 0.962 (0.0688) | 0.960 (0.920, 1.030) | 0.86, 1.04 | 6 | -0.060 (0.0352) | -0.045 (-0.060, -0.040) | -0.13, -0.04 |
|  | C11D1 | 6 | 0.985 (0.1178) | 0.945 (0.920, 1.030) | 0.87, 1.20 | 6 | -0.037 (0.0869) | -0.065 (-0.090, 0.000) | -0.12, 0.12 |
|  | C12D1 | 5 | 0.956 (0.0647) | 0.950 (0.940, 0.970) | 0.87, 1.05 | 5 | -0.054 (0.0493) | -0.050 (-0.080, -0.030) | -0.12, 0.01 |
|  | C13D1 | 4 | 0.938 (0.0690) | 0.945 (0.885, 0.990) | 0.85, 1.01 | 4 | -0.055 (0.0794) | -0.065 (-0.110, 0.000) | -0.14, 0.05 |
|  | C14D1 | 4 | 0.928 (0.0634) | 0.930 (0.880, 0.975) | 0.85, 1.00 | 4 | -0.065 (0.0794) | -0.080 (-0.125, -0.005) | -0.14, 0.04 |
|  | C15D1 | 3 | 0.943 (0.0569) | 0.960 (0.880, 0.990) | 0.88, 0.99 | 3 | -0.047 (0.0569) | -0.030 (-0.110, 0.000) | -0.11, 0.00 |
|  | C16D1 | 2 | 0.920 (0.0141) | 0.920 (0.910, 0.930) | 0.91, 0.93 | 2 | -0.070 (0.0283) | -0.070 (-0.090, -0.050) | -0.09, -0.05 |
|  | C17D1 | 2 | 0.970 (0.0141) | 0.970 (0.960, 0.980) | 0.96, 0.98 | 2 | -0.020 (0.0283) | -0.020 (-0.040, 0.000) | -0.04, 0.00 |
|  | C18D1 | 1 | 0.980 (NA) | 0.980 (0.980, 0.980) | 0.98, 0.98 | 1 | 0.020 (NA) | 0.020 (0.020, 0.020) | 0.02, 0.02 |
|  | End of Treatment | 4 | 1.035 (0.0785) | 1.035 (0.980, 1.090) | 0.94, 1.13 | 4 | -0.015 (0.0751) | -0.015 (-0.075, 0.045) | -0.10, 0.07 |

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

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

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

**Table 14.3.5.2.2 Shift Table for Laboratory Test from Baseline to Last/Worst Post-baseline CTCAE Grade - Phase II part 1 treatment-naive locally-advanced or metastatic NSCLC (Safety Analysis Set)**

|  | | | Post-baseline Grade | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Parameter | Visit | Baseline Grade | 0 | 1 | 2 | 3 | 4 | Missing | Total |
| Hemoglobin (Anemia) (N = 33) | Last Post-Baseline | 0 | 14 (42.4) | 6 (18.2) | 1 (3.0) | 0 | 0 | 0 | 21 (63.6) |
|  |  | 1 | 1 (3.0) | 9 (27.3) | 1 (3.0) | 0 | 0 | 0 | 11 (33.3) |
|  |  | 2 | 0 | 0 | 0 | 1 (3.0) | 0 | 0 | 1 (3.0) |
|  |  | 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  | 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  | Total | 15 (45.5) | 15 (45.5) | 2 (6.1) | 1 (3.0) | 0 | 0 | 33 (100) |
|  | | | | | | | | | |
|  | Worst Post-Baseline | 0 | 9 (27.3) | 11 (33.3) | 1 (3.0) | 0 | 0 | 0 | 21 (63.6) |
|  |  | 1 | 1 (3.0) | 9 (27.3) | 1 (3.0) | 0 | 0 | 0 | 11 (33.3) |
|  |  | 2 | 0 | 0 | 0 | 1 (3.0) | 0 | 0 | 1 (3.0) |
|  |  | 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  | 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  | Total | 10 (30.3) | 20 (60.6) | 2 (6.1) | 1 (3.0) | 0 | 0 | 33 (100) |
|  | | | | | | | | | |
| Hemoglobin (Hemoglobin increased) (N = 33) | Last Post-Baseline | 0 | 32 (97.0) | 0 | 1 (3.0) | 0 | 0 | 0 | 33 (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 | 32 (97.0) | 0 | 1 (3.0) | 0 | 0 | 0 | 33 (100) |
|  | | | | | | | | | |
|  | Worst Post-Baseline | 0 | 32 (97.0) | 0 | 1 (3.0) | 0 | 0 | 0 | 33 (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 | 32 (97.0) | 0 | 1 (3.0) | 0 | 0 | 0 | 33 (100) |
|  | | | | | | | | | |
| Leukocytes (White blood cell decreased) (N = 33) | Last Post-Baseline | 0 | 33 (100) | 0 | 0 | 0 | 0 | 0 | 33 (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 | 33 (100) | 0 | 0 | 0 | 0 | 0 | 33 (100) |
|  | | | | | | | | | |
|  | Worst Post-Baseline | 0 | 33 (100) | 0 | 0 | 0 | 0 | 0 | 33 (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 | 33 (100) | 0 | 0 | 0 | 0 | 0 | 33 (100) |
|  | | | | | | | | | |
| Leukocytes (Leukocytosis) (N = 33) | Last Post-Baseline | 0 | 33 (100) | 0 | 0 | 0 | 0 | 0 | 33 (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 | 33 (100) | 0 | 0 | 0 | 0 | 0 | 33 (100) |
|  | | | | | | | | | |
|  | Worst Post-Baseline | 0 | 33 (100) | 0 | 0 | 0 | 0 | 0 | 33 (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 | 33 (100) | 0 | 0 | 0 | 0 | 0 | 33 (100) |
|  | | | | | | | | | |
| Neutrophils (Neutrophil count decreased) (N = 33) | Last Post-Baseline | 0 | 33 (100) | 0 | 0 | 0 | 0 | 0 | 33 (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 | 33 (100) | 0 | 0 | 0 | 0 | 0 | 33 (100) |
|  | | | | | | | | | |
|  | Worst Post-Baseline | 0 | 33 (100) | 0 | 0 | 0 | 0 | 0 | 33 (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 | 33 (100) | 0 | 0 | 0 | 0 | 0 | 33 (100) |
|  | | | | | | | | | |
| Eosinophils (Eosinophilia) (N = 33) | Last Post-Baseline | 0 | 28 (84.8) | 0 | 0 | 0 | 0 | 0 | 28 (84.8) |
|  |  | 1 | 4 (12.1) | 1 (3.0) | 0 | 0 | 0 | 0 | 5 (15.2) |
|  |  | 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 | 32 (97.0) | 1 (3.0) | 0 | 0 | 0 | 0 | 33 (100) |
|  | | | | | | | | | |
|  | Worst Post-Baseline | 0 | 19 (57.6) | 9 (27.3) | 0 | 0 | 0 | 0 | 28 (84.8) |
|  |  | 1 | 1 (3.0) | 4 (12.1) | 0 | 0 | 0 | 0 | 5 (15.2) |
|  |  | 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 | 20 (60.6) | 13 (39.4) | 0 | 0 | 0 | 0 | 33 (100) |
|  | | | | | | | | | |
| Lymphocytes (Lymphocyte count decreased) (N = 33) | Last Post-Baseline | 0 | 27 (81.8) | 1 (3.0) | 1 (3.0) | 0 | 0 | 0 | 29 (87.9) |
|  |  | 1 | 1 (3.0) | 0 | 0 | 0 | 0 | 0 | 1 (3.0) |
|  |  | 2 | 1 (3.0) | 1 (3.0) | 0 | 0 | 0 | 0 | 2 (6.1) |
|  |  | 3 | 0 | 0 | 0 | 1 (3.0) | 0 | 0 | 1 (3.0) |
|  |  | 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  | Total | 29 (87.9) | 2 (6.1) | 1 (3.0) | 1 (3.0) | 0 | 0 | 33 (100) |
|  | | | | | | | | | |
|  | Worst Post-Baseline | 0 | 26 (78.8) | 2 (6.1) | 1 (3.0) | 0 | 0 | 0 | 29 (87.9) |
|  |  | 1 | 0 | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
|  |  | 2 | 0 | 2 (6.1) | 0 | 0 | 0 | 0 | 2 (6.1) |
|  |  | 3 | 0 | 0 | 0 | 1 (3.0) | 0 | 0 | 1 (3.0) |
|  |  | 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  | Total | 26 (78.8) | 5 (15.2) | 1 (3.0) | 1 (3.0) | 0 | 0 | 33 (100) |
|  | | | | | | | | | |
| Lymphocytes (Lymphocyte count increased) (N = 33) | Last Post-Baseline | 0 | 33 (100) | 0 | 0 | 0 | 0 | 0 | 33 (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 | 33 (100) | 0 | 0 | 0 | 0 | 0 | 33 (100) |
|  | | | | | | | | | |
|  | Worst Post-Baseline | 0 | 33 (100) | 0 | 0 | 0 | 0 | 0 | 33 (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 | 33 (100) | 0 | 0 | 0 | 0 | 0 | 33 (100) |
|  | | | | | | | | | |
| Platelets (Platelet count decreased) (N = 33) | Last Post-Baseline | 0 | 33 (100) | 0 | 0 | 0 | 0 | 0 | 33 (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 | 33 (100) | 0 | 0 | 0 | 0 | 0 | 33 (100) |
|  | | | | | | | | | |
|  | Worst Post-Baseline | 0 | 33 (100) | 0 | 0 | 0 | 0 | 0 | 33 (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 | 33 (100) | 0 | 0 | 0 | 0 | 0 | 33 (100) |
|  | | | | | | | | | |
| Bilirubin (Blood bilirubin increased) (N = 33) | Last Post-Baseline | 0 | 29 (87.9) | 2 (6.1) | 0 | 0 | 0 | 0 | 31 (93.9) |
|  |  | 1 | 2 (6.1) | 0 | 0 | 0 | 0 | 0 | 2 (6.1) |
|  |  | 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 | 31 (93.9) | 2 (6.1) | 0 | 0 | 0 | 0 | 33 (100) |
|  | | | | | | | | | |
|  | Worst Post-Baseline | 0 | 26 (78.8) | 5 (15.2) | 0 | 0 | 0 | 0 | 31 (93.9) |
|  |  | 1 | 1 (3.0) | 1 (3.0) | 0 | 0 | 0 | 0 | 2 (6.1) |
|  |  | 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 | 27 (81.8) | 6 (18.2) | 0 | 0 | 0 | 0 | 33 (100) |
|  | | | | | | | | | |
| Alanine Aminotransferase (Alanine aminotransferase increased) (N = 33) | Last Post-Baseline | 0 | 32 (97.0) | 0 | 0 | 0 | 0 | 0 | 32 (97.0) |
|  |  | 1 | 1 (3.0) | 0 | 0 | 0 | 0 | 0 | 1 (3.0) |
|  |  | 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 | 33 (100) | 0 | 0 | 0 | 0 | 0 | 33 (100) |
|  | | | | | | | | | |
|  | Worst Post-Baseline | 0 | 21 (63.6) | 10 (30.3) | 1 (3.0) | 0 | 0 | 0 | 32 (97.0) |
|  |  | 1 | 0 | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
|  |  | 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 | 21 (63.6) | 11 (33.3) | 1 (3.0) | 0 | 0 | 0 | 33 (100) |
|  | | | | | | | | | |
| Aspartate Aminotransferase (Aspartate aminotransferase increased) (N = 33) | Last Post-Baseline | 0 | 32 (97.0) | 0 | 0 | 0 | 0 | 0 | 32 (97.0) |
|  |  | 1 | 1 (3.0) | 0 | 0 | 0 | 0 | 0 | 1 (3.0) |
|  |  | 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 | 33 (100) | 0 | 0 | 0 | 0 | 0 | 33 (100) |
|  | | | | | | | | | |
|  | Worst Post-Baseline | 0 | 21 (63.6) | 9 (27.3) | 2 (6.1) | 0 | 0 | 0 | 32 (97.0) |
|  |  | 1 | 0 | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
|  |  | 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 | 21 (63.6) | 10 (30.3) | 2 (6.1) | 0 | 0 | 0 | 33 (100) |
|  | | | | | | | | | |
| Gamma Glutamyl Transferase (GGT increased) (N = 33) | Last Post-Baseline | 0 | 25 (75.8) | 4 (12.1) | 0 | 0 | 0 | 0 | 29 (87.9) |
|  |  | 1 | 2 (6.1) | 0 | 0 | 0 | 0 | 0 | 2 (6.1) |
|  |  | 2 | 1 (3.0) | 0 | 0 | 0 | 0 | 0 | 1 (3.0) |
|  |  | 3 | 1 (3.0) | 0 | 0 | 0 | 0 | 0 | 1 (3.0) |
|  |  | 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  | Total | 29 (87.9) | 4 (12.1) | 0 | 0 | 0 | 0 | 33 (100) |
|  | | | | | | | | | |
|  | Worst Post-Baseline | 0 | 20 (60.6) | 3 (9.1) | 5 (15.2) | 1 (3.0) | 0 | 0 | 29 (87.9) |
|  |  | 1 | 2 (6.1) | 0 | 0 | 0 | 0 | 0 | 2 (6.1) |
|  |  | 2 | 1 (3.0) | 0 | 0 | 0 | 0 | 0 | 1 (3.0) |
|  |  | 3 | 1 (3.0) | 0 | 0 | 0 | 0 | 0 | 1 (3.0) |
|  |  | 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  | Total | 24 (72.7) | 3 (9.1) | 5 (15.2) | 1 (3.0) | 0 | 0 | 33 (100) |
|  | | | | | | | | | |
| Alkaline Phosphatase (Alkaline phosphatase increased) (N = 33) | Last Post-Baseline | 0 | 26 (78.8) | 2 (6.1) | 0 | 0 | 0 | 0 | 28 (84.8) |
|  |  | 1 | 5 (15.2) | 0 | 0 | 0 | 0 | 0 | 5 (15.2) |
|  |  | 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 | 31 (93.9) | 2 (6.1) | 0 | 0 | 0 | 0 | 33 (100) |
|  | | | | | | | | | |
|  | Worst Post-Baseline | 0 | 18 (54.5) | 10 (30.3) | 0 | 0 | 0 | 0 | 28 (84.8) |
|  |  | 1 | 5 (15.2) | 0 | 0 | 0 | 0 | 0 | 5 (15.2) |
|  |  | 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 | 23 (69.7) | 10 (30.3) | 0 | 0 | 0 | 0 | 33 (100) |
|  | | | | | | | | | |
| Lactate Dehydrogenase (Blood lactate dehydrogenase increased) (N = 33) | Last Post-Baseline | 0 | 22 (66.7) | 2 (6.1) | 0 | 0 | 0 | 0 | 24 (72.7) |
|  |  | 1 | 2 (6.1) | 7 (21.2) | 0 | 0 | 0 | 0 | 9 (27.3) |
|  |  | 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 | 24 (72.7) | 9 (27.3) | 0 | 0 | 0 | 0 | 33 (100) |
|  | | | | | | | | | |
|  | Worst Post-Baseline | 0 | 14 (42.4) | 10 (30.3) | 0 | 0 | 0 | 0 | 24 (72.7) |
|  |  | 1 | 0 | 9 (27.3) | 0 | 0 | 0 | 0 | 9 (27.3) |
|  |  | 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 | 14 (42.4) | 19 (57.6) | 0 | 0 | 0 | 0 | 33 (100) |
|  | | | | | | | | | |
| Albumin (Hypoalbuminemia) (N = 33) | Last Post-Baseline | 0 | 14 (42.4) | 8 (24.2) | 1 (3.0) | 0 | 0 | 0 | 23 (69.7) |
|  |  | 1 | 0 | 9 (27.3) | 1 (3.0) | 0 | 0 | 0 | 10 (30.3) |
|  |  | 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 | 14 (42.4) | 17 (51.5) | 2 (6.1) | 0 | 0 | 0 | 33 (100) |
|  | | | | | | | | | |
|  | Worst Post-Baseline | 0 | 6 (18.2) | 16 (48.5) | 1 (3.0) | 0 | 0 | 0 | 23 (69.7) |
|  |  | 1 | 0 | 7 (21.2) | 3 (9.1) | 0 | 0 | 0 | 10 (30.3) |
|  |  | 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 | 6 (18.2) | 23 (69.7) | 4 (12.1) | 0 | 0 | 0 | 33 (100) |
|  | | | | | | | | | |
| Triglycerides (Hypertriglyceridemia) (N = 33) | Last Post-Baseline | 0 | 23 (69.7) | 6 (18.2) | 0 | 0 | 0 | 0 | 29 (87.9) |
|  |  | 1 | 1 (3.0) | 2 (6.1) | 1 (3.0) | 0 | 0 | 0 | 4 (12.1) |
|  |  | 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 | 24 (72.7) | 8 (24.2) | 1 (3.0) | 0 | 0 | 0 | 33 (100) |
|  | | | | | | | | | |
|  | Worst Post-Baseline | 0 | 13 (39.4) | 16 (48.5) | 0 | 0 | 0 | 0 | 29 (87.9) |
|  |  | 1 | 0 | 1 (3.0) | 3 (9.1) | 0 | 0 | 0 | 4 (12.1) |
|  |  | 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 | 13 (39.4) | 17 (51.5) | 3 (9.1) | 0 | 0 | 0 | 33 (100) |
|  | | | | | | | | | |
| Cholesterol (Cholesterol high) (N = 33) | Last Post-Baseline | 0 | 19 (57.6) | 5 (15.2) | 0 | 0 | 0 | 0 | 24 (72.7) |
|  |  | 1 | 3 (9.1) | 5 (15.2) | 0 | 0 | 0 | 0 | 8 (24.2) |
|  |  | 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 (3.0) | 1 (3.0) |
|  |  | Total | 22 (66.7) | 10 (30.3) | 0 | 0 | 0 | 1 (3.0) | 33 (100) |
|  | | | | | | | | | |
|  | Worst Post-Baseline | 0 | 14 (42.4) | 9 (27.3) | 1 (3.0) | 0 | 0 | 0 | 24 (72.7) |
|  |  | 1 | 0 | 8 (24.2) | 0 | 0 | 0 | 0 | 8 (24.2) |
|  |  | 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 (3.0) | 1 (3.0) |
|  |  | Total | 14 (42.4) | 17 (51.5) | 1 (3.0) | 0 | 0 | 1 (3.0) | 33 (100) |
|  | | | | | | | | | |
| Sodium (Hyponatremia) (N = 33) | Last Post-Baseline | 0 | 26 (78.8) | 3 (9.1) | 0 | 0 | 0 | 0 | 29 (87.9) |
|  |  | 1 | 2 (6.1) | 1 (3.0) | 0 | 1 (3.0) | 0 | 0 | 4 (12.1) |
|  |  | 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 | 28 (84.8) | 4 (12.1) | 0 | 1 (3.0) | 0 | 0 | 33 (100) |
|  | | | | | | | | | |
|  | Worst Post-Baseline | 0 | 19 (57.6) | 10 (30.3) | 0 | 0 | 0 | 0 | 29 (87.9) |
|  |  | 1 | 0 | 3 (9.1) | 0 | 1 (3.0) | 0 | 0 | 4 (12.1) |
|  |  | 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 | 19 (57.6) | 13 (39.4) | 0 | 1 (3.0) | 0 | 0 | 33 (100) |
|  | | | | | | | | | |
| Sodium (Hypernatremia) (N = 33) | Last Post-Baseline | 0 | 32 (97.0) | 1 (3.0) | 0 | 0 | 0 | 0 | 33 (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 | 32 (97.0) | 1 (3.0) | 0 | 0 | 0 | 0 | 33 (100) |
|  | | | | | | | | | |
|  | Worst Post-Baseline | 0 | 32 (97.0) | 1 (3.0) | 0 | 0 | 0 | 0 | 33 (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 | 32 (97.0) | 1 (3.0) | 0 | 0 | 0 | 0 | 33 (100) |
|  | | | | | | | | | |
| Potassium (Hypokalemia) (N = 33) | Last Post-Baseline | 0 | 31 (93.9) | 1 (3.0) | 0 | 0 | 0 | 0 | 32 (97.0) |
|  |  | 1 | 0 | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
|  |  | 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 | 31 (93.9) | 2 (6.1) | 0 | 0 | 0 | 0 | 33 (100) |
|  | | | | | | | | | |
|  | Worst Post-Baseline | 0 | 27 (81.8) | 4 (12.1) | 0 | 0 | 1 (3.0) | 0 | 32 (97.0) |
|  |  | 1 | 0 | 0 | 0 | 1 (3.0) | 0 | 0 | 1 (3.0) |
|  |  | 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 | 27 (81.8) | 4 (12.1) | 0 | 1 (3.0) | 1 (3.0) | 0 | 33 (100) |
|  | | | | | | | | | |
| Potassium (Hyperkalemia) (N = 33) | Last Post-Baseline | 0 | 33 (100) | 0 | 0 | 0 | 0 | 0 | 33 (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 | 33 (100) | 0 | 0 | 0 | 0 | 0 | 33 (100) |
|  | | | | | | | | | |
|  | Worst Post-Baseline | 0 | 31 (93.9) | 1 (3.0) | 1 (3.0) | 0 | 0 | 0 | 33 (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 | 31 (93.9) | 1 (3.0) | 1 (3.0) | 0 | 0 | 0 | 33 (100) |
|  | | | | | | | | | |
| Magnesium (Hypomagnesemia) (N = 33) | Last Post-Baseline | 0 | 31 (93.9) | 1 (3.0) | 0 | 0 | 0 | 0 | 32 (97.0) |
|  |  | 1 | 0 | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
|  |  | 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 | 31 (93.9) | 2 (6.1) | 0 | 0 | 0 | 0 | 33 (100) |
|  | | | | | | | | | |
|  | Worst Post-Baseline | 0 | 28 (84.8) | 4 (12.1) | 0 | 0 | 0 | 0 | 32 (97.0) |
|  |  | 1 | 0 | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
|  |  | 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 | 28 (84.8) | 5 (15.2) | 0 | 0 | 0 | 0 | 33 (100) |
|  | | | | | | | | | |
| Magnesium (Hypermagnesemia) (N = 33) | Last Post-Baseline | 0 | 32 (97.0) | 0 | 0 | 0 | 0 | 0 | 32 (97.0) |
|  |  | 1 | 1 (3.0) | 0 | 0 | 0 | 0 | 0 | 1 (3.0) |
|  |  | 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 | 33 (100) | 0 | 0 | 0 | 0 | 0 | 33 (100) |
|  | | | | | | | | | |
|  | Worst Post-Baseline | 0 | 31 (93.9) | 1 (3.0) | 0 | 0 | 0 | 0 | 32 (97.0) |
|  |  | 1 | 0 | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
|  |  | 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 | 31 (93.9) | 2 (6.1) | 0 | 0 | 0 | 0 | 33 (100) |
|  | | | | | | | | | |
| Calcium (Hypocalcemia) (N = 33) | Last Post-Baseline | 0 | 29 (87.9) | 1 (3.0) | 1 (3.0) | 1 (3.0) | 0 | 0 | 32 (97.0) |
|  |  | 1 | 1 (3.0) | 0 | 0 | 0 | 0 | 0 | 1 (3.0) |
|  |  | 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 | 30 (90.9) | 1 (3.0) | 1 (3.0) | 1 (3.0) | 0 | 0 | 33 (100) |
|  | | | | | | | | | |
|  | Worst Post-Baseline | 0 | 27 (81.8) | 2 (6.1) | 2 (6.1) | 1 (3.0) | 0 | 0 | 32 (97.0) |
|  |  | 1 | 0 | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
|  |  | 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 | 27 (81.8) | 3 (9.1) | 2 (6.1) | 1 (3.0) | 0 | 0 | 33 (100) |
|  | | | | | | | | | |
| Calcium (Hypercalcemia) (N = 33) | Last Post-Baseline | 0 | 30 (90.9) | 0 | 0 | 0 | 0 | 0 | 30 (90.9) |
|  |  | 1 | 3 (9.1) | 0 | 0 | 0 | 0 | 0 | 3 (9.1) |
|  |  | 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 | 33 (100) | 0 | 0 | 0 | 0 | 0 | 33 (100) |
|  | | | | | | | | | |
|  | Worst Post-Baseline | 0 | 28 (84.8) | 2 (6.1) | 0 | 0 | 0 | 0 | 30 (90.9) |
|  |  | 1 | 1 (3.0) | 2 (6.1) | 0 | 0 | 0 | 0 | 3 (9.1) |
|  |  | 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 | 29 (87.9) | 4 (12.1) | 0 | 0 | 0 | 0 | 33 (100) |
|  | | | | | | | | | |
| Creatinine (Creatinine increased) (N = 33) | Last Post-Baseline | 0 | 30 (90.9) | 3 (9.1) | 0 | 0 | 0 | 0 | 33 (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 | 30 (90.9) | 3 (9.1) | 0 | 0 | 0 | 0 | 33 (100) |
|  | | | | | | | | | |
|  | Worst Post-Baseline | 0 | 30 (90.9) | 3 (9.1) | 0 | 0 | 0 | 0 | 33 (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 | 30 (90.9) | 3 (9.1) | 0 | 0 | 0 | 0 | 33 (100) |
|  | | | | | | | | | |
| Urate (Hyperuricemia) (N = 33) | Last Post-Baseline | 0 | 28 (84.8) | 1 (3.0) | 0 | 0 | 0 | 0 | 29 (87.9) |
|  |  | 1 | 2 (6.1) | 2 (6.1) | 0 | 0 | 0 | 0 | 4 (12.1) |
|  |  | 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 | 30 (90.9) | 3 (9.1) | 0 | 0 | 0 | 0 | 33 (100) |
|  | | | | | | | | | |
|  | Worst Post-Baseline | 0 | 24 (72.7) | 5 (15.2) | 0 | 0 | 0 | 0 | 29 (87.9) |
|  |  | 1 | 1 (3.0) | 3 (9.1) | 0 | 0 | 0 | 0 | 4 (12.1) |
|  |  | 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 | 25 (75.8) | 8 (24.2) | 0 | 0 | 0 | 0 | 33 (100) |
|  | | | | | | | | | |
| Glucose (Hypoglycemia) (N = 33) | Last Post-Baseline | 0 | 32 (97.0) | 0 | 0 | 0 | 0 | 0 | 32 (97.0) |
|  |  | 1 | 1 (3.0) | 0 | 0 | 0 | 0 | 0 | 1 (3.0) |
|  |  | 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 | 33 (100) | 0 | 0 | 0 | 0 | 0 | 33 (100) |
|  | | | | | | | | | |
|  | Worst Post-Baseline | 0 | 29 (87.9) | 3 (9.1) | 0 | 0 | 0 | 0 | 32 (97.0) |
|  |  | 1 | 0 | 1 (3.0) | 0 | 0 | 0 | 0 | 1 (3.0) |
|  |  | 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 | 29 (87.9) | 4 (12.1) | 0 | 0 | 0 | 0 | 33 (100) |
|  | | | | | | | | | |
| Amylase (Serum amylase increased) (N = 33) | Last Post-Baseline | 0 | 19 (57.6) | 0 | 0 | 0 | 0 | 1 (3.0) | 20 (60.6) |
|  |  | 1 | 1 (3.0) | 0 | 0 | 0 | 0 | 0 | 1 (3.0) |
|  |  | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  | 3 | 1 (3.0) | 0 | 0 | 0 | 0 | 0 | 1 (3.0) |
|  |  | 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  | Missing | 0 | 0 | 0 | 0 | 0 | 11 (33.3) | 11 (33.3) |
|  |  | Total | 21 (63.6) | 0 | 0 | 0 | 0 | 12 (36.4) | 33 (100) |
|  | | | | | | | | | |
|  | Worst Post-Baseline | 0 | 17 (51.5) | 2 (6.1) | 0 | 0 | 0 | 1 (3.0) | 20 (60.6) |
|  |  | 1 | 1 (3.0) | 0 | 0 | 0 | 0 | 0 | 1 (3.0) |
|  |  | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  | 3 | 1 (3.0) | 0 | 0 | 0 | 0 | 0 | 1 (3.0) |
|  |  | 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  | Missing | 0 | 0 | 0 | 0 | 0 | 11 (33.3) | 11 (33.3) |
|  |  | Total | 19 (57.6) | 2 (6.1) | 0 | 0 | 0 | 12 (36.4) | 33 (100) |
|  | | | | | | | | | |
| Lipase (Lipase increased) (N = 33) | Last Post-Baseline | 0 | 17 (51.5) | 0 | 0 | 0 | 0 | 0 | 17 (51.5) |
|  |  | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  | 2 | 1 (3.0) | 0 | 0 | 0 | 0 | 0 | 1 (3.0) |
|  |  | 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  | 4 | 1 (3.0) | 0 | 0 | 0 | 0 | 0 | 1 (3.0) |
|  |  | Missing | 0 | 0 | 0 | 0 | 0 | 14 (42.4) | 14 (42.4) |
|  |  | Total | 19 (57.6) | 0 | 0 | 0 | 0 | 14 (42.4) | 33 (100) |
|  | | | | | | | | | |
|  | Worst Post-Baseline | 0 | 17 (51.5) | 0 | 0 | 0 | 0 | 0 | 17 (51.5) |
|  |  | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  | 2 | 1 (3.0) | 0 | 0 | 0 | 0 | 0 | 1 (3.0) |
|  |  | 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  |  | 4 | 1 (3.0) | 0 | 0 | 0 | 0 | 0 | 1 (3.0) |
|  |  | Missing | 0 | 0 | 0 | 0 | 0 | 14 (42.4) | 14 (42.4) |
|  |  | Total | 19 (57.6) | 0 | 0 | 0 | 0 | 14 (42.4) | 33 (100) |
|  | | | | | | | | | |
| Creatine Kinase (CPK increased) (N = 33) | Last Post-Baseline | 0 | 21 (63.6) | 1 (3.0) | 0 | 0 | 0 | 0 | 22 (66.7) |
|  |  | 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 | 11 (33.3) | 11 (33.3) |
|  |  | Total | 21 (63.6) | 1 (3.0) | 0 | 0 | 0 | 11 (33.3) | 33 (100) |
|  | | | | | | | | | |
|  | Worst Post-Baseline | 0 | 17 (51.5) | 5 (15.2) | 0 | 0 | 0 | 0 | 22 (66.7) |
|  |  | 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 | 11 (33.3) | 11 (33.3) |
|  |  | Total | 17 (51.5) | 5 (15.2) | 0 | 0 | 0 | 11 (33.3) | 33 (100) |
|  | | | | | | | | | |
| Activated Partial Thromboplastin Time (Activated partial thromboplastin time prolonged) (N = 33) | Last Post-Baseline | 0 | 27 (81.8) | 3 (9.1) | 0 | 0 | 0 | 0 | 30 (90.9) |
|  |  | 1 | 1 (3.0) | 2 (6.1) | 0 | 0 | 0 | 0 | 3 (9.1) |
|  |  | 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 | 28 (84.8) | 5 (15.2) | 0 | 0 | 0 | 0 | 33 (100) |
|  | | | | | | | | | |
|  | Worst Post-Baseline | 0 | 22 (66.7) | 8 (24.2) | 0 | 0 | 0 | 0 | 30 (90.9) |
|  |  | 1 | 1 (3.0) | 2 (6.1) | 0 | 0 | 0 | 0 | 3 (9.1) |
|  |  | 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 | 23 (69.7) | 10 (30.3) | 0 | 0 | 0 | 0 | 33 (100) |
|  | | | | | | | | | |
| Prothrombin Intl. Normalized Ratio (INR increased) (N = 33) | Last Post-Baseline | 0 | 32 (97.0) | 1 (3.0) | 0 | 0 | 0 | 0 | 33 (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 | 32 (97.0) | 1 (3.0) | 0 | 0 | 0 | 0 | 33 (100) |
|  | | | | | | | | | |
|  | Worst Post-Baseline | 0 | 30 (90.9) | 3 (9.1) | 0 | 0 | 0 | 0 | 33 (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 | 30 (90.9) | 3 (9.1) | 0 | 0 | 0 | 0 | 33 (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 14.3.5.3.1.2 Summary of Shifts from Baseline in Hematology According to Investigator’s Assessment - Phase II part 1 treatment-naive locally-advanced or metastatic NSCLC (Safety Analysis Set)**

|  | | | Post-baseline | | | |
| --- | --- | --- | --- | --- | --- | --- |
| Parameter | Visit | Baseline | Normal | Abnormal, NCS | Abnormal, CS | Total |
| Erythrocytes (N = 33) | Last Post-Baseline | Normal | 11 (33.3) | 10 (30.3) | 2 (6.1) | 23 (69.7) |
|  |  | Abnormal, NCS | 0 | 6 (18.2) | 1 (3.0) | 7 (21.2) |
|  |  | Abnormal, CS | 0 | 0 | 3 (9.1) | 3 (9.1) |
|  |  | Total | 11 (33.3) | 16 (48.5) | 6 (18.2) | 33 (100) |
|  | | | | | | |
|  | Worst Post-Baseline | Normal | 7 (21.2) | 14 (42.4) | 2 (6.1) | 23 (69.7) |
|  |  | Abnormal, NCS | 0 | 6 (18.2) | 1 (3.0) | 7 (21.2) |
|  |  | Abnormal, CS | 0 | 0 | 3 (9.1) | 3 (9.1) |
|  |  | Total | 7 (21.2) | 20 (60.6) | 6 (18.2) | 33 (100) |
|  | | | | | | |
| Hemoglobin (N = 33) | Last Post-Baseline | Normal | 13 (39.4) | 3 (9.1) | 5 (15.2) | 21 (63.6) |
|  |  | Abnormal, NCS | 1 (3.0) | 4 (12.1) | 1 (3.0) | 6 (18.2) |
|  |  | Abnormal, CS | 0 | 0 | 6 (18.2) | 6 (18.2) |
|  |  | Total | 14 (42.4) | 7 (21.2) | 12 (36.4) | 33 (100) |
|  | | | | | | |
|  | Worst Post-Baseline | Normal | 8 (24.2) | 4 (12.1) | 9 (27.3) | 21 (63.6) |
|  |  | Abnormal, NCS | 1 (3.0) | 4 (12.1) | 1 (3.0) | 6 (18.2) |
|  |  | Abnormal, CS | 0 | 0 | 6 (18.2) | 6 (18.2) |
|  |  | Total | 9 (27.3) | 8 (24.2) | 16 (48.5) | 33 (100) |
|  | | | | | | |
| Hematocrit (N = 33) | Last Post-Baseline | Normal | 11 (33.3) | 7 (21.2) | 0 | 18 (54.5) |
|  |  | Abnormal, NCS | 1 (3.0) | 12 (36.4) | 1 (3.0) | 14 (42.4) |
|  |  | Abnormal, CS | 0 | 0 | 1 (3.0) | 1 (3.0) |
|  |  | Total | 12 (36.4) | 19 (57.6) | 2 (6.1) | 33 (100) |
|  | | | | | | |
|  | Worst Post-Baseline | Normal | 7 (21.2) | 11 (33.3) | 0 | 18 (54.5) |
|  |  | Abnormal, NCS | 0 | 13 (39.4) | 1 (3.0) | 14 (42.4) |
|  |  | Abnormal, CS | 0 | 0 | 1 (3.0) | 1 (3.0) |
|  |  | Total | 7 (21.2) | 24 (72.7) | 2 (6.1) | 33 (100) |
|  | | | | | | |
| Leukocytes (N = 33) | Last Post-Baseline | Normal | 21 (63.6) | 3 (9.1) | 2 (6.1) | 26 (78.8) |
|  |  | Abnormal, NCS | 3 (9.1) | 3 (9.1) | 1 (3.0) | 7 (21.2) |
|  |  | Abnormal, CS | 0 | 0 | 0 | 0 |
|  |  | Total | 24 (72.7) | 6 (18.2) | 3 (9.1) | 33 (100) |
|  | | | | | | |
|  | Worst Post-Baseline | Normal | 11 (33.3) | 10 (30.3) | 5 (15.2) | 26 (78.8) |
|  |  | Abnormal, NCS | 2 (6.1) | 3 (9.1) | 2 (6.1) | 7 (21.2) |
|  |  | Abnormal, CS | 0 | 0 | 0 | 0 |
|  |  | Total | 13 (39.4) | 13 (39.4) | 7 (21.2) | 33 (100) |
|  | | | | | | |
| Neutrophils (N = 33) | Last Post-Baseline | Normal | 21 (63.6) | 2 (6.1) | 2 (6.1) | 25 (75.8) |
|  |  | Abnormal, NCS | 3 (9.1) | 4 (12.1) | 1 (3.0) | 8 (24.2) |
|  |  | Abnormal, CS | 0 | 0 | 0 | 0 |
|  |  | Total | 24 (72.7) | 6 (18.2) | 3 (9.1) | 33 (100) |
|  | | | | | | |
|  | Worst Post-Baseline | Normal | 12 (36.4) | 8 (24.2) | 5 (15.2) | 25 (75.8) |
|  |  | Abnormal, NCS | 1 (3.0) | 5 (15.2) | 2 (6.1) | 8 (24.2) |
|  |  | Abnormal, CS | 0 | 0 | 0 | 0 |
|  |  | Total | 13 (39.4) | 13 (39.4) | 7 (21.2) | 33 (100) |
|  | | | | | | |
| Eosinophils (N = 33) | Last Post-Baseline | Normal | 26 (78.8) | 1 (3.0) | 0 | 27 (81.8) |
|  |  | Abnormal, NCS | 4 (12.1) | 2 (6.1) | 0 | 6 (18.2) |
|  |  | Abnormal, CS | 0 | 0 | 0 | 0 |
|  |  | Total | 30 (90.9) | 3 (9.1) | 0 | 33 (100) |
|  | | | | | | |
|  | Worst Post-Baseline | Normal | 16 (48.5) | 10 (30.3) | 1 (3.0) | 27 (81.8) |
|  |  | Abnormal, NCS | 1 (3.0) | 5 (15.2) | 0 | 6 (18.2) |
|  |  | Abnormal, CS | 0 | 0 | 0 | 0 |
|  |  | Total | 17 (51.5) | 15 (45.5) | 1 (3.0) | 33 (100) |
|  | | | | | | |
| Basophils (N = 33) | Last Post-Baseline | Normal | 19 (57.6) | 10 (30.3) | 0 | 29 (87.9) |
|  |  | Abnormal, NCS | 0 | 4 (12.1) | 0 | 4 (12.1) |
|  |  | Abnormal, CS | 0 | 0 | 0 | 0 |
|  |  | Total | 19 (57.6) | 14 (42.4) | 0 | 33 (100) |
|  | | | | | | |
|  | Worst Post-Baseline | Normal | 12 (36.4) | 17 (51.5) | 0 | 29 (87.9) |
|  |  | Abnormal, NCS | 0 | 4 (12.1) | 0 | 4 (12.1) |
|  |  | Abnormal, CS | 0 | 0 | 0 | 0 |
|  |  | Total | 12 (36.4) | 21 (63.6) | 0 | 33 (100) |
|  | | | | | | |
| Lymphocytes (N = 33) | Last Post-Baseline | Normal | 27 (81.8) | 2 (6.1) | 0 | 29 (87.9) |
|  |  | Abnormal, NCS | 1 (3.0) | 2 (6.1) | 0 | 3 (9.1) |
|  |  | Abnormal, CS | 1 (3.0) | 0 | 0 | 1 (3.0) |
|  |  | Total | 29 (87.9) | 4 (12.1) | 0 | 33 (100) |
|  | | | | | | |
|  | Worst Post-Baseline | Normal | 25 (75.8) | 4 (12.1) | 0 | 29 (87.9) |
|  |  | Abnormal, NCS | 0 | 3 (9.1) | 0 | 3 (9.1) |
|  |  | Abnormal, CS | 0 | 0 | 1 (3.0) | 1 (3.0) |
|  |  | Total | 25 (75.8) | 7 (21.2) | 1 (3.0) | 33 (100) |
|  | | | | | | |
| Monocytes (N = 33) | Last Post-Baseline | Normal | 15 (45.5) | 9 (27.3) | 0 | 24 (72.7) |
|  |  | Abnormal, NCS | 2 (6.1) | 6 (18.2) | 1 (3.0) | 9 (27.3) |
|  |  | Abnormal, CS | 0 | 0 | 0 | 0 |
|  |  | Total | 17 (51.5) | 15 (45.5) | 1 (3.0) | 33 (100) |
|  | | | | | | |
|  | Worst Post-Baseline | Normal | 8 (24.2) | 16 (48.5) | 0 | 24 (72.7) |
|  |  | Abnormal, NCS | 1 (3.0) | 7 (21.2) | 1 (3.0) | 9 (27.3) |
|  |  | Abnormal, CS | 0 | 0 | 0 | 0 |
|  |  | Total | 9 (27.3) | 23 (69.7) | 1 (3.0) | 33 (100) |
|  | | | | | | |
| Platelets (N = 33) | Last Post-Baseline | Normal | 27 (81.8) | 5 (15.2) | 0 | 32 (97.0) |
|  |  | Abnormal, NCS | 0 | 1 (3.0) | 0 | 1 (3.0) |
|  |  | Abnormal, CS | 0 | 0 | 0 | 0 |
|  |  | Total | 27 (81.8) | 6 (18.2) | 0 | 33 (100) |
|  | | | | | | |
|  | Worst Post-Baseline | Normal | 16 (48.5) | 16 (48.5) | 0 | 32 (97.0) |
|  |  | Abnormal, NCS | 0 | 1 (3.0) | 0 | 1 (3.0) |
|  |  | Abnormal, CS | 0 | 0 | 0 | 0 |
|  |  | Total | 16 (48.5) | 17 (51.5) | 0 | 33 (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 16.2.8.1.1

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

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

**Table 14.3.5.3.2.2 Summary of Shifts from Baseline in Chemistry According to Investigator’s Assessment - Phase II part 1 treatment-naive locally-advanced or metastatic NSCLC (Safety Analysis Set)**

|  | | | Post-baseline | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Parameter | Visit | Baseline | Normal | Abnormal, NCS | Abnormal, CS | Missing | Total |
| Bilirubin (N = 33) | Last Post-Baseline | Normal | 29 (87.9) | 2 (6.1) | 0 | 0 | 31 (93.9) |
|  |  | Abnormal, NCS | 1 (3.0) | 0 | 0 | 0 | 1 (3.0) |
|  |  | Abnormal, CS | 1 (3.0) | 0 | 0 | 0 | 1 (3.0) |
|  |  | Total | 31 (93.9) | 2 (6.1) | 0 | 0 | 33 (100) |
|  | | | | | | | |
|  | Worst Post-Baseline | Normal | 25 (75.8) | 4 (12.1) | 2 (6.1) | 0 | 31 (93.9) |
|  |  | Abnormal, NCS | 1 (3.0) | 0 | 0 | 0 | 1 (3.0) |
|  |  | Abnormal, CS | 0 | 0 | 1 (3.0) | 0 | 1 (3.0) |
|  |  | Total | 26 (78.8) | 4 (12.1) | 3 (9.1) | 0 | 33 (100) |
|  | | | | | | | |
| Direct Bilirubin (N = 33) | Last Post-Baseline | Normal | 28 (84.8) | 2 (6.1) | 1 (3.0) | 0 | 31 (93.9) |
|  |  | Abnormal, NCS | 0 | 0 | 1 (3.0) | 0 | 1 (3.0) |
|  |  | Abnormal, CS | 0 | 0 | 1 (3.0) | 0 | 1 (3.0) |
|  |  | Total | 28 (84.8) | 2 (6.1) | 3 (9.1) | 0 | 33 (100) |
|  | | | | | | | |
|  | Worst Post-Baseline | Normal | 25 (75.8) | 3 (9.1) | 3 (9.1) | 0 | 31 (93.9) |
|  |  | Abnormal, NCS | 0 | 0 | 1 (3.0) | 0 | 1 (3.0) |
|  |  | Abnormal, CS | 0 | 0 | 1 (3.0) | 0 | 1 (3.0) |
|  |  | Total | 25 (75.8) | 3 (9.1) | 5 (15.2) | 0 | 33 (100) |
|  | | | | | | | |
| Indirect Bilirubin (N = 33) | Last Post-Baseline | Normal | 26 (78.8) | 2 (6.1) | 0 | 0 | 28 (84.8) |
|  |  | Abnormal, NCS | 1 (3.0) | 0 | 0 | 0 | 1 (3.0) |
|  |  | Abnormal, CS | 1 (3.0) | 0 | 0 | 0 | 1 (3.0) |
|  |  | Missing | 0 | 0 | 0 | 3 (9.1) | 3 (9.1) |
|  |  | Total | 28 (84.8) | 2 (6.1) | 0 | 3 (9.1) | 33 (100) |
|  | | | | | | | |
|  | Worst Post-Baseline | Normal | 25 (75.8) | 2 (6.1) | 1 (3.0) | 0 | 28 (84.8) |
|  |  | Abnormal, NCS | 1 (3.0) | 0 | 0 | 0 | 1 (3.0) |
|  |  | Abnormal, CS | 0 | 0 | 1 (3.0) | 0 | 1 (3.0) |
|  |  | Missing | 0 | 0 | 0 | 3 (9.1) | 3 (9.1) |
|  |  | Total | 26 (78.8) | 2 (6.1) | 2 (6.1) | 3 (9.1) | 33 (100) |
|  | | | | | | | |
| Alanine Aminotransferase (N = 33) | Last Post-Baseline | Normal | 26 (78.8) | 4 (12.1) | 0 | 0 | 30 (90.9) |
|  |  | Abnormal, NCS | 1 (3.0) | 1 (3.0) | 0 | 0 | 2 (6.1) |
|  |  | Abnormal, CS | 1 (3.0) | 0 | 0 | 0 | 1 (3.0) |
|  |  | Total | 28 (84.8) | 5 (15.2) | 0 | 0 | 33 (100) |
|  | | | | | | | |
|  | Worst Post-Baseline | Normal | 14 (42.4) | 7 (21.2) | 9 (27.3) | 0 | 30 (90.9) |
|  |  | Abnormal, NCS | 0 | 1 (3.0) | 1 (3.0) | 0 | 2 (6.1) |
|  |  | Abnormal, CS | 0 | 0 | 1 (3.0) | 0 | 1 (3.0) |
|  |  | Total | 14 (42.4) | 8 (24.2) | 11 (33.3) | 0 | 33 (100) |
|  | | | | | | | |
| Aspartate Aminotransferase (N = 33) | Last Post-Baseline | Normal | 28 (84.8) | 0 | 0 | 0 | 28 (84.8) |
|  |  | Abnormal, NCS | 4 (12.1) | 0 | 0 | 0 | 4 (12.1) |
|  |  | Abnormal, CS | 1 (3.0) | 0 | 0 | 0 | 1 (3.0) |
|  |  | Total | 33 (100) | 0 | 0 | 0 | 33 (100) |
|  | | | | | | | |
|  | Worst Post-Baseline | Normal | 17 (51.5) | 3 (9.1) | 8 (24.2) | 0 | 28 (84.8) |
|  |  | Abnormal, NCS | 2 (6.1) | 1 (3.0) | 1 (3.0) | 0 | 4 (12.1) |
|  |  | Abnormal, CS | 0 | 0 | 1 (3.0) | 0 | 1 (3.0) |
|  |  | Total | 19 (57.6) | 4 (12.1) | 10 (30.3) | 0 | 33 (100) |
|  | | | | | | | |
| Gamma Glutamyl Transferase (N = 33) | Last Post-Baseline | Normal | 25 (75.8) | 1 (3.0) | 3 (9.1) | 0 | 29 (87.9) |
|  |  | Abnormal, NCS | 0 | 2 (6.1) | 0 | 0 | 2 (6.1) |
|  |  | Abnormal, CS | 2 (6.1) | 0 | 0 | 0 | 2 (6.1) |
|  |  | Total | 27 (81.8) | 3 (9.1) | 3 (9.1) | 0 | 33 (100) |
|  | | | | | | | |
|  | Worst Post-Baseline | Normal | 18 (54.5) | 4 (12.1) | 7 (21.2) | 0 | 29 (87.9) |
|  |  | Abnormal, NCS | 0 | 2 (6.1) | 0 | 0 | 2 (6.1) |
|  |  | Abnormal, CS | 0 | 0 | 2 (6.1) | 0 | 2 (6.1) |
|  |  | Total | 18 (54.5) | 6 (18.2) | 9 (27.3) | 0 | 33 (100) |
|  | | | | | | | |
| Alkaline Phosphatase (N = 33) | Last Post-Baseline | Normal | 25 (75.8) | 1 (3.0) | 1 (3.0) | 0 | 27 (81.8) |
|  |  | Abnormal, NCS | 0 | 4 (12.1) | 0 | 0 | 4 (12.1) |
|  |  | Abnormal, CS | 1 (3.0) | 1 (3.0) | 0 | 0 | 2 (6.1) |
|  |  | Total | 26 (78.8) | 6 (18.2) | 1 (3.0) | 0 | 33 (100) |
|  | | | | | | | |
|  | Worst Post-Baseline | Normal | 17 (51.5) | 7 (21.2) | 3 (9.1) | 0 | 27 (81.8) |
|  |  | Abnormal, NCS | 0 | 4 (12.1) | 0 | 0 | 4 (12.1) |
|  |  | Abnormal, CS | 0 | 1 (3.0) | 1 (3.0) | 0 | 2 (6.1) |
|  |  | Total | 17 (51.5) | 12 (36.4) | 4 (12.1) | 0 | 33 (100) |
|  | | | | | | | |
| Lactate Dehydrogenase (N = 33) | Last Post-Baseline | Normal | 22 (66.7) | 2 (6.1) | 0 | 0 | 24 (72.7) |
|  |  | Abnormal, NCS | 2 (6.1) | 7 (21.2) | 0 | 0 | 9 (27.3) |
|  |  | Abnormal, CS | 0 | 0 | 0 | 0 | 0 |
|  |  | Total | 24 (72.7) | 9 (27.3) | 0 | 0 | 33 (100) |
|  | | | | | | | |
|  | Worst Post-Baseline | Normal | 12 (36.4) | 12 (36.4) | 0 | 0 | 24 (72.7) |
|  |  | Abnormal, NCS | 0 | 9 (27.3) | 0 | 0 | 9 (27.3) |
|  |  | Abnormal, CS | 0 | 0 | 0 | 0 | 0 |
|  |  | Total | 12 (36.4) | 21 (63.6) | 0 | 0 | 33 (100) |
|  | | | | | | | |
| Protein (N = 33) | Last Post-Baseline | Normal | 28 (84.8) | 3 (9.1) | 0 | 0 | 31 (93.9) |
|  |  | Abnormal, NCS | 1 (3.0) | 1 (3.0) | 0 | 0 | 2 (6.1) |
|  |  | Abnormal, CS | 0 | 0 | 0 | 0 | 0 |
|  |  | Total | 29 (87.9) | 4 (12.1) | 0 | 0 | 33 (100) |
|  | | | | | | | |
|  | Worst Post-Baseline | Normal | 17 (51.5) | 14 (42.4) | 0 | 0 | 31 (93.9) |
|  |  | Abnormal, NCS | 1 (3.0) | 1 (3.0) | 0 | 0 | 2 (6.1) |
|  |  | Abnormal, CS | 0 | 0 | 0 | 0 | 0 |
|  |  | Total | 18 (54.5) | 15 (45.5) | 0 | 0 | 33 (100) |
|  | | | | | | | |
| Albumin (N = 33) | Last Post-Baseline | Normal | 14 (42.4) | 4 (12.1) | 5 (15.2) | 0 | 23 (69.7) |
|  |  | Abnormal, NCS | 0 | 6 (18.2) | 1 (3.0) | 0 | 7 (21.2) |
|  |  | Abnormal, CS | 0 | 0 | 3 (9.1) | 0 | 3 (9.1) |
|  |  | Total | 14 (42.4) | 10 (30.3) | 9 (27.3) | 0 | 33 (100) |
|  | | | | | | | |
|  | Worst Post-Baseline | Normal | 6 (18.2) | 7 (21.2) | 10 (30.3) | 0 | 23 (69.7) |
|  |  | Abnormal, NCS | 0 | 4 (12.1) | 3 (9.1) | 0 | 7 (21.2) |
|  |  | Abnormal, CS | 0 | 0 | 3 (9.1) | 0 | 3 (9.1) |
|  |  | Total | 6 (18.2) | 11 (33.3) | 16 (48.5) | 0 | 33 (100) |
|  | | | | | | | |
| Triglycerides (N = 33) | Last Post-Baseline | Normal | 21 (63.6) | 4 (12.1) | 3 (9.1) | 0 | 28 (84.8) |
|  |  | Abnormal, NCS | 0 | 0 | 1 (3.0) | 0 | 1 (3.0) |
|  |  | Abnormal, CS | 0 | 0 | 4 (12.1) | 0 | 4 (12.1) |
|  |  | Total | 21 (63.6) | 4 (12.1) | 8 (24.2) | 0 | 33 (100) |
|  | | | | | | | |
|  | Worst Post-Baseline | Normal | 10 (30.3) | 5 (15.2) | 13 (39.4) | 0 | 28 (84.8) |
|  |  | Abnormal, NCS | 0 | 0 | 1 (3.0) | 0 | 1 (3.0) |
|  |  | Abnormal, CS | 0 | 0 | 4 (12.1) | 0 | 4 (12.1) |
|  |  | Total | 10 (30.3) | 5 (15.2) | 18 (54.5) | 0 | 33 (100) |
|  | | | | | | | |
| Cholesterol (N = 33) | Last Post-Baseline | Normal | 16 (48.5) | 5 (15.2) | 1 (3.0) | 0 | 22 (66.7) |
|  |  | Abnormal, NCS | 2 (6.1) | 1 (3.0) | 0 | 0 | 3 (9.1) |
|  |  | Abnormal, CS | 3 (9.1) | 0 | 4 (12.1) | 0 | 7 (21.2) |
|  |  | Missing | 0 | 0 | 0 | 1 (3.0) | 1 (3.0) |
|  |  | Total | 21 (63.6) | 6 (18.2) | 5 (15.2) | 1 (3.0) | 33 (100) |
|  | | | | | | | |
|  | Worst Post-Baseline | Normal | 11 (33.3) | 7 (21.2) | 4 (12.1) | 0 | 22 (66.7) |
|  |  | Abnormal, NCS | 0 | 3 (9.1) | 0 | 0 | 3 (9.1) |
|  |  | Abnormal, CS | 0 | 0 | 7 (21.2) | 0 | 7 (21.2) |
|  |  | Missing | 0 | 0 | 0 | 1 (3.0) | 1 (3.0) |
|  |  | Total | 11 (33.3) | 10 (30.3) | 11 (33.3) | 1 (3.0) | 33 (100) |
|  | | | | | | | |
| Sodium (N = 33) | Last Post-Baseline | Normal | 25 (75.8) | 2 (6.1) | 2 (6.1) | 0 | 29 (87.9) |
|  |  | Abnormal, NCS | 1 (3.0) | 0 | 1 (3.0) | 0 | 2 (6.1) |
|  |  | Abnormal, CS | 1 (3.0) | 0 | 1 (3.0) | 0 | 2 (6.1) |
|  |  | Total | 27 (81.8) | 2 (6.1) | 4 (12.1) | 0 | 33 (100) |
|  | | | | | | | |
|  | Worst Post-Baseline | Normal | 18 (54.5) | 7 (21.2) | 4 (12.1) | 0 | 29 (87.9) |
|  |  | Abnormal, NCS | 0 | 1 (3.0) | 1 (3.0) | 0 | 2 (6.1) |
|  |  | Abnormal, CS | 0 | 0 | 2 (6.1) | 0 | 2 (6.1) |
|  |  | Total | 18 (54.5) | 8 (24.2) | 7 (21.2) | 0 | 33 (100) |
|  | | | | | | | |
| Potassium (N = 33) | Last Post-Baseline | Normal | 31 (93.9) | 0 | 1 (3.0) | 0 | 32 (97.0) |
|  |  | Abnormal, NCS | 0 | 0 | 0 | 0 | 0 |
|  |  | Abnormal, CS | 0 | 0 | 1 (3.0) | 0 | 1 (3.0) |
|  |  | Total | 31 (93.9) | 0 | 2 (6.1) | 0 | 33 (100) |
|  | | | | | | | |
|  | Worst Post-Baseline | Normal | 25 (75.8) | 5 (15.2) | 2 (6.1) | 0 | 32 (97.0) |
|  |  | Abnormal, NCS | 0 | 0 | 0 | 0 | 0 |
|  |  | Abnormal, CS | 0 | 0 | 1 (3.0) | 0 | 1 (3.0) |
|  |  | Total | 25 (75.8) | 5 (15.2) | 3 (9.1) | 0 | 33 (100) |
|  | | | | | | | |
| Magnesium (N = 33) | Last Post-Baseline | Normal | 30 (90.9) | 1 (3.0) | 0 | 0 | 31 (93.9) |
|  |  | Abnormal, NCS | 1 (3.0) | 1 (3.0) | 0 | 0 | 2 (6.1) |
|  |  | Abnormal, CS | 0 | 0 | 0 | 0 | 0 |
|  |  | Total | 31 (93.9) | 2 (6.1) | 0 | 0 | 33 (100) |
|  | | | | | | | |
|  | Worst Post-Baseline | Normal | 26 (78.8) | 5 (15.2) | 0 | 0 | 31 (93.9) |
|  |  | Abnormal, NCS | 0 | 2 (6.1) | 0 | 0 | 2 (6.1) |
|  |  | Abnormal, CS | 0 | 0 | 0 | 0 | 0 |
|  |  | Total | 26 (78.8) | 7 (21.2) | 0 | 0 | 33 (100) |
|  | | | | | | | |
| Chloride (N = 33) | Last Post-Baseline | Normal | 27 (81.8) | 3 (9.1) | 1 (3.0) | 0 | 31 (93.9) |
|  |  | Abnormal, NCS | 0 | 1 (3.0) | 0 | 0 | 1 (3.0) |
|  |  | Abnormal, CS | 0 | 0 | 1 (3.0) | 0 | 1 (3.0) |
|  |  | Total | 27 (81.8) | 4 (12.1) | 2 (6.1) | 0 | 33 (100) |
|  | | | | | | | |
|  | Worst Post-Baseline | Normal | 20 (60.6) | 10 (30.3) | 1 (3.0) | 0 | 31 (93.9) |
|  |  | Abnormal, NCS | 0 | 1 (3.0) | 0 | 0 | 1 (3.0) |
|  |  | Abnormal, CS | 0 | 0 | 1 (3.0) | 0 | 1 (3.0) |
|  |  | Total | 20 (60.6) | 11 (33.3) | 2 (6.1) | 0 | 33 (100) |
|  | | | | | | | |
| Calcium (N = 33) | Last Post-Baseline | Normal | 26 (78.8) | 1 (3.0) | 2 (6.1) | 0 | 29 (87.9) |
|  |  | Abnormal, NCS | 3 (9.1) | 0 | 0 | 0 | 3 (9.1) |
|  |  | Abnormal, CS | 1 (3.0) | 0 | 0 | 0 | 1 (3.0) |
|  |  | Total | 30 (90.9) | 1 (3.0) | 2 (6.1) | 0 | 33 (100) |
|  | | | | | | | |
|  | Worst Post-Baseline | Normal | 22 (66.7) | 4 (12.1) | 3 (9.1) | 0 | 29 (87.9) |
|  |  | Abnormal, NCS | 1 (3.0) | 2 (6.1) | 0 | 0 | 3 (9.1) |
|  |  | Abnormal, CS | 0 | 0 | 1 (3.0) | 0 | 1 (3.0) |
|  |  | Total | 23 (69.7) | 6 (18.2) | 4 (12.1) | 0 | 33 (100) |
|  | | | | | | | |
| Phosphorus (N = 33) | Last Post-Baseline | Normal | 28 (84.8) | 3 (9.1) | 0 | 0 | 31 (93.9) |
|  |  | Abnormal, NCS | 1 (3.0) | 0 | 0 | 0 | 1 (3.0) |
|  |  | Abnormal, CS | 0 | 0 | 1 (3.0) | 0 | 1 (3.0) |
|  |  | Total | 29 (87.9) | 3 (9.1) | 1 (3.0) | 0 | 33 (100) |
|  | | | | | | | |
|  | Worst Post-Baseline | Normal | 18 (54.5) | 13 (39.4) | 0 | 0 | 31 (93.9) |
|  |  | Abnormal, NCS | 1 (3.0) | 0 | 0 | 0 | 1 (3.0) |
|  |  | Abnormal, CS | 0 | 0 | 1 (3.0) | 0 | 1 (3.0) |
|  |  | Total | 19 (57.6) | 13 (39.4) | 1 (3.0) | 0 | 33 (100) |
|  | | | | | | | |
| Urea (N = 33) | Last Post-Baseline | Normal | 29 (87.9) | 0 | 0 | 0 | 29 (87.9) |
|  |  | Abnormal, NCS | 1 (3.0) | 0 | 0 | 0 | 1 (3.0) |
|  |  | Abnormal, CS | 0 | 0 | 0 | 0 | 0 |
|  |  | Missing | 0 | 0 | 0 | 3 (9.1) | 3 (9.1) |
|  |  | Total | 30 (90.9) | 0 | 0 | 3 (9.1) | 33 (100) |
|  | | | | | | | |
|  | Worst Post-Baseline | Normal | 24 (72.7) | 5 (15.2) | 0 | 0 | 29 (87.9) |
|  |  | Abnormal, NCS | 1 (3.0) | 0 | 0 | 0 | 1 (3.0) |
|  |  | Abnormal, CS | 0 | 0 | 0 | 0 | 0 |
|  |  | Missing | 0 | 0 | 0 | 3 (9.1) | 3 (9.1) |
|  |  | Total | 25 (75.8) | 5 (15.2) | 0 | 3 (9.1) | 33 (100) |
|  | | | | | | | |
| Urea Nitrogen (N = 33) | Last Post-Baseline | Normal | 1 (3.0) | 1 (3.0) | 0 | 0 | 2 (6.1) |
|  |  | Abnormal, NCS | 0 | 1 (3.0) | 0 | 0 | 1 (3.0) |
|  |  | Abnormal, CS | 0 | 0 | 0 | 0 | 0 |
|  |  | Missing | 0 | 0 | 0 | 30 (90.9) | 30 (90.9) |
|  |  | Total | 1 (3.0) | 2 (6.1) | 0 | 30 (90.9) | 33 (100) |
|  | | | | | | | |
|  | Worst Post-Baseline | Normal | 1 (3.0) | 1 (3.0) | 0 | 0 | 2 (6.1) |
|  |  | Abnormal, NCS | 0 | 1 (3.0) | 0 | 0 | 1 (3.0) |
|  |  | Abnormal, CS | 0 | 0 | 0 | 0 | 0 |
|  |  | Missing | 0 | 0 | 0 | 30 (90.9) | 30 (90.9) |
|  |  | Total | 1 (3.0) | 2 (6.1) | 0 | 30 (90.9) | 33 (100) |
|  | | | | | | | |
| Creatinine (N = 33) | Last Post-Baseline | Normal | 22 (66.7) | 3 (9.1) | 1 (3.0) | 0 | 26 (78.8) |
|  |  | Abnormal, NCS | 4 (12.1) | 2 (6.1) | 0 | 0 | 6 (18.2) |
|  |  | Abnormal, CS | 0 | 0 | 1 (3.0) | 0 | 1 (3.0) |
|  |  | Total | 26 (78.8) | 5 (15.2) | 2 (6.1) | 0 | 33 (100) |
|  | | | | | | | |
|  | Worst Post-Baseline | Normal | 19 (57.6) | 6 (18.2) | 1 (3.0) | 0 | 26 (78.8) |
|  |  | Abnormal, NCS | 1 (3.0) | 5 (15.2) | 0 | 0 | 6 (18.2) |
|  |  | Abnormal, CS | 0 | 0 | 1 (3.0) | 0 | 1 (3.0) |
|  |  | Total | 20 (60.6) | 11 (33.3) | 2 (6.1) | 0 | 33 (100) |
|  | | | | | | | |
| Urate (N = 33) | Last Post-Baseline | Normal | 23 (69.7) | 3 (9.1) | 0 | 1 (3.0) | 27 (81.8) |
|  |  | Abnormal, NCS | 3 (9.1) | 2 (6.1) | 0 | 0 | 5 (15.2) |
|  |  | Abnormal, CS | 1 (3.0) | 0 | 0 | 0 | 1 (3.0) |
|  |  | Total | 27 (81.8) | 5 (15.2) | 0 | 1 (3.0) | 33 (100) |
|  | | | | | | | |
|  | Worst Post-Baseline | Normal | 20 (60.6) | 7 (21.2) | 0 | 0 | 27 (81.8) |
|  |  | Abnormal, NCS | 1 (3.0) | 4 (12.1) | 0 | 0 | 5 (15.2) |
|  |  | Abnormal, CS | 1 (3.0) | 0 | 0 | 0 | 1 (3.0) |
|  |  | Total | 22 (66.7) | 11 (33.3) | 0 | 0 | 33 (100) |
|  | | | | | | | |
| Glucose (N = 33) | Last Post-Baseline | Normal | 25 (75.8) | 1 (3.0) | 0 | 0 | 26 (78.8) |
|  |  | Abnormal, NCS | 2 (6.1) | 0 | 1 (3.0) | 0 | 3 (9.1) |
|  |  | Abnormal, CS | 2 (6.1) | 0 | 2 (6.1) | 0 | 4 (12.1) |
|  |  | Total | 29 (87.9) | 1 (3.0) | 3 (9.1) | 0 | 33 (100) |
|  | | | | | | | |
|  | Worst Post-Baseline | Normal | 21 (63.6) | 5 (15.2) | 0 | 0 | 26 (78.8) |
|  |  | Abnormal, NCS | 0 | 2 (6.1) | 1 (3.0) | 0 | 3 (9.1) |
|  |  | Abnormal, CS | 1 (3.0) | 0 | 3 (9.1) | 0 | 4 (12.1) |
|  |  | Total | 22 (66.7) | 7 (21.2) | 4 (12.1) | 0 | 33 (100) |
|  | | | | | | | |
| Amylase (N = 33) | Last Post-Baseline | Normal | 18 (54.5) | 0 | 0 | 1 (3.0) | 19 (57.6) |
|  |  | Abnormal, NCS | 3 (9.1) | 0 | 0 | 0 | 3 (9.1) |
|  |  | Abnormal, CS | 0 | 0 | 0 | 0 | 0 |
|  |  | Missing | 0 | 0 | 0 | 11 (33.3) | 11 (33.3) |
|  |  | Total | 21 (63.6) | 0 | 0 | 12 (36.4) | 33 (100) |
|  | | | | | | | |
|  | Worst Post-Baseline | Normal | 16 (48.5) | 2 (6.1) | 0 | 1 (3.0) | 19 (57.6) |
|  |  | Abnormal, NCS | 3 (9.1) | 0 | 0 | 0 | 3 (9.1) |
|  |  | Abnormal, CS | 0 | 0 | 0 | 0 | 0 |
|  |  | Missing | 0 | 0 | 0 | 11 (33.3) | 11 (33.3) |
|  |  | Total | 19 (57.6) | 2 (6.1) | 0 | 12 (36.4) | 33 (100) |
|  | | | | | | | |
| Lipase (N = 33) | Last Post-Baseline | Normal | 14 (42.4) | 0 | 0 | 0 | 14 (42.4) |
|  |  | Abnormal, NCS | 4 (12.1) | 1 (3.0) | 0 | 0 | 5 (15.2) |
|  |  | Abnormal, CS | 0 | 0 | 0 | 0 | 0 |
|  |  | Missing | 0 | 0 | 0 | 14 (42.4) | 14 (42.4) |
|  |  | Total | 18 (54.5) | 1 (3.0) | 0 | 14 (42.4) | 33 (100) |
|  | | | | | | | |
|  | Worst Post-Baseline | Normal | 13 (39.4) | 1 (3.0) | 0 | 0 | 14 (42.4) |
|  |  | Abnormal, NCS | 3 (9.1) | 2 (6.1) | 0 | 0 | 5 (15.2) |
|  |  | Abnormal, CS | 0 | 0 | 0 | 0 | 0 |
|  |  | Missing | 0 | 0 | 0 | 14 (42.4) | 14 (42.4) |
|  |  | Total | 16 (48.5) | 3 (9.1) | 0 | 14 (42.4) | 33 (100) |
|  | | | | | | | |
| Creatine Kinase (N = 33) | Last Post-Baseline | Normal | 15 (45.5) | 2 (6.1) | 0 | 0 | 17 (51.5) |
|  |  | Abnormal, NCS | 1 (3.0) | 4 (12.1) | 0 | 0 | 5 (15.2) |
|  |  | Abnormal, CS | 0 | 0 | 0 | 0 | 0 |
|  |  | Missing | 0 | 0 | 0 | 11 (33.3) | 11 (33.3) |
|  |  | Total | 16 (48.5) | 6 (18.2) | 0 | 11 (33.3) | 33 (100) |
|  | | | | | | | |
|  | Worst Post-Baseline | Normal | 10 (30.3) | 5 (15.2) | 2 (6.1) | 0 | 17 (51.5) |
|  |  | Abnormal, NCS | 1 (3.0) | 4 (12.1) | 0 | 0 | 5 (15.2) |
|  |  | Abnormal, CS | 0 | 0 | 0 | 0 | 0 |
|  |  | Missing | 0 | 0 | 0 | 11 (33.3) | 11 (33.3) |
|  |  | Total | 11 (33.3) | 9 (27.3) | 2 (6.1) | 11 (33.3) | 33 (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

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

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

**Table 14.3.5.3.3.2 Summary of Shifts from Baseline in Urinalysis According to Investigator’s Assessment - Phase II part 1 treatment-naive locally-advanced or metastatic NSCLC (Safety Analysis Set)**

|  | | | Post-baseline | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Parameter | Visit | Baseline | Normal | Abnormal, NCS | Abnormal, CS | Missing | Total |
| pH (N = 33) | Last Post-Baseline | Normal | 31 (93.9) | 2 (6.1) | 0 | 0 | 33 (100) |
|  |  | Abnormal, NCS | 0 | 0 | 0 | 0 | 0 |
|  |  | Abnormal, CS | 0 | 0 | 0 | 0 | 0 |
|  |  | Total | 31 (93.9) | 2 (6.1) | 0 | 0 | 33 (100) |
|  | | | | | | | |
|  | Worst Post-Baseline | Normal | 30 (90.9) | 3 (9.1) | 0 | 0 | 33 (100) |
|  |  | Abnormal, NCS | 0 | 0 | 0 | 0 | 0 |
|  |  | Abnormal, CS | 0 | 0 | 0 | 0 | 0 |
|  |  | Total | 30 (90.9) | 3 (9.1) | 0 | 0 | 33 (100) |
|  | | | | | | | |
| Specific Gravity (N = 33) | Last Post-Baseline | Normal | 26 (78.8) | 4 (12.1) | 0 | 0 | 30 (90.9) |
|  |  | Abnormal, NCS | 1 (3.0) | 2 (6.1) | 0 | 0 | 3 (9.1) |
|  |  | Abnormal, CS | 0 | 0 | 0 | 0 | 0 |
|  |  | Total | 27 (81.8) | 6 (18.2) | 0 | 0 | 33 (100) |
|  | | | | | | | |
|  | Worst Post-Baseline | Normal | 13 (39.4) | 17 (51.5) | 0 | 0 | 30 (90.9) |
|  |  | Abnormal, NCS | 0 | 3 (9.1) | 0 | 0 | 3 (9.1) |
|  |  | Abnormal, CS | 0 | 0 | 0 | 0 | 0 |
|  |  | Total | 13 (39.4) | 20 (60.6) | 0 | 0 | 33 (100) |
|  | | | | | | | |
| Protein (N = 33) | Last Post-Baseline | Normal | 16 (48.5) | 1 (3.0) | 8 (24.2) | 0 | 25 (75.8) |
|  |  | Abnormal, NCS | 1 (3.0) | 2 (6.1) | 1 (3.0) | 0 | 4 (12.1) |
|  |  | Abnormal, CS | 0 | 0 | 4 (12.1) | 0 | 4 (12.1) |
|  |  | Total | 17 (51.5) | 3 (9.1) | 13 (39.4) | 0 | 33 (100) |
|  | | | | | | | |
|  | Worst Post-Baseline | Normal | 6 (18.2) | 3 (9.1) | 16 (48.5) | 0 | 25 (75.8) |
|  |  | Abnormal, NCS | 0 | 2 (6.1) | 2 (6.1) | 0 | 4 (12.1) |
|  |  | Abnormal, CS | 0 | 0 | 4 (12.1) | 0 | 4 (12.1) |
|  |  | Total | 6 (18.2) | 5 (15.2) | 22 (66.7) | 0 | 33 (100) |
|  | | | | | | | |
| Glucose (N = 33) | Last Post-Baseline | Normal | 32 (97.0) | 0 | 0 | 0 | 32 (97.0) |
|  |  | Abnormal, NCS | 1 (3.0) | 0 | 0 | 0 | 1 (3.0) |
|  |  | Abnormal, CS | 0 | 0 | 0 | 0 | 0 |
|  |  | Total | 33 (100) | 0 | 0 | 0 | 33 (100) |
|  | | | | | | | |
|  | Worst Post-Baseline | Normal | 29 (87.9) | 2 (6.1) | 1 (3.0) | 0 | 32 (97.0) |
|  |  | Abnormal, NCS | 1 (3.0) | 0 | 0 | 0 | 1 (3.0) |
|  |  | Abnormal, CS | 0 | 0 | 0 | 0 | 0 |
|  |  | Total | 30 (90.9) | 2 (6.1) | 1 (3.0) | 0 | 33 (100) |
|  | | | | | | | |
| Ketones (N = 33) | Last Post-Baseline | Normal | 32 (97.0) | 0 | 0 | 0 | 32 (97.0) |
|  |  | Abnormal, NCS | 1 (3.0) | 0 | 0 | 0 | 1 (3.0) |
|  |  | Abnormal, CS | 0 | 0 | 0 | 0 | 0 |
|  |  | Total | 33 (100) | 0 | 0 | 0 | 33 (100) |
|  | | | | | | | |
|  | Worst Post-Baseline | Normal | 30 (90.9) | 2 (6.1) | 0 | 0 | 32 (97.0) |
|  |  | Abnormal, NCS | 0 | 1 (3.0) | 0 | 0 | 1 (3.0) |
|  |  | Abnormal, CS | 0 | 0 | 0 | 0 | 0 |
|  |  | Total | 30 (90.9) | 3 (9.1) | 0 | 0 | 33 (100) |
|  | | | | | | | |
| Erythrocytes (N = 33) | Last Post-Baseline | Normal | 10 (30.3) | 13 (39.4) | 5 (15.2) | 0 | 28 (84.8) |
|  |  | Abnormal, NCS | 4 (12.1) | 0 | 1 (3.0) | 0 | 5 (15.2) |
|  |  | Abnormal, CS | 0 | 0 | 0 | 0 | 0 |
|  |  | Total | 14 (42.4) | 13 (39.4) | 6 (18.2) | 0 | 33 (100) |
|  | | | | | | | |
|  | Worst Post-Baseline | Normal | 3 (9.1) | 15 (45.5) | 10 (30.3) | 0 | 28 (84.8) |
|  |  | Abnormal, NCS | 2 (6.1) | 1 (3.0) | 2 (6.1) | 0 | 5 (15.2) |
|  |  | Abnormal, CS | 0 | 0 | 0 | 0 | 0 |
|  |  | Total | 5 (15.2) | 16 (48.5) | 12 (36.4) | 0 | 33 (100) |
|  | | | | | | | |
| Leukocytes (N = 33) | Last Post-Baseline | Normal | 27 (81.8) | 1 (3.0) | 1 (3.0) | 0 | 29 (87.9) |
|  |  | Abnormal, NCS | 1 (3.0) | 1 (3.0) | 0 | 0 | 2 (6.1) |
|  |  | Abnormal, CS | 1 (3.0) | 0 | 1 (3.0) | 0 | 2 (6.1) |
|  |  | Total | 29 (87.9) | 2 (6.1) | 2 (6.1) | 0 | 33 (100) |
|  | | | | | | | |
|  | Worst Post-Baseline | Normal | 24 (72.7) | 4 (12.1) | 1 (3.0) | 0 | 29 (87.9) |
|  |  | Abnormal, NCS | 0 | 2 (6.1) | 0 | 0 | 2 (6.1) |
|  |  | Abnormal, CS | 0 | 0 | 2 (6.1) | 0 | 2 (6.1) |
|  |  | Total | 24 (72.7) | 6 (18.2) | 3 (9.1) | 0 | 33 (100) |
|  | | | | | | | |
| Bilirubin (N = 33) | Last Post-Baseline | Normal | 32 (97.0) | 1 (3.0) | 0 | 0 | 33 (100) |
|  |  | Abnormal, NCS | 0 | 0 | 0 | 0 | 0 |
|  |  | Abnormal, CS | 0 | 0 | 0 | 0 | 0 |
|  |  | Total | 32 (97.0) | 1 (3.0) | 0 | 0 | 33 (100) |
|  | | | | | | | |
|  | Worst Post-Baseline | Normal | 31 (93.9) | 2 (6.1) | 0 | 0 | 33 (100) |
|  |  | Abnormal, NCS | 0 | 0 | 0 | 0 | 0 |
|  |  | Abnormal, CS | 0 | 0 | 0 | 0 | 0 |
|  |  | Total | 31 (93.9) | 2 (6.1) | 0 | 0 | 33 (100) |
|  | | | | | | | |
| Creatinine (N = 33) | Last Post-Baseline | Normal | 9 (27.3) | 0 | 0 | 1 (3.0) | 10 (30.3) |
|  |  | Abnormal, NCS | 0 | 0 | 0 | 0 | 0 |
|  |  | Abnormal, CS | 0 | 0 | 0 | 0 | 0 |
|  |  | Missing | 0 | 0 | 0 | 23 (69.7) | 23 (69.7) |
|  |  | Total | 9 (27.3) | 0 | 0 | 24 (72.7) | 33 (100) |
|  | | | | | | | |
|  | Worst Post-Baseline | Normal | 10 (30.3) | 0 | 0 | 0 | 10 (30.3) |
|  |  | Abnormal, NCS | 0 | 0 | 0 | 0 | 0 |
|  |  | Abnormal, CS | 0 | 0 | 0 | 0 | 0 |
|  |  | Missing | 0 | 0 | 0 | 23 (69.7) | 23 (69.7) |
|  |  | Total | 10 (30.3) | 0 | 0 | 23 (69.7) | 33 (100) |
|  | | | | | | | |
| Protein/Creatinine (N = 33) | 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 | 33 (100) | 33 (100) |
|  |  | Total | 0 | 0 | 0 | 33 (100) | 33 (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 | 33 (100) | 33 (100) |
|  |  | Total | 0 | 0 | 0 | 33 (100) | 33 (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

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

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

**Table 14.3.5.3.4.2 Summary of Shifts from Baseline in Coagulation Function According to Investigator’s Assessment - Phase II part 1 treatment-naive locally-advanced or metastatic NSCLC (Safety Analysis Set)**

|  | | | Post-baseline | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Parameter | Visit | Baseline | Normal | Abnormal, NCS | Abnormal, CS | Missing | Total |
| Activated Partial Thromboplastin Time (N = 33) | Last Post-Baseline | Normal | 26 (78.8) | 3 (9.1) | 0 | 0 | 29 (87.9) |
|  |  | Abnormal, NCS | 2 (6.1) | 2 (6.1) | 0 | 0 | 4 (12.1) |
|  |  | Abnormal, CS | 0 | 0 | 0 | 0 | 0 |
|  |  | Total | 28 (84.8) | 5 (15.2) | 0 | 0 | 33 (100) |
|  | | | | | | | |
|  | Worst Post-Baseline | Normal | 19 (57.6) | 10 (30.3) | 0 | 0 | 29 (87.9) |
|  |  | Abnormal, NCS | 2 (6.1) | 2 (6.1) | 0 | 0 | 4 (12.1) |
|  |  | Abnormal, CS | 0 | 0 | 0 | 0 | 0 |
|  |  | Total | 21 (63.6) | 12 (36.4) | 0 | 0 | 33 (100) |
|  | | | | | | | |
| Prothrombin Time (N = 33) | Last Post-Baseline | Normal | 29 (87.9) | 0 | 0 | 0 | 29 (87.9) |
|  |  | Abnormal, NCS | 2 (6.1) | 1 (3.0) | 0 | 0 | 3 (9.1) |
|  |  | Abnormal, CS | 0 | 0 | 0 | 0 | 0 |
|  |  | Missing | 0 | 0 | 0 | 1 (3.0) | 1 (3.0) |
|  |  | Total | 31 (93.9) | 1 (3.0) | 0 | 1 (3.0) | 33 (100) |
|  | | | | | | | |
|  | Worst Post-Baseline | Normal | 25 (75.8) | 4 (12.1) | 0 | 0 | 29 (87.9) |
|  |  | Abnormal, NCS | 2 (6.1) | 1 (3.0) | 0 | 0 | 3 (9.1) |
|  |  | Abnormal, CS | 0 | 0 | 0 | 0 | 0 |
|  |  | Missing | 0 | 0 | 0 | 1 (3.0) | 1 (3.0) |
|  |  | Total | 27 (81.8) | 5 (15.2) | 0 | 1 (3.0) | 33 (100) |
|  | | | | | | | |
| Prothrombin Intl. Normalized Ratio (N = 33) | Last Post-Baseline | Normal | 32 (97.0) | 1 (3.0) | 0 | 0 | 33 (100) |
|  |  | Abnormal, NCS | 0 | 0 | 0 | 0 | 0 |
|  |  | Abnormal, CS | 0 | 0 | 0 | 0 | 0 |
|  |  | Total | 32 (97.0) | 1 (3.0) | 0 | 0 | 33 (100) |
|  | | | | | | | |
|  | Worst Post-Baseline | Normal | 29 (87.9) | 3 (9.1) | 1 (3.0) | 0 | 33 (100) |
|  |  | Abnormal, NCS | 0 | 0 | 0 | 0 | 0 |
|  |  | Abnormal, CS | 0 | 0 | 0 | 0 | 0 |
|  |  | Total | 29 (87.9) | 3 (9.1) | 1 (3.0) | 0 | 33 (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 |

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

**Table 14.3.5.4.2 Summary of Subjects with At Least One Level Increase in CTCAE Grade by Abnormality - Phase II part 1 treatment-naive locally-advanced or metastatic NSCLC (Safety Analysis Set)**

|  | Treatment-naive locally-advanced or metastatic NSCLC (N = 33) n (%) |
| --- | --- |
| Subjects with At Least One Level Increase in CTCAE Grade | 33 (100) |
|  | |
| Hypoalbuminemia | 24 (72.7) |
| Hypertriglyceridemia | 19 (57.6) |
| Anemia | 16 (48.5) |
| Blood lactate dehydrogenase increased | 16 (48.5) |
| Cholesterol high | 13 (39.4) |
| Hyponatremia | 13 (39.4) |
| Eosinophilia | 12 (36.4) |
| Alanine aminotransferase increased | 11 (33.3) |
| Aspartate aminotransferase increased | 11 (33.3) |
| Activated partial thromboplastin time prolonged | 10 (30.3) |
| Alkaline phosphatase increased | 10 (30.3) |
| GGT increased | 9 (27.3) |
| Hyperuricemia | 7 (21.2) |
| Blood bilirubin increased | 6 (18.2) |
| Hypocalcemia | 6 (18.2) |
| Hypokalemia | 6 (18.2) |
| Lymphocyte count decreased | 6 (18.2) |
| CPK increased | 5 (15.2) |
| Hypomagnesemia | 5 (15.2) |
| Hypercalcemia | 4 (12.1) |
| Hypoglycemia | 4 (12.1) |
| Creatinine increased | 3 (9.1) |
| INR increased | 3 (9.1) |
| Hyperkalemia | 2 (6.1) |
| Hypermagnesemia | 2 (6.1) |
| Serum amylase increased | 2 (6.1) |
| Hemoglobin increased | 1 (3.0) |
| Hypernatremia | 1 (3.0) |

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 14.3.5.5.2 Summary of Subjects with At least One Abnormal Chemistry Result Related to Liver Function Abnormality - Phase II part 1 treatment-naive locally-advanced or metastatic NSCLC (Safety Analysis Set)**

|  | Treatment-naive locally-advanced or metastatic NSCLC (N = 33) n (%) |
| --- | --- |
| Alanine Transaminase (ALT) |  |
| Subjects with non-missing value | 33 |
| ≥ 3×ULN | 2 (6.1) |
|  | |
| Aspartate Transaminase (AST) |  |
| Subjects with non-missing value | 33 |
| ≥ 3×ULN | 3 (9.1) |
|  | |
| ALT and/or AST |  |
| Subjects with non-missing value | 33 |
| ≥ 3×ULN | 3 (9.1) |
|  | |
| ALT |  |
| Subjects with non-missing value | 33 |
| ≥ 8×ULN | 0 |
|  | |
| AST |  |
| Subjects with non-missing value | 33 |
| ≥ 8×ULN | 0 |
|  | |
| ALT and/or AST |  |
| Subjects with non-missing value | 33 |
| ≥ 8×ULN | 0 |
|  | |
| Total Bilirubin (TBIL) |  |
| Subjects with non-missing value | 33 |
| ≥ 2×ULN | 0 |
|  | |
| TBIL |  |
| Subjects with non-missing value | 33 |
| ≥ 3×ULN | 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 |

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

**Table 14.3.5.5.5 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 1 treatment-naive locally-advanced or metastatic NSCLC (Safety Analysis Set)**

|  | Treatment-naive locally-advanced or metastatic NSCLC (N = 33) n (%) |
| --- | --- |
| Alanine Transaminase (ALT) |  |
| Subjects with non-missing value | 30 |
| ≥ 3×ULN | 1 (3.0) |
|  | |
| Aspartate Transaminase (AST) |  |
| Subjects with non-missing value | 28 |
| ≥ 3×ULN | 2 (6.1) |
|  | |
| ALT and/or AST |  |
| Subjects with non-missing value | 30 |
| ≥ 3×ULN | 2 (6.1) |
|  | |
| ALT |  |
| Subjects with non-missing value | 30 |
| ≥ 8×ULN | 0 |
|  | |
| AST |  |
| Subjects with non-missing value | 28 |
| ≥ 8×ULN | 0 |
|  | |
| ALT and/or AST |  |
| Subjects with non-missing value | 30 |
| ≥ 8×ULN | 0 |
|  | |
| Total Bilirubin (TBIL) |  |
| Subjects with non-missing value | 31 |
| ≥ 2×ULN | 0 |
|  | |
| TBIL |  |
| Subjects with non-missing value | 31 |
| ≥ 3×ULN | 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 14.3.5.5.8 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 1 treatment-naive locally-advanced or metastatic NSCLC (Safety Analysis Set)**

|  | Treatment-naive locally-advanced or metastatic NSCLC (N = 33) n (%) |
| --- | --- |
| Alanine Transaminase (ALT) |  |
| Subjects with non-missing value | 3 |
| ≥ 3×ULN | 1 (3.0) |
|  | |
| Aspartate Transaminase (AST) |  |
| Subjects with non-missing value | 5 |
| ≥ 3×ULN | 1 (3.0) |
|  | |
| ALT and/or AST |  |
| Subjects with non-missing value | 5 |
| ≥ 3×ULN | 1 (3.0) |
|  | |
| ALT |  |
| Subjects with non-missing value | 3 |
| ≥ 8×ULN | 0 |
|  | |
| AST |  |
| Subjects with non-missing value | 5 |
| ≥ 8×ULN | 0 |
|  | |
| ALT and/or AST |  |
| Subjects with non-missing value | 5 |
| ≥ 8×ULN | 0 |
|  | |
| Total Bilirubin (TBIL) |  |
| Subjects with non-missing value | 2 |
| ≥ 2×ULN | 0 |
|  | |
| TBIL |  |
| Subjects with non-missing value | 2 |
| ≥ 3×ULN | 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 14.3.6.2 Summary of Vital Sign Results - Phase II part 1 treatment-naive locally-advanced or metastatic NSCLC (Safety Analysis Set)**

|  | | Observed Value | | | |  | Change from Baseline | | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Parameter | Visit | n | Mean (STD) | Median (Q1, Q3) | Min, Max |  | n | Mean (STD) | Median (Q1, Q3) | Min, Max |
| Systolic Blood Pressure (mmHg) (N = 33) | Baseline | 33 | 121.8 (11.55) | 120.0 (113.0, 130.0) | 105, 151 |  | 0 |  |  |  |
|  | C1D1 Postdose | 33 | 125.4 (12.18) | 123.0 (117.0, 133.0) | 100, 152 |  | 33 | 3.5 (7.22) | 2.0 (-2.0, 5.0) | -8, 25 |
|  | C2D1 Predose | 32 | 120.1 (9.79) | 120.5 (112.5, 126.0) | 102, 145 |  | 32 | -1.4 (10.31) | 0.0 (-6.0, 3.0) | -28, 18 |
|  | C2D1 Postdose | 32 | 123.1 (9.40) | 122.0 (115.5, 128.5) | 109, 149 |  | 32 | 1.6 (10.50) | 3.0 (-7.0, 7.0) | -18, 33 |
|  | C3D1 Predose | 31 | 121.9 (9.48) | 121.0 (116.0, 129.0) | 104, 142 |  | 31 | 0.4 (10.87) | 0.0 (-7.0, 7.0) | -18, 26 |
|  | C3D1 Postdose | 31 | 121.9 (9.92) | 124.0 (113.0, 127.0) | 104, 143 |  | 31 | 0.4 (10.29) | 1.0 (-7.0, 7.0) | -20, 25 |
|  | C4D1 Predose | 30 | 120.9 (13.21) | 120.0 (112.0, 125.0) | 102, 155 |  | 30 | -1.1 (14.43) | 1.0 (-10.0, 4.0) | -33, 36 |
|  | C4D1 Postdose | 30 | 122.5 (12.08) | 122.0 (115.0, 127.0) | 102, 155 |  | 30 | 0.5 (12.41) | 2.5 (-6.0, 5.0) | -22, 35 |
|  | C5D1 Predose | 27 | 123.0 (9.61) | 121.0 (117.0, 130.0) | 105, 142 |  | 27 | 1.3 (10.48) | 2.0 (-4.0, 4.0) | -28, 26 |
|  | C5D1 Postdose | 27 | 122.2 (7.33) | 121.0 (118.0, 126.0) | 109, 142 |  | 27 | 0.5 (11.94) | 3.0 (-10.0, 6.0) | -31, 29 |
|  | C6D1 Predose | 27 | 122.3 (11.81) | 121.0 (112.0, 128.0) | 107, 148 |  | 27 | 0.7 (10.77) | 0.0 (-6.0, 6.0) | -19, 27 |
|  | C6D1 Postdose | 27 | 121.6 (12.72) | 122.0 (115.0, 128.0) | 96, 159 |  | 27 | -0.1 (13.04) | 0.0 (-10.0, 9.0) | -21, 32 |
|  | C7D1 Predose | 22 | 121.6 (10.80) | 121.0 (112.0, 130.0) | 106, 144 |  | 22 | -0.9 (13.12) | -1.0 (-9.0, 8.0) | -28, 25 |
|  | C7D1 Postdose | 22 | 123.8 (10.62) | 122.5 (115.0, 132.0) | 107, 146 |  | 22 | 1.3 (11.79) | 1.5 (-7.0, 6.0) | -22, 26 |
|  | C8D1 Predose | 15 | 123.2 (10.69) | 127.0 (115.0, 130.0) | 97, 139 |  | 15 | 2.4 (8.92) | 5.0 (-8.0, 10.0) | -12, 14 |
|  | C8D1 Postdose | 14 | 120.0 (9.77) | 119.5 (118.0, 124.0) | 103, 144 |  | 14 | 1.4 (9.65) | 3.5 (-10.0, 10.0) | -16, 13 |
|  | C9D1 Predose | 11 | 126.4 (15.43) | 131.0 (112.0, 140.0) | 101, 143 |  | 11 | 7.2 (12.15) | 10.0 (-6.0, 18.0) | -8, 27 |
|  | C9D1 Postdose | 11 | 123.5 (12.54) | 124.0 (115.0, 134.0) | 107, 147 |  | 11 | 4.3 (13.66) | 4.0 (-4.0, 15.0) | -23, 29 |
|  | C10D1 Predose | 6 | 135.5 (12.82) | 138.0 (125.0, 147.0) | 118, 147 |  | 6 | 15.3 (13.63) | 14.0 (8.0, 27.0) | -4, 33 |
|  | C10D1 Postdose | 6 | 124.3 (10.76) | 121.5 (117.0, 130.0) | 113, 143 |  | 6 | 4.2 (9.15) | 8.5 (-7.0, 11.0) | -8, 12 |
|  | C11D1 Predose | 6 | 125.5 (13.90) | 123.5 (115.0, 138.0) | 108, 145 |  | 6 | 5.3 (17.36) | 7.5 (2.0, 16.0) | -26, 25 |
|  | C11D1 Postdose | 6 | 129.8 (14.74) | 124.5 (121.0, 146.0) | 113, 150 |  | 6 | 9.7 (14.54) | 12.0 (-5.0, 18.0) | -9, 30 |
|  | C12D1 Predose | 5 | 130.0 (11.49) | 127.0 (124.0, 131.0) | 119, 149 |  | 5 | 8.4 (18.61) | 13.0 (2.0, 18.0) | -20, 29 |
|  | C12D1 Postdose | 4 | 128.0 (11.20) | 130.0 (119.0, 137.0) | 114, 138 |  | 4 | 6.5 (14.93) | 11.5 (-3.5, 16.5) | -15, 18 |
|  | C13D1 Predose | 4 | 125.5 (9.54) | 125.0 (117.5, 133.5) | 116, 136 |  | 4 | 0.0 (11.86) | 2.5 (-9.5, 9.5) | -15, 10 |
|  | C13D1 Postdose | 4 | 126.3 (5.12) | 125.5 (122.5, 130.0) | 121, 133 |  | 4 | 0.8 (18.63) | 9.0 (-10.0, 11.5) | -27, 12 |
|  | C14D1 Predose | 4 | 131.5 (8.54) | 135.0 (126.0, 137.0) | 119, 137 |  | 4 | 6.0 (13.69) | 10.5 (-2.0, 14.0) | -14, 17 |
|  | C14D1 Postdose | 4 | 127.0 (7.35) | 125.5 (121.0, 133.0) | 121, 136 |  | 4 | 1.5 (21.25) | 10.0 (-11.0, 14.0) | -30, 16 |
|  | C15D1 Predose | 3 | 139.0 (15.39) | 135.0 (126.0, 156.0) | 126, 156 |  | 3 | 8.0 (30.81) | 13.0 (-25.0, 36.0) | -25, 36 |
|  | C15D1 Postdose | 3 | 141.7 (13.61) | 137.0 (131.0, 157.0) | 131, 157 |  | 3 | 10.7 (28.75) | 15.0 (-20.0, 37.0) | -20, 37 |
|  | C16D1 Predose | 2 | 136.0 (19.80) | 136.0 (122.0, 150.0) | 122, 150 |  | 2 | 0.5 (41.72) | 0.5 (-29.0, 30.0) | -29, 30 |
|  | C16D1 Postdose | 2 | 136.5 (16.26) | 136.5 (125.0, 148.0) | 125, 148 |  | 2 | 1.0 (38.18) | 1.0 (-26.0, 28.0) | -26, 28 |
|  | C17D1 Predose | 2 | 127.5 (6.36) | 127.5 (123.0, 132.0) | 123, 132 |  | 2 | -8.0 (28.28) | -8.0 (-28.0, 12.0) | -28, 12 |
|  | C17D1 Postdose | 2 | 144.5 (28.99) | 144.5 (124.0, 165.0) | 124, 165 |  | 2 | 9.0 (50.91) | 9.0 (-27.0, 45.0) | -27, 45 |
|  | C18D1 Predose | 1 | 157.0 (NA) | 157.0 (157.0, 157.0) | 157, 157 |  | 1 | 37.0 (NA) | 37.0 (37.0, 37.0) | 37, 37 |
|  | C18D1 Postdose | 1 | 145.0 (NA) | 145.0 (145.0, 145.0) | 145, 145 |  | 1 | 25.0 (NA) | 25.0 (25.0, 25.0) | 25, 25 |
|  | End of Treatment | 6 | 114.5 (11.11) | 115.0 (105.0, 124.0) | 101, 127 |  | 6 | -0.5 (5.13) | 0.0 (-4.0, 3.0) | -8, 6 |
|  | | | | | | | | | | |
| Diastolic Blood Pressure (mmHg) (N = 33) | Baseline | 33 | 74.9 (8.35) | 75.0 (71.0, 79.0) | 56, 98 |  | 0 |  |  |  |
|  | C1D1 Postdose | 33 | 77.8 (7.59) | 77.0 (72.0, 82.0) | 65, 99 |  | 33 | 2.8 (7.43) | 1.0 (-1.0, 4.0) | -12, 22 |
|  | C2D1 Predose | 32 | 73.9 (8.48) | 72.5 (69.0, 78.0) | 55, 96 |  | 32 | -0.9 (7.66) | 0.0 (-7.0, 5.5) | -15, 15 |
|  | C2D1 Postdose | 32 | 75.5 (8.39) | 75.0 (68.0, 81.5) | 65, 100 |  | 32 | 0.8 (8.55) | -0.5 (-5.5, 5.0) | -16, 21 |
|  | C3D1 Predose | 31 | 73.3 (8.42) | 72.0 (68.0, 79.0) | 57, 100 |  | 31 | -1.3 (8.33) | -3.0 (-7.0, 4.0) | -17, 18 |
|  | C3D1 Postdose | 31 | 74.8 (10.01) | 73.0 (68.0, 82.0) | 57, 109 |  | 31 | 0.1 (8.48) | -1.0 (-6.0, 6.0) | -20, 22 |
|  | C4D1 Predose | 30 | 75.6 (9.84) | 76.0 (68.0, 82.0) | 58, 94 |  | 30 | 0.8 (9.31) | 1.0 (-5.0, 4.0) | -15, 29 |
|  | C4D1 Postdose | 30 | 75.0 (10.89) | 75.0 (65.0, 85.0) | 57, 95 |  | 30 | 0.2 (10.39) | 0.0 (-7.0, 5.0) | -22, 33 |
|  | C5D1 Predose | 27 | 74.8 (7.15) | 75.0 (70.0, 81.0) | 59, 87 |  | 27 | 0.5 (8.53) | 1.0 (-3.0, 5.0) | -24, 17 |
|  | C5D1 Postdose | 27 | 75.7 (7.83) | 76.0 (69.0, 82.0) | 62, 88 |  | 27 | 1.4 (9.26) | 2.0 (-3.0, 7.0) | -22, 16 |
|  | C6D1 Predose | 27 | 74.1 (9.77) | 77.0 (65.0, 81.0) | 57, 90 |  | 27 | -0.1 (9.05) | 0.0 (-5.0, 3.0) | -19, 28 |
|  | C6D1 Postdose | 27 | 73.8 (10.38) | 73.0 (65.0, 81.0) | 56, 99 |  | 27 | -0.5 (7.81) | 0.0 (-4.0, 4.0) | -20, 15 |
|  | C7D1 Predose | 22 | 74.5 (8.31) | 75.5 (69.0, 80.0) | 60, 93 |  | 22 | 0.1 (7.56) | 1.5 (-6.0, 5.0) | -18, 18 |
|  | C7D1 Postdose | 22 | 74.6 (9.72) | 77.5 (68.0, 81.0) | 49, 89 |  | 22 | 0.3 (8.94) | 1.5 (-7.0, 5.0) | -17, 24 |
|  | C8D1 Predose | 15 | 74.0 (8.91) | 73.0 (69.0, 79.0) | 61, 92 |  | 15 | 0.5 (8.31) | 1.0 (-5.0, 7.0) | -14, 15 |
|  | C8D1 Postdose | 14 | 74.2 (8.89) | 75.0 (69.0, 79.0) | 54, 90 |  | 14 | 2.5 (6.79) | 3.5 (-4.0, 6.0) | -9, 16 |
|  | C9D1 Predose | 11 | 76.4 (9.58) | 78.0 (72.0, 80.0) | 53, 88 |  | 11 | 3.7 (9.31) | 6.0 (-3.0, 12.0) | -11, 18 |
|  | C9D1 Postdose | 11 | 76.1 (8.47) | 78.0 (70.0, 84.0) | 60, 86 |  | 11 | 3.5 (7.72) | 5.0 (-3.0, 8.0) | -14, 14 |
|  | C10D1 Predose | 6 | 80.8 (8.84) | 82.5 (81.0, 85.0) | 64, 90 |  | 6 | 8.0 (9.65) | 9.5 (4.0, 12.0) | -8, 21 |
|  | C10D1 Postdose | 6 | 80.7 (8.82) | 81.0 (74.0, 89.0) | 68, 91 |  | 6 | 7.8 (9.72) | 12.0 (2.0, 12.0) | -9, 18 |
|  | C11D1 Predose | 6 | 81.0 (11.05) | 82.5 (75.0, 91.0) | 63, 92 |  | 6 | 8.2 (12.89) | 4.5 (2.0, 15.0) | -7, 30 |
|  | C11D1 Postdose | 6 | 79.3 (8.45) | 77.0 (72.0, 88.0) | 72, 90 |  | 6 | 6.5 (12.41) | 3.0 (-1.0, 16.0) | -8, 26 |
|  | C12D1 Predose | 5 | 82.0 (12.69) | 81.0 (73.0, 91.0) | 67, 98 |  | 5 | 9.2 (13.59) | 4.0 (0.0, 17.0) | -4, 29 |
|  | C12D1 Postdose | 4 | 84.3 (12.18) | 82.5 (75.0, 93.5) | 72, 100 |  | 4 | 11.0 (11.58) | 9.0 (1.5, 20.5) | 1, 25 |
|  | C13D1 Predose | 4 | 85.8 (11.62) | 84.5 (76.5, 95.0) | 74, 100 |  | 4 | 8.8 (12.84) | 2.5 (2.0, 15.5) | 2, 28 |
|  | C13D1 Postdose | 4 | 83.5 (7.85) | 82.5 (78.5, 88.5) | 75, 94 |  | 4 | 6.5 (10.47) | 4.5 (0.0, 13.0) | -4, 21 |
|  | C14D1 Predose | 4 | 82.8 (12.09) | 79.5 (75.0, 90.5) | 72, 100 |  | 4 | 5.8 (8.85) | 1.5 (1.0, 10.5) | 1, 19 |
|  | C14D1 Postdose | 4 | 81.8 (10.24) | 81.0 (75.5, 88.0) | 70, 95 |  | 4 | 4.8 (9.95) | 1.5 (-2.0, 11.5) | -3, 19 |
|  | C15D1 Predose | 3 | 84.0 (12.12) | 91.0 (70.0, 91.0) | 70, 91 |  | 3 | 7.0 (19.29) | -1.0 (-7.0, 29.0) | -7, 29 |
|  | C15D1 Postdose | 3 | 86.7 (8.39) | 91.0 (77.0, 92.0) | 77, 92 |  | 3 | 9.7 (18.77) | 6.0 (-7.0, 30.0) | -7, 30 |
|  | C16D1 Predose | 2 | 88.5 (2.12) | 88.5 (87.0, 90.0) | 87, 90 |  | 2 | 8.5 (23.33) | 8.5 (-8.0, 25.0) | -8, 25 |
|  | C16D1 Postdose | 2 | 90.5 (7.78) | 90.5 (85.0, 96.0) | 85, 96 |  | 2 | 10.5 (17.68) | 10.5 (-2.0, 23.0) | -2, 23 |
|  | C17D1 Predose | 2 | 98.5 (9.19) | 98.5 (92.0, 105.0) | 92, 105 |  | 2 | 18.5 (34.65) | 18.5 (-6.0, 43.0) | -6, 43 |
|  | C17D1 Postdose | 2 | 99.0 (11.31) | 99.0 (91.0, 107.0) | 91, 107 |  | 2 | 19.0 (36.77) | 19.0 (-7.0, 45.0) | -7, 45 |
|  | C18D1 Predose | 1 | 95.0 (NA) | 95.0 (95.0, 95.0) | 95, 95 |  | 1 | 33.0 (NA) | 33.0 (33.0, 33.0) | 33, 33 |
|  | C18D1 Postdose | 1 | 90.0 (NA) | 90.0 (90.0, 90.0) | 90, 90 |  | 1 | 28.0 (NA) | 28.0 (28.0, 28.0) | 28, 28 |
|  | End of Treatment | 6 | 73.5 (6.89) | 74.5 (70.0, 79.0) | 62, 81 |  | 6 | -2.3 (6.71) | -2.5 (-8.0, 0.0) | -10, 9 |
|  | | | | | | | | | | |
| Pulse Rate (beats/min) (N = 33) | Baseline | 33 | 79.2 (10.43) | 81.0 (72.0, 87.0) | 60, 98 |  | 0 |  |  |  |
|  | C1D1 Postdose | 33 | 80.7 (9.65) | 82.0 (74.0, 87.0) | 62, 96 |  | 33 | 1.5 (5.20) | 1.0 (-1.0, 4.0) | -6, 22 |
|  | C2D1 Predose | 32 | 81.5 (11.76) | 79.5 (72.0, 93.0) | 60, 107 |  | 32 | 2.7 (11.97) | 4.5 (-5.0, 10.5) | -29, 30 |
|  | C2D1 Postdose | 32 | 80.8 (10.72) | 80.0 (71.0, 88.5) | 65, 101 |  | 32 | 1.9 (11.69) | 1.5 (-4.0, 7.5) | -30, 31 |
|  | C3D1 Predose | 31 | 80.6 (9.86) | 81.0 (72.0, 89.0) | 61, 99 |  | 31 | 1.7 (12.12) | 1.0 (-5.0, 8.0) | -28, 27 |
|  | C3D1 Postdose | 31 | 79.9 (9.91) | 80.0 (74.0, 86.0) | 62, 102 |  | 31 | 1.0 (11.21) | 0.0 (-6.0, 7.0) | -24, 27 |
|  | C4D1 Predose | 30 | 84.0 (12.26) | 85.5 (76.0, 92.0) | 60, 116 |  | 30 | 5.1 (15.24) | 3.0 (-4.0, 13.0) | -23, 42 |
|  | C4D1 Postdose | 30 | 82.7 (11.23) | 83.0 (74.0, 89.0) | 60, 110 |  | 30 | 3.8 (13.44) | 3.0 (-5.0, 11.0) | -20, 36 |
|  | C5D1 Predose | 27 | 84.8 (14.31) | 83.0 (72.0, 96.0) | 62, 119 |  | 27 | 5.9 (12.08) | 5.0 (-4.0, 18.0) | -13, 32 |
|  | C5D1 Postdose | 27 | 83.4 (11.73) | 82.0 (75.0, 94.0) | 61, 110 |  | 27 | 4.5 (11.97) | 5.0 (-3.0, 15.0) | -16, 26 |
|  | C6D1 Predose | 27 | 81.8 (12.63) | 87.0 (69.0, 92.0) | 58, 106 |  | 27 | 2.9 (12.49) | 3.0 (-6.0, 10.0) | -15, 31 |
|  | C6D1 Postdose | 27 | 80.4 (12.17) | 82.0 (68.0, 90.0) | 60, 101 |  | 27 | 1.6 (12.58) | 1.0 (-9.0, 10.0) | -14, 29 |
|  | C7D1 Predose | 22 | 83.8 (13.37) | 81.5 (75.0, 97.0) | 62, 106 |  | 22 | 4.4 (9.20) | 7.0 (-1.0, 12.0) | -12, 19 |
|  | C7D1 Postdose | 22 | 81.9 (11.50) | 82.0 (72.0, 88.0) | 61, 108 |  | 22 | 2.4 (10.10) | 3.0 (-4.0, 6.0) | -18, 22 |
|  | C8D1 Predose | 15 | 84.2 (13.31) | 88.0 (76.0, 91.0) | 63, 112 |  | 15 | 1.2 (12.50) | 0.0 (-7.0, 5.0) | -19, 27 |
|  | C8D1 Postdose | 14 | 82.2 (11.26) | 84.0 (77.0, 88.0) | 63, 99 |  | 14 | -0.5 (11.21) | -1.0 (-7.0, 4.0) | -21, 21 |
|  | C9D1 Predose | 11 | 78.3 (12.35) | 76.0 (65.0, 91.0) | 60, 93 |  | 11 | -2.8 (13.00) | -4.0 (-10.0, 8.0) | -24, 21 |
|  | C9D1 Postdose | 11 | 80.5 (13.97) | 81.0 (64.0, 92.0) | 62, 103 |  | 11 | -0.5 (17.05) | -3.0 (-9.0, 10.0) | -22, 40 |
|  | C10D1 Predose | 6 | 92.5 (11.22) | 95.0 (80.0, 101.0) | 79, 105 |  | 6 | 12.3 (9.03) | 15.0 (9.0, 18.0) | -4, 21 |
|  | C10D1 Postdose | 6 | 91.0 (12.36) | 93.5 (86.0, 100.0) | 70, 103 |  | 6 | 10.8 (12.98) | 14.0 (7.0, 20.0) | -13, 23 |
|  | C11D1 Predose | 6 | 80.3 (4.46) | 80.5 (76.0, 83.0) | 75, 87 |  | 6 | 0.2 (7.05) | -1.5 (-4.0, 4.0) | -8, 12 |
|  | C11D1 Postdose | 6 | 80.8 (4.83) | 79.0 (78.0, 82.0) | 77, 90 |  | 6 | 0.7 (7.12) | -2.0 (-4.0, 3.0) | -5, 14 |
|  | C12D1 Predose | 5 | 85.2 (8.64) | 87.0 (78.0, 90.0) | 75, 96 |  | 5 | 5.6 (5.68) | 6.0 (4.0, 9.0) | -3, 12 |
|  | C12D1 Postdose | 4 | 86.8 (8.26) | 83.5 (82.0, 91.5) | 81, 99 |  | 4 | 8.0 (9.80) | 6.0 (0.0, 16.0) | 0, 20 |
|  | C13D1 Predose | 4 | 86.5 (9.47) | 86.5 (80.0, 93.0) | 75, 98 |  | 4 | 8.0 (13.29) | 6.5 (-2.0, 18.0) | -6, 25 |
|  | C13D1 Postdose | 4 | 89.8 (9.88) | 89.5 (83.0, 96.5) | 78, 102 |  | 4 | 11.3 (13.38) | 10.0 (1.0, 21.5) | -3, 28 |
|  | C14D1 Predose | 4 | 81.8 (9.74) | 80.0 (75.0, 88.5) | 72, 95 |  | 4 | 3.3 (10.47) | 3.5 (-5.0, 11.5) | -9, 15 |
|  | C14D1 Postdose | 4 | 82.3 (7.63) | 80.5 (77.5, 87.0) | 75, 93 |  | 4 | 3.8 (10.78) | 1.5 (-4.5, 12.0) | -6, 18 |
|  | C15D1 Predose | 3 | 94.0 (7.94) | 97.0 (85.0, 100.0) | 85, 100 |  | 3 | 16.3 (6.03) | 17.0 (10.0, 22.0) | 10, 22 |
|  | C15D1 Postdose | 3 | 94.7 (5.13) | 96.0 (89.0, 99.0) | 89, 99 |  | 3 | 17.0 (8.54) | 16.0 (9.0, 26.0) | 9, 26 |
|  | C16D1 Predose | 2 | 80.0 (9.90) | 80.0 (73.0, 87.0) | 73, 87 |  | 2 | 5.0 (7.07) | 5.0 (0.0, 10.0) | 0, 10 |
|  | C16D1 Postdose | 2 | 82.5 (7.78) | 82.5 (77.0, 88.0) | 77, 88 |  | 2 | 7.5 (9.19) | 7.5 (1.0, 14.0) | 1, 14 |
|  | C17D1 Predose | 2 | 80.0 (7.07) | 80.0 (75.0, 85.0) | 75, 85 |  | 2 | 5.0 (9.90) | 5.0 (-2.0, 12.0) | -2, 12 |
|  | C17D1 Postdose | 2 | 91.0 (5.66) | 91.0 (87.0, 95.0) | 87, 95 |  | 2 | 16.0 (22.63) | 16.0 (0.0, 32.0) | 0, 32 |
|  | C18D1 Predose | 1 | 85.0 (NA) | 85.0 (85.0, 85.0) | 85, 85 |  | 1 | 22.0 (NA) | 22.0 (22.0, 22.0) | 22, 22 |
|  | C18D1 Postdose | 1 | 97.0 (NA) | 97.0 (97.0, 97.0) | 97, 97 |  | 1 | 34.0 (NA) | 34.0 (34.0, 34.0) | 34, 34 |
|  | End of Treatment | 6 | 90.5 (17.57) | 91.5 (82.0, 98.0) | 64, 116 |  | 6 | 11.7 (19.87) | 8.5 (0.0, 25.0) | -14, 42 |
|  | | | | | | | | | | |
| Respiratory Rate (breaths/min) (N = 33) | Baseline | 33 | 18.6 (1.03) | 18.0 (18.0, 19.0) | 16, 20 |  | 0 |  |  |  |
|  | C1D1 Postdose | 33 | 18.5 (1.00) | 18.0 (18.0, 19.0) | 16, 20 |  | 33 | -0.0 (0.64) | 0.0 (0.0, 0.0) | -1, 2 |
|  | C2D1 Predose | 32 | 18.8 (1.30) | 18.0 (18.0, 20.0) | 16, 21 |  | 32 | 0.2 (0.87) | 0.0 (0.0, 1.0) | -2, 2 |
|  | C2D1 Postdose | 32 | 18.7 (1.15) | 18.0 (18.0, 20.0) | 17, 21 |  | 32 | 0.1 (0.71) | 0.0 (0.0, 0.0) | -1, 2 |
|  | C3D1 Predose | 31 | 18.4 (1.09) | 18.0 (18.0, 19.0) | 15, 20 |  | 31 | -0.1 (0.68) | 0.0 (0.0, 0.0) | -2, 1 |
|  | C3D1 Postdose | 31 | 18.5 (1.06) | 18.0 (18.0, 19.0) | 16, 21 |  | 31 | 0.0 (0.80) | 0.0 (0.0, 0.0) | -1, 2 |
|  | C4D1 Predose | 30 | 18.4 (1.17) | 18.0 (18.0, 19.0) | 16, 21 |  | 30 | 0.0 (0.53) | 0.0 (0.0, 0.0) | -1, 1 |
|  | C4D1 Postdose | 30 | 18.6 (1.13) | 18.0 (18.0, 20.0) | 17, 21 |  | 30 | 0.2 (0.65) | 0.0 (0.0, 0.0) | -1, 2 |
|  | C5D1 Predose | 27 | 18.6 (1.31) | 18.0 (18.0, 20.0) | 16, 21 |  | 27 | 0.2 (0.85) | 0.0 (0.0, 1.0) | -1, 2 |
|  | C5D1 Postdose | 27 | 18.6 (1.05) | 18.0 (18.0, 20.0) | 17, 20 |  | 27 | 0.1 (0.66) | 0.0 (0.0, 1.0) | -1, 1 |
|  | C6D1 Predose | 27 | 18.4 (1.19) | 18.0 (18.0, 19.0) | 17, 21 |  | 27 | 0.0 (0.83) | 0.0 (-1.0, 1.0) | -1, 2 |
|  | C6D1 Postdose | 27 | 18.7 (1.27) | 18.0 (18.0, 20.0) | 17, 21 |  | 27 | 0.3 (1.02) | 0.0 (-1.0, 1.0) | -1, 2 |
|  | C7D1 Predose | 22 | 18.4 (1.33) | 18.0 (18.0, 19.0) | 16, 22 |  | 22 | 0.1 (0.87) | 0.0 (0.0, 0.0) | -1, 3 |
|  | C7D1 Postdose | 22 | 18.6 (1.01) | 18.5 (18.0, 19.0) | 17, 20 |  | 22 | 0.3 (0.72) | 0.0 (0.0, 1.0) | -1, 1 |
|  | C8D1 Predose | 15 | 18.5 (1.41) | 18.0 (18.0, 20.0) | 16, 21 |  | 15 | 0.3 (0.80) | 0.0 (0.0, 1.0) | -1, 2 |
|  | C8D1 Postdose | 14 | 18.5 (1.29) | 19.0 (18.0, 19.0) | 16, 21 |  | 14 | 0.4 (0.93) | 1.0 (0.0, 1.0) | -2, 1 |
|  | C9D1 Predose | 11 | 18.5 (1.04) | 18.0 (18.0, 20.0) | 17, 20 |  | 11 | 0.4 (0.50) | 0.0 (0.0, 1.0) | 0, 1 |
|  | C9D1 Postdose | 11 | 17.8 (2.89) | 18.0 (17.0, 20.0) | 10, 21 |  | 11 | -0.4 (2.98) | 0.0 (0.0, 1.0) | -9, 2 |
|  | C10D1 Predose | 6 | 19.2 (1.33) | 19.0 (18.0, 20.0) | 18, 21 |  | 6 | 0.5 (0.84) | 0.0 (0.0, 1.0) | 0, 2 |
|  | C10D1 Postdose | 6 | 19.2 (0.98) | 19.5 (18.0, 20.0) | 18, 20 |  | 6 | 0.5 (0.55) | 0.5 (0.0, 1.0) | 0, 1 |
|  | C11D1 Predose | 6 | 18.5 (0.55) | 18.5 (18.0, 19.0) | 18, 19 |  | 6 | -0.2 (0.41) | 0.0 (0.0, 0.0) | -1, 0 |
|  | C11D1 Postdose | 6 | 18.7 (1.21) | 18.5 (18.0, 20.0) | 17, 20 |  | 6 | 0.0 (0.63) | 0.0 (0.0, 0.0) | -1, 1 |
|  | C12D1 Predose | 5 | 19.4 (0.89) | 20.0 (19.0, 20.0) | 18, 20 |  | 5 | 0.6 (0.55) | 1.0 (0.0, 1.0) | 0, 1 |
|  | C12D1 Postdose | 4 | 19.5 (1.00) | 20.0 (19.0, 20.0) | 18, 20 |  | 4 | 0.5 (0.58) | 0.5 (0.0, 1.0) | 0, 1 |
|  | C13D1 Predose | 4 | 19.3 (0.96) | 19.5 (18.5, 20.0) | 18, 20 |  | 4 | 0.5 (0.58) | 0.5 (0.0, 1.0) | 0, 1 |
|  | C13D1 Postdose | 4 | 18.8 (1.50) | 19.0 (17.5, 20.0) | 17, 20 |  | 4 | 0.0 (0.82) | 0.0 (-0.5, 0.5) | -1, 1 |
|  | C14D1 Predose | 4 | 18.8 (0.96) | 18.5 (18.0, 19.5) | 18, 20 |  | 4 | 0.0 (0.00) | 0.0 (0.0, 0.0) | 0, 0 |
|  | C14D1 Postdose | 4 | 18.5 (1.73) | 18.5 (17.0, 20.0) | 17, 20 |  | 4 | -0.3 (0.96) | -0.5 (-1.0, 0.5) | -1, 1 |
|  | C15D1 Predose | 3 | 19.7 (0.58) | 20.0 (19.0, 20.0) | 19, 20 |  | 3 | 0.7 (0.58) | 1.0 (0.0, 1.0) | 0, 1 |
|  | C15D1 Postdose | 3 | 19.7 (1.53) | 20.0 (18.0, 21.0) | 18, 21 |  | 3 | 0.7 (1.15) | 0.0 (0.0, 2.0) | 0, 2 |
|  | C16D1 Predose | 2 | 19.0 (0.00) | 19.0 (19.0, 19.0) | 19, 19 |  | 2 | -0.5 (0.71) | -0.5 (-1.0, 0.0) | -1, 0 |
|  | C16D1 Postdose | 2 | 20.0 (0.00) | 20.0 (20.0, 20.0) | 20, 20 |  | 2 | 0.5 (0.71) | 0.5 (0.0, 1.0) | 0, 1 |
|  | C17D1 Predose | 2 | 19.0 (0.00) | 19.0 (19.0, 19.0) | 19, 19 |  | 2 | -0.5 (0.71) | -0.5 (-1.0, 0.0) | -1, 0 |
|  | C17D1 Postdose | 2 | 19.5 (0.71) | 19.5 (19.0, 20.0) | 19, 20 |  | 2 | 0.0 (1.41) | 0.0 (-1.0, 1.0) | -1, 1 |
|  | C18D1 Predose | 1 | 20.0 (NA) | 20.0 (20.0, 20.0) | 20, 20 |  | 1 | 1.0 (NA) | 1.0 (1.0, 1.0) | 1, 1 |
|  | C18D1 Postdose | 1 | 21.0 (NA) | 21.0 (21.0, 21.0) | 21, 21 |  | 1 | 2.0 (NA) | 2.0 (2.0, 2.0) | 2, 2 |
|  | End of Treatment | 6 | 19.2 (0.98) | 19.5 (18.0, 20.0) | 18, 20 |  | 6 | 0.0 (0.63) | 0.0 (0.0, 0.0) | -1, 1 |
|  | | | | | | | | | | |
| Temperature (C) (N = 33) | Baseline | 33 | 36.51 (0.304) | 36.50 (36.30, 36.60) | 36.1, 37.3 |  | 0 |  |  |  |
|  | C1D1 Postdose | 33 | 36.56 (0.254) | 36.50 (36.40, 36.80) | 36.2, 37.2 |  | 33 | 0.05 (0.173) | 0.10 (0.00, 0.10) | -0.4, 0.4 |
|  | C2D1 Predose | 32 | 36.49 (0.246) | 36.50 (36.30, 36.65) | 36.1, 37.0 |  | 32 | -0.01 (0.265) | 0.00 (-0.20, 0.10) | -0.5, 0.5 |
|  | C2D1 Postdose | 32 | 36.49 (0.266) | 36.45 (36.30, 36.65) | 36.1, 37.1 |  | 32 | -0.01 (0.268) | 0.00 (-0.15, 0.20) | -0.7, 0.6 |
|  | C3D1 Predose | 31 | 36.49 (0.240) | 36.50 (36.30, 36.60) | 36.2, 37.2 |  | 31 | -0.01 (0.261) | 0.00 (-0.10, 0.10) | -0.7, 0.4 |
|  | C3D1 Postdose | 31 | 36.52 (0.235) | 36.50 (36.30, 36.70) | 36.2, 37.0 |  | 31 | 0.02 (0.220) | 0.00 (-0.10, 0.20) | -0.4, 0.5 |
|  | C4D1 Predose | 30 | 36.48 (0.277) | 36.45 (36.30, 36.60) | 36.1, 37.2 |  | 30 | -0.03 (0.331) | 0.00 (-0.10, 0.10) | -0.9, 0.6 |
|  | C4D1 Postdose | 30 | 36.47 (0.269) | 36.40 (36.30, 36.60) | 36.1, 37.1 |  | 30 | -0.04 (0.237) | 0.00 (-0.20, 0.10) | -0.8, 0.4 |
|  | C5D1 Predose | 27 | 36.47 (0.262) | 36.50 (36.30, 36.60) | 36.0, 37.4 |  | 27 | -0.06 (0.330) | 0.00 (-0.20, 0.10) | -1.0, 0.5 |
|  | C5D1 Postdose | 27 | 36.53 (0.266) | 36.50 (36.30, 36.70) | 36.2, 37.4 |  | 27 | 0.01 (0.303) | 0.00 (-0.10, 0.20) | -0.7, 0.7 |
|  | C6D1 Predose | 27 | 36.44 (0.238) | 36.40 (36.20, 36.60) | 36.1, 36.9 |  | 27 | -0.08 (0.298) | -0.10 (-0.20, 0.10) | -0.8, 0.5 |
|  | C6D1 Postdose | 27 | 36.53 (0.235) | 36.50 (36.40, 36.70) | 36.1, 37.1 |  | 27 | 0.01 (0.216) | 0.00 (-0.10, 0.20) | -0.5, 0.5 |
|  | C7D1 Predose | 22 | 36.50 (0.336) | 36.50 (36.20, 36.50) | 36.0, 37.3 |  | 22 | -0.07 (0.333) | -0.05 (-0.20, 0.10) | -0.8, 0.7 |
|  | C7D1 Postdose | 22 | 36.55 (0.311) | 36.50 (36.30, 36.60) | 36.2, 37.4 |  | 22 | -0.01 (0.318) | 0.00 (-0.10, 0.10) | -0.8, 0.9 |
|  | C8D1 Predose | 15 | 36.51 (0.303) | 36.60 (36.30, 36.70) | 36.0, 37.2 |  | 15 | -0.10 (0.307) | -0.10 (-0.20, 0.10) | -0.8, 0.3 |
|  | C8D1 Postdose | 14 | 36.44 (0.265) | 36.40 (36.30, 36.70) | 36.0, 36.8 |  | 14 | -0.16 (0.287) | -0.15 (-0.40, 0.00) | -0.7, 0.3 |
|  | C9D1 Predose | 11 | 36.40 (0.228) | 36.40 (36.20, 36.60) | 36.1, 36.8 |  | 11 | -0.24 (0.375) | -0.10 (-0.50, 0.00) | -1.0, 0.1 |
|  | C9D1 Postdose | 11 | 36.39 (0.255) | 36.30 (36.20, 36.60) | 36.1, 36.9 |  | 11 | -0.25 (0.308) | -0.20 (-0.30, -0.10) | -1.0, 0.1 |
|  | C10D1 Predose | 6 | 36.78 (0.445) | 36.65 (36.60, 36.90) | 36.3, 37.6 |  | 6 | -0.05 (0.274) | -0.05 (-0.30, 0.20) | -0.4, 0.3 |
|  | C10D1 Postdose | 6 | 36.72 (0.542) | 36.60 (36.30, 36.90) | 36.2, 37.7 |  | 6 | -0.12 (0.449) | -0.10 (-0.20, 0.20) | -0.9, 0.4 |
|  | C11D1 Predose | 6 | 36.48 (0.240) | 36.55 (36.20, 36.60) | 36.2, 36.8 |  | 6 | -0.35 (0.251) | -0.35 (-0.60, -0.20) | -0.6, 0.0 |
|  | C11D1 Postdose | 6 | 36.60 (0.405) | 36.60 (36.20, 36.70) | 36.2, 37.3 |  | 6 | -0.23 (0.225) | -0.20 (-0.50, 0.00) | -0.5, 0.0 |
|  | C12D1 Predose | 5 | 36.62 (0.342) | 36.50 (36.50, 36.80) | 36.2, 37.1 |  | 5 | -0.16 (0.182) | -0.20 (-0.20, -0.10) | -0.4, 0.1 |
|  | C12D1 Postdose | 4 | 36.50 (0.216) | 36.45 (36.35, 36.65) | 36.3, 36.8 |  | 4 | -0.15 (0.493) | -0.10 (-0.45, 0.15) | -0.8, 0.4 |
|  | C13D1 Predose | 4 | 36.45 (0.370) | 36.40 (36.15, 36.75) | 36.1, 36.9 |  | 4 | -0.23 (0.171) | -0.25 (-0.35, -0.10) | -0.4, 0.0 |
|  | C13D1 Postdose | 4 | 36.48 (0.275) | 36.45 (36.25, 36.70) | 36.2, 36.8 |  | 4 | -0.20 (0.216) | -0.15 (-0.35, -0.05) | -0.5, 0.0 |
|  | C14D1 Predose | 4 | 36.45 (0.265) | 36.40 (36.25, 36.65) | 36.2, 36.8 |  | 4 | -0.23 (0.189) | -0.15 (-0.35, -0.10) | -0.5, -0.1 |
|  | C14D1 Postdose | 4 | 36.65 (0.300) | 36.70 (36.40, 36.90) | 36.3, 36.9 |  | 4 | -0.03 (0.377) | -0.10 (-0.25, 0.20) | -0.4, 0.5 |
|  | C15D1 Predose | 3 | 36.70 (0.458) | 36.60 (36.30, 37.20) | 36.3, 37.2 |  | 3 | -0.07 (0.058) | -0.10 (-0.10, 0.00) | -0.1, 0.0 |
|  | C15D1 Postdose | 3 | 36.63 (0.416) | 36.50 (36.30, 37.10) | 36.3, 37.1 |  | 3 | -0.13 (0.058) | -0.10 (-0.20, -0.10) | -0.2, -0.1 |
|  | C16D1 Predose | 2 | 36.25 (0.071) | 36.25 (36.20, 36.30) | 36.2, 36.3 |  | 2 | -0.25 (0.071) | -0.25 (-0.30, -0.20) | -0.3, -0.2 |
|  | C16D1 Postdose | 2 | 36.55 (0.354) | 36.55 (36.30, 36.80) | 36.3, 36.8 |  | 2 | 0.05 (0.495) | 0.05 (-0.30, 0.40) | -0.3, 0.4 |
|  | C17D1 Predose | 2 | 36.45 (0.212) | 36.45 (36.30, 36.60) | 36.3, 36.6 |  | 2 | -0.05 (0.071) | -0.05 (-0.10, 0.00) | -0.1, 0.0 |
|  | C17D1 Postdose | 2 | 36.40 (0.141) | 36.40 (36.30, 36.50) | 36.3, 36.5 |  | 2 | -0.10 (0.000) | -0.10 (-0.10, -0.10) | -0.1, -0.1 |
|  | C18D1 Predose | 1 | 36.60 (NA) | 36.60 (36.60, 36.60) | 36.6, 36.6 |  | 1 | 0.20 (NA) | 0.20 (0.20, 0.20) | 0.2, 0.2 |
|  | C18D1 Postdose | 1 | 36.30 (NA) | 36.30 (36.30, 36.30) | 36.3, 36.3 |  | 1 | -0.10 (NA) | -0.10 (-0.10, -0.10) | -0.1, -0.1 |
|  | End of Treatment | 6 | 36.38 (0.117) | 36.40 (36.30, 36.50) | 36.2, 36.5 |  | 6 | 0.07 (0.186) | 0.05 (-0.10, 0.10) | -0.1, 0.4 |

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 14.3.7.2 Summary of Shifts from Baseline to Last/Worst Post-baseline in ECOG Assessment - Phase II part 1 treatment-naive locally-advanced or metastatic NSCLC (Safety Analysis Set)**

|  | | Post-baseline | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Visit | Baseline | 0 | 1 | 2 |  | 3 | 4 | Missing | Total |
| Last Post-Baseline (N = 33) | 0 | 3 (9.1) | 0 | 0 |  | 0 | 0 | 0 | 3 (9.1) |
|  | 1 | 0 | 28 (84.8) | 0 |  | 1 (3.0) | 0 | 1 (3.0) | 30 (90.9) |
|  | Total | 3 (9.1) | 28 (84.8) | 0 |  | 1 (3.0) | 0 | 1 (3.0) | 33 (100) |
|  | | | | | | | | | |
| Worst Post-Baseline (N = 33) | 0 | 3 (9.1) | 0 | 0 |  | 0 | 0 | 0 | 3 (9.1) |
|  | 1 | 0 | 28 (84.8) | 0 |  | 1 (3.0) | 0 | 1 (3.0) | 30 (90.9) |
|  | Total | 3 (9.1) | 28 (84.8) | 0 |  | 1 (3.0) | 0 | 1 (3.0) | 33 (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 14.3.8.1.2 Summary of 12-Lead ECG Parameters - Phase II part 1 treatment-naive locally-advanced or metastatic NSCLC (Safety Analysis Set)**

|  | | Observed Value | | | |  | Change from Baseline | | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Parameter | Visit | n | Mean (STD) | Median (Q1, Q3) | Min, Max |  | n | Mean (STD) | Median (Q1, Q3) | Min, Max |
| Heart Rate (beats/min) (N = 33) | Baseline | 33 | 82.3 (15.58) | 81.0 (72.0, 88.0) | 62, 132 |  | 0 |  |  |  |
|  | C1D1 | 33 | 72.8 (12.79) | 73.0 (64.0, 81.0) | 49, 112 |  | 33 | -9.4 (14.23) | -6.0 (-13.0, -3.0) | -69, 15 |
|  | C1D8 | 33 | 74.5 (12.07) | 74.0 (67.0, 82.0) | 53, 102 |  | 33 | -7.7 (16.75) | -5.0 (-10.0, 1.0) | -75, 19 |
|  | C2D1 | 32 | 77.3 (11.63) | 75.0 (69.0, 88.0) | 57, 99 |  | 32 | -3.8 (15.36) | -1.0 (-14.5, 5.0) | -59, 26 |
|  | C3D1 | 31 | 77.6 (10.95) | 77.0 (72.0, 86.0) | 53, 99 |  | 31 | -4.0 (12.87) | -3.0 (-9.0, 4.0) | -43, 16 |
|  | C4D1 | 30 | 79.6 (14.39) | 77.5 (70.0, 88.0) | 49, 120 |  | 30 | -2.4 (13.69) | -1.5 (-10.0, 8.0) | -41, 22 |
|  | C5D1 | 27 | 78.0 (11.10) | 79.0 (72.0, 86.0) | 60, 103 |  | 27 | -2.9 (10.55) | -2.0 (-8.0, 4.0) | -27, 18 |
|  | C6D1 | 27 | 77.4 (12.30) | 74.0 (68.0, 87.0) | 60, 103 |  | 27 | -3.4 (10.04) | -1.0 (-7.0, 3.0) | -30, 11 |
|  | C7D1 | 22 | 75.5 (10.90) | 72.5 (68.0, 86.0) | 57, 98 |  | 22 | -4.6 (11.41) | -4.0 (-9.0, 4.0) | -30, 13 |
|  | C8D1 | 15 | 75.2 (11.09) | 72.0 (68.0, 84.0) | 59, 96 |  | 15 | -4.4 (9.36) | -3.0 (-11.0, 3.0) | -28, 6 |
|  | C9D1 | 11 | 77.2 (14.06) | 75.0 (68.0, 89.0) | 59, 105 |  | 11 | -1.1 (15.14) | 1.0 (-11.0, 6.0) | -31, 30 |
|  | C10D1 | 6 | 81.3 (11.71) | 84.0 (71.0, 90.0) | 64, 95 |  | 6 | -0.8 (14.25) | 1.5 (-5.0, 8.0) | -26, 15 |
|  | C11D1 | 6 | 76.8 (14.47) | 79.5 (67.0, 86.0) | 54, 95 |  | 6 | -5.3 (15.76) | 0.0 (-7.0, 4.0) | -36, 7 |
|  | C12D1 | 5 | 76.8 (5.54) | 78.0 (76.0, 79.0) | 68, 83 |  | 5 | -3.8 (5.31) | -4.0 (-8.0, 1.0) | -10, 2 |
|  | C13D1 | 4 | 75.8 (8.81) | 74.0 (70.5, 81.0) | 67, 88 |  | 4 | -3.3 (9.71) | -3.5 (-11.0, 4.5) | -14, 8 |
|  | C14D1 | 4 | 83.5 (15.84) | 79.5 (71.0, 96.0) | 71, 104 |  | 4 | 4.5 (8.50) | 3.0 (-1.5, 10.5) | -4, 16 |
|  | C15D1 | 3 | 88.3 (2.08) | 89.0 (86.0, 90.0) | 86, 90 |  | 3 | 8.0 (13.23) | 3.0 (-2.0, 23.0) | -2, 23 |
|  | C16D1 | 2 | 77.5 (17.68) | 77.5 (65.0, 90.0) | 65, 90 |  | 2 | 0.5 (2.12) | 0.5 (-1.0, 2.0) | -1, 2 |
|  | C17D1 | 2 | 75.5 (2.12) | 75.5 (74.0, 77.0) | 74, 77 |  | 2 | -1.5 (13.44) | -1.5 (-11.0, 8.0) | -11, 8 |
|  | C18D1 | 1 | 85.0 (NA) | 85.0 (85.0, 85.0) | 85, 85 |  | 1 | 19.0 (NA) | 19.0 (19.0, 19.0) | 19, 19 |
|  | End of Treatment | 6 | 98.2 (22.09) | 89.5 (85.0, 102.0) | 82, 141 |  | 6 | 7.5 (32.97) | 12.0 (-4.0, 18.0) | -47, 54 |
|  | | | | | | | | | | |
| PR Interval (ms) (N = 33) | Baseline | 33 | 166.5 (28.98) | 162.0 (154.0, 178.0) | 126, 256 |  | 0 |  |  |  |
|  | C1D1 | 33 | 172.6 (34.25) | 168.0 (148.0, 186.0) | 122, 276 |  | 33 | 6.1 (13.91) | 7.0 (-2.0, 12.0) | -28, 38 |
|  | C1D8 | 33 | 179.1 (29.99) | 176.0 (160.0, 190.0) | 138, 258 |  | 33 | 12.6 (16.82) | 12.0 (5.0, 22.0) | -36, 50 |
|  | C2D1 | 32 | 178.3 (32.04) | 170.0 (159.0, 185.5) | 136, 280 |  | 32 | 12.3 (14.13) | 12.5 (2.0, 22.0) | -18, 44 |
|  | C3D1 | 31 | 180.4 (30.61) | 178.0 (156.0, 196.0) | 134, 270 |  | 31 | 14.6 (14.86) | 18.0 (8.0, 24.0) | -24, 40 |
|  | C4D1 | 30 | 184.3 (32.75) | 178.0 (163.0, 198.0) | 144, 280 |  | 30 | 19.0 (17.32) | 17.0 (5.0, 32.0) | -12, 60 |
|  | C5D1 | 27 | 180.9 (34.33) | 176.0 (156.0, 197.0) | 142, 298 |  | 27 | 16.9 (12.78) | 16.0 (8.0, 20.0) | -10, 50 |
|  | C6D1 | 27 | 179.1 (32.70) | 171.0 (156.0, 196.0) | 136, 292 |  | 27 | 15.1 (14.25) | 14.0 (8.0, 28.0) | -18, 36 |
|  | C7D1 | 22 | 185.4 (34.83) | 183.0 (162.0, 194.0) | 132, 280 |  | 22 | 18.0 (14.93) | 15.0 (10.0, 29.0) | -18, 54 |
|  | C8D1 | 15 | 179.3 (28.58) | 177.0 (154.0, 196.0) | 145, 256 |  | 15 | 17.7 (8.54) | 16.0 (12.0, 26.0) | 0, 34 |
|  | C9D1 | 11 | 173.7 (27.40) | 172.0 (153.0, 180.0) | 140, 228 |  | 11 | 21.0 (15.09) | 20.0 (10.0, 27.0) | 4, 48 |
|  | C10D1 | 6 | 163.3 (20.42) | 170.0 (152.0, 176.0) | 128, 184 |  | 6 | 12.3 (15.92) | 16.0 (-4.0, 26.0) | -8, 28 |
|  | C11D1 | 6 | 170.0 (17.16) | 167.0 (158.0, 176.0) | 152, 200 |  | 6 | 19.0 (8.46) | 19.0 (12.0, 26.0) | 8, 30 |
|  | C12D1 | 5 | 160.2 (14.67) | 158.0 (151.0, 174.0) | 142, 176 |  | 5 | 13.0 (8.19) | 8.0 (8.0, 18.0) | 6, 25 |
|  | C13D1 | 4 | 170.5 (16.68) | 173.0 (157.0, 184.0) | 150, 186 |  | 4 | 18.0 (5.66) | 16.0 (14.0, 22.0) | 14, 26 |
|  | C14D1 | 4 | 160.8 (13.45) | 159.5 (149.5, 172.0) | 148, 176 |  | 4 | 8.3 (9.54) | 6.5 (0.5, 16.0) | 0, 20 |
|  | C15D1 | 3 | 156.0 (18.33) | 160.0 (136.0, 172.0) | 136, 172 |  | 3 | 8.7 (8.08) | 10.0 (0.0, 16.0) | 0, 16 |
|  | C16D1 | 2 | 167.0 (15.56) | 167.0 (156.0, 178.0) | 156, 178 |  | 2 | 14.0 (11.31) | 14.0 (6.0, 22.0) | 6, 22 |
|  | C17D1 | 2 | 171.5 (6.36) | 171.5 (167.0, 176.0) | 167, 176 |  | 2 | 18.5 (2.12) | 18.5 (17.0, 20.0) | 17, 20 |
|  | C18D1 | 1 | 169.0 (NA) | 169.0 (169.0, 169.0) | 169, 169 |  | 1 | 19.0 (NA) | 19.0 (19.0, 19.0) | 19, 19 |
|  | End of Treatment | 6 | 143.0 (18.79) | 148.0 (146.0, 150.0) | 106, 160 |  | 6 | -16.7 (22.54) | -13.0 (-26.0, -6.0) | -54, 12 |
|  | | | | | | | | | | |
| QRS Interval (ms) (N = 33) | Baseline | 33 | 96.3 (12.10) | 96.0 (86.0, 102.0) | 80, 140 |  | 0 |  |  |  |
|  | C1D1 | 33 | 97.2 (14.56) | 96.0 (88.0, 102.0) | 78, 150 |  | 33 | 1.0 (8.79) | 0.0 (-4.0, 4.0) | -26, 18 |
|  | C1D8 | 33 | 98.8 (16.96) | 96.0 (88.0, 104.0) | 78, 152 |  | 33 | 2.5 (11.14) | 0.0 (-4.0, 4.0) | -12, 52 |
|  | C2D1 | 32 | 96.7 (11.37) | 96.5 (90.0, 102.0) | 78, 140 |  | 32 | 1.0 (6.01) | 1.5 (-3.0, 4.0) | -16, 16 |
|  | C3D1 | 31 | 97.2 (13.27) | 96.0 (88.0, 104.0) | 76, 150 |  | 31 | 1.5 (8.04) | 1.0 (-4.0, 6.0) | -16, 24 |
|  | C4D1 | 30 | 96.3 (14.87) | 94.0 (88.0, 102.0) | 78, 156 |  | 30 | 0.4 (10.14) | 2.0 (-2.0, 6.0) | -26, 22 |
|  | C5D1 | 27 | 97.4 (12.22) | 95.0 (88.0, 104.0) | 82, 140 |  | 27 | 1.2 (7.45) | 0.0 (-1.0, 6.0) | -18, 24 |
|  | C6D1 | 27 | 98.0 (14.51) | 98.0 (86.0, 104.0) | 80, 154 |  | 27 | 1.9 (8.43) | 2.0 (-2.0, 8.0) | -20, 20 |
|  | C7D1 | 22 | 97.8 (12.18) | 98.0 (90.0, 104.0) | 80, 136 |  | 22 | 0.8 (6.77) | 1.0 (-2.0, 5.0) | -22, 12 |
|  | C8D1 | 15 | 100.7 (12.88) | 98.0 (94.0, 104.0) | 86, 140 |  | 15 | 1.5 (3.80) | 2.0 (-1.0, 4.0) | -6, 8 |
|  | C9D1 | 11 | 101.9 (17.60) | 101.0 (92.0, 108.0) | 80, 148 |  | 11 | 3.0 (3.87) | 2.0 (0.0, 8.0) | -2, 8 |
|  | C10D1 | 6 | 105.8 (19.17) | 104.5 (90.0, 110.0) | 86, 140 |  | 6 | 3.5 (3.67) | 3.5 (0.0, 4.0) | 0, 10 |
|  | C11D1 | 6 | 107.0 (25.23) | 100.5 (89.0, 108.0) | 88, 156 |  | 6 | 4.7 (6.15) | 3.0 (2.0, 6.0) | -2, 16 |
|  | C12D1 | 5 | 105.8 (24.44) | 96.0 (95.0, 104.0) | 86, 148 |  | 5 | 4.2 (4.49) | 4.0 (4.0, 8.0) | -3, 8 |
|  | C13D1 | 4 | 111.0 (33.25) | 99.0 (92.0, 130.0) | 86, 160 |  | 4 | 5.8 (9.74) | 2.0 (-0.5, 12.0) | -1, 20 |
|  | C14D1 | 4 | 110.5 (33.32) | 102.0 (91.0, 130.0) | 80, 158 |  | 4 | 5.3 (8.77) | 2.5 (0.0, 10.5) | -2, 18 |
|  | C15D1 | 3 | 116.7 (30.62) | 100.0 (98.0, 152.0) | 98, 152 |  | 3 | 3.7 (7.37) | 1.0 (-2.0, 12.0) | -2, 12 |
|  | C16D1 | 2 | 99.5 (0.71) | 99.5 (99.0, 100.0) | 99, 100 |  | 2 | 0.0 (0.00) | 0.0 (0.0, 0.0) | 0, 0 |
|  | C17D1 | 2 | 103.5 (3.54) | 103.5 (101.0, 106.0) | 101, 106 |  | 2 | 4.0 (2.83) | 4.0 (2.0, 6.0) | 2, 6 |
|  | C18D1 | 1 | 101.0 (NA) | 101.0 (101.0, 101.0) | 101, 101 |  | 1 | 2.0 (NA) | 2.0 (2.0, 2.0) | 2, 2 |
|  | End of Treatment | 6 | 93.3 (8.26) | 95.0 (92.0, 98.0) | 78, 102 |  | 6 | 2.7 (8.64) | 1.0 (-4.0, 6.0) | -6, 18 |
|  | | | | | | | | | | |
| QT Interval (ms) (N = 33) | Baseline | 33 | 370.9 (25.79) | 370.0 (352.0, 385.0) | 320, 428 |  | 0 |  |  |  |
|  | C1D1 | 33 | 380.8 (23.53) | 380.0 (366.0, 392.0) | 342, 436 |  | 33 | 9.9 (24.50) | 8.0 (-4.0, 22.0) | -50, 84 |
|  | C1D8 | 33 | 387.8 (28.28) | 385.0 (372.0, 408.0) | 340, 446 |  | 33 | 16.9 (32.41) | 6.0 (0.0, 23.0) | -36, 95 |
|  | C2D1 | 32 | 378.7 (25.85) | 381.5 (358.5, 399.0) | 332, 438 |  | 32 | 6.3 (26.92) | 5.5 (-11.5, 22.0) | -58, 70 |
|  | C3D1 | 31 | 381.2 (23.67) | 379.0 (368.0, 396.0) | 348, 448 |  | 31 | 10.5 (20.21) | 10.0 (-4.0, 26.0) | -30, 52 |
|  | C4D1 | 30 | 375.0 (27.83) | 373.0 (360.0, 394.0) | 324, 442 |  | 30 | 4.6 (24.91) | 0.0 (-10.0, 16.0) | -30, 72 |
|  | C5D1 | 27 | 374.9 (25.45) | 376.0 (356.0, 400.0) | 334, 410 |  | 27 | 5.4 (23.83) | 0.0 (-8.0, 20.0) | -40, 50 |
|  | C6D1 | 27 | 371.6 (33.58) | 370.0 (344.0, 400.0) | 289, 422 |  | 27 | 2.1 (25.65) | 2.0 (-12.0, 20.0) | -51, 54 |
|  | C7D1 | 22 | 380.0 (24.60) | 380.0 (360.0, 400.0) | 338, 424 |  | 22 | 9.0 (24.64) | 4.0 (-4.0, 18.0) | -40, 58 |
|  | C8D1 | 15 | 378.1 (22.29) | 370.0 (360.0, 392.0) | 344, 420 |  | 15 | 6.1 (18.05) | 8.0 (-6.0, 22.0) | -30, 40 |
|  | C9D1 | 11 | 386.2 (33.93) | 386.0 (370.0, 402.0) | 326, 446 |  | 11 | 6.6 (34.14) | 2.0 (-15.0, 24.0) | -54, 76 |
|  | C10D1 | 6 | 381.3 (26.31) | 375.0 (370.0, 390.0) | 350, 428 |  | 6 | 6.5 (30.13) | 4.0 (-13.0, 16.0) | -30, 58 |
|  | C11D1 | 6 | 391.0 (30.95) | 384.0 (366.0, 400.0) | 364, 448 |  | 6 | 16.2 (35.82) | 1.5 (-10.0, 40.0) | -14, 78 |
|  | C12D1 | 5 | 386.4 (9.18) | 385.0 (381.0, 390.0) | 376, 400 |  | 5 | 10.6 (21.90) | 0.0 (-4.0, 30.0) | -11, 38 |
|  | C13D1 | 4 | 389.8 (14.24) | 395.0 (380.5, 399.0) | 369, 400 |  | 4 | 18.0 (23.66) | 26.0 (2.0, 34.0) | -16, 36 |
|  | C14D1 | 4 | 372.0 (35.59) | 386.0 (349.0, 395.0) | 320, 396 |  | 4 | 0.3 (33.19) | 3.5 (-24.5, 25.0) | -42, 36 |
|  | C15D1 | 3 | 361.3 (4.16) | 360.0 (358.0, 366.0) | 358, 366 |  | 3 | -7.7 (16.86) | 0.0 (-27.0, 4.0) | -27, 4 |
|  | C16D1 | 2 | 364.0 (31.11) | 364.0 (342.0, 386.0) | 342, 386 |  | 2 | -9.5 (14.85) | -9.5 (-20.0, 1.0) | -20, 1 |
|  | C17D1 | 2 | 380.5 (21.92) | 380.5 (365.0, 396.0) | 365, 396 |  | 2 | 7.0 (38.18) | 7.0 (-20.0, 34.0) | -20, 34 |
|  | C18D1 | 1 | 354.0 (NA) | 354.0 (354.0, 354.0) | 354, 354 |  | 1 | -31.0 (NA) | -31.0 (-31.0, -31.0) | -31, -31 |
|  | End of Treatment | 6 | 350.3 (32.92) | 349.0 (340.0, 378.0) | 296, 390 |  | 6 | -15.0 (31.77) | -11.0 (-40.0, 6.0) | -60, 26 |
|  | | | | | | | | | | |
| QTcF Interval (ms) (N = 33) | Baseline | 33 | 408.876 (17.9609) | 406.960 (397.300, 417.920) | 374.50, 456.61 |  | 0 |  |  |  |
|  | C1D1 | 33 | 403.731 (18.5682) | 400.400 (391.140, 418.620) | 353.56, 443.08 |  | 33 | -5.145 (14.0188) | -7.410 (-11.800, -2.230) | -42.70, 27.35 |
|  | C1D8 | 33 | 414.443 (24.0451) | 412.220 (399.750, 428.680) | 366.51, 470.91 |  | 33 | 5.567 (22.2137) | 3.850 (-5.370, 9.560) | -51.41, 70.04 |
|  | C2D1 | 32 | 409.656 (17.1958) | 406.215 (397.880, 424.935) | 376.99, 442.77 |  | 32 | 0.573 (14.9638) | -0.805 (-11.795, 8.900) | -19.41, 35.78 |
|  | C3D1 | 31 | 413.199 (16.0073) | 412.170 (401.570, 425.630) | 382.66, 440.48 |  | 31 | 4.950 (17.0775) | 6.980 (-3.870, 16.000) | -36.83, 39.37 |
|  | C4D1 | 30 | 408.593 (13.6113) | 407.115 (398.680, 416.110) | 384.79, 440.76 |  | 30 | 0.250 (14.7317) | 1.310 (-9.670, 7.910) | -49.34, 24.27 |
|  | C5D1 | 27 | 406.865 (19.1124) | 405.470 (392.390, 418.830) | 365.74, 441.64 |  | 27 | 0.823 (17.4109) | 2.780 (-8.150, 7.040) | -52.18, 30.45 |
|  | C6D1 | 27 | 402.073 (27.8622) | 408.610 (390.080, 419.560) | 295.22, 439.80 |  | 27 | -3.970 (23.9783) | -2.800 (-12.390, 9.870) | -96.29, 30.69 |
|  | C7D1 | 22 | 407.990 (14.6709) | 410.685 (396.400, 420.000) | 376.92, 432.44 |  | 22 | 1.775 (15.4012) | 2.945 (-10.700, 12.610) | -24.83, 34.00 |
|  | C8D1 | 15 | 405.717 (18.0160) | 413.450 (397.480, 415.730) | 358.51, 429.35 |  | 15 | -0.928 (12.2391) | -1.220 (-8.510, 8.160) | -29.31, 14.79 |
|  | C9D1 | 11 | 416.549 (18.3091) | 418.620 (398.270, 434.610) | 391.41, 443.53 |  | 11 | 4.141 (16.0168) | 5.640 (-14.880, 19.760) | -20.46, 27.65 |
|  | C10D1 | 6 | 419.897 (19.1113) | 425.655 (400.110, 437.210) | 393.25, 437.50 |  | 6 | 4.867 (13.0077) | 2.950 (-5.640, 14.240) | -8.93, 23.63 |
|  | C11D1 | 6 | 421.235 (16.8441) | 426.895 (400.780, 432.690) | 400.32, 439.83 |  | 6 | 6.205 (16.4533) | 6.370 (-8.260, 12.830) | -12.95, 32.87 |
|  | C12D1 | 5 | 419.008 (14.6415) | 424.060 (406.510, 427.060) | 401.23, 436.18 |  | 5 | 5.566 (17.8932) | 3.930 (-2.530, 20.100) | -19.08, 25.41 |
|  | C13D1 | 4 | 420.400 (20.7150) | 420.675 (405.135, 435.665) | 395.44, 444.81 |  | 4 | 14.383 (17.2264) | 10.770 (1.965, 26.800) | -1.86, 37.85 |
|  | C14D1 | 4 | 412.285 (28.1099) | 408.050 (391.640, 432.930) | 383.69, 449.35 |  | 4 | 6.268 (28.4848) | 4.880 (-12.395, 24.930) | -27.08, 42.39 |
|  | C15D1 | 3 | 410.487 (2.3909) | 411.540 (407.750, 412.170) | 407.75, 412.17 |  | 3 | 5.477 (4.5911) | 4.580 (1.400, 10.450) | 1.40, 10.45 |
|  | C16D1 | 2 | 393.645 (3.7972) | 393.645 (390.960, 396.330) | 390.96, 396.33 |  | 2 | -10.390 (13.3219) | -10.390 (-19.810, -0.970) | -19.81, -0.97 |
|  | C17D1 | 2 | 410.570 (27.4499) | 410.570 (391.160, 429.980) | 391.16, 429.98 |  | 2 | 6.535 (17.9252) | 6.535 (-6.140, 19.210) | -6.14, 19.21 |
|  | C18D1 | 1 | 397.120 (NA) | 397.120 (397.120, 397.120) | 397.12, 397.12 |  | 1 | -0.180 (NA) | -0.180 (-0.180, -0.180) | -0.18, -0.18 |
|  | End of Treatment | 6 | 408.492 (19.1556) | 408.170 (392.410, 424.040) | 385.81, 432.35 |  | 6 | -7.293 (18.8421) | -7.855 (-19.600, 1.440) | -32.57, 22.68 |
|  | | | | | | | | | | |
| RR Interval (ms) (N = 33) | Baseline | 33 | 752.0 (127.52) | 741.0 (682.0, 833.0) | 455, 968 |  | 0 |  |  |  |
|  | C1D1 | 33 | 847.8 (146.92) | 822.0 (741.0, 938.0) | 536, 1224 |  | 33 | 95.8 (127.89) | 51.0 (27.0, 159.0) | -183, 497 |
|  | C1D8 | 33 | 825.6 (134.41) | 811.0 (732.0, 896.0) | 588, 1132 |  | 33 | 73.5 (152.35) | 58.0 (-13.0, 103.0) | -220, 598 |
|  | C2D1 | 32 | 793.4 (118.64) | 800.0 (682.0, 870.0) | 606, 1053 |  | 32 | 33.5 (130.94) | 10.0 (-53.0, 142.0) | -278, 367 |
|  | C3D1 | 31 | 789.2 (123.20) | 779.0 (698.0, 833.0) | 606, 1132 |  | 31 | 35.5 (125.10) | 27.0 (-49.0, 79.0) | -146, 465 |
|  | C4D1 | 30 | 778.2 (142.92) | 774.0 (682.0, 857.0) | 500, 1224 |  | 30 | 26.7 (154.85) | 14.5 (-58.0, 76.0) | -236, 557 |
|  | C5D1 | 27 | 785.4 (116.04) | 759.0 (698.0, 833.0) | 583, 1000 |  | 27 | 29.5 (106.32) | 21.0 (-31.0, 87.0) | -218, 271 |
|  | C6D1 | 27 | 793.2 (121.61) | 811.0 (690.0, 882.0) | 583, 1000 |  | 27 | 37.3 (106.73) | 8.0 (-23.0, 78.0) | -123, 333 |
|  | C7D1 | 22 | 810.5 (115.86) | 828.5 (698.0, 882.0) | 612, 1053 |  | 22 | 45.7 (120.62) | 35.0 (-26.0, 101.0) | -168, 333 |
|  | C8D1 | 15 | 813.8 (116.78) | 833.0 (714.0, 882.0) | 625, 1017 |  | 15 | 46.3 (102.89) | 24.0 (-26.0, 107.0) | -86, 301 |
|  | C9D1 | 11 | 799.5 (136.25) | 800.0 (674.0, 882.0) | 571, 1017 |  | 11 | 15.9 (149.35) | -6.0 (-86.0, 99.0) | -229, 350 |
|  | C10D1 | 6 | 751.8 (116.47) | 714.5 (667.0, 845.0) | 632, 938 |  | 6 | 12.2 (141.17) | -21.0 (-64.0, 41.0) | -133, 271 |
|  | C11D1 | 6 | 807.7 (172.27) | 754.5 (698.0, 896.0) | 632, 1111 |  | 6 | 68.0 (188.36) | -2.5 (-41.0, 60.0) | -50, 444 |
|  | C12D1 | 5 | 784.4 (59.58) | 769.0 (759.0, 789.0) | 723, 882 |  | 5 | 30.2 (49.27) | 33.0 (-11.0, 69.0) | -27, 87 |
|  | C13D1 | 4 | 800.0 (88.28) | 811.0 (746.5, 853.5) | 682, 896 |  | 4 | 29.8 (103.25) | 44.0 (-53.0, 112.5) | -98, 129 |
|  | C14D1 | 4 | 737.3 (131.60) | 763.5 (629.5, 845.0) | 577, 845 |  | 4 | -33.0 (65.46) | -36.0 (-84.5, 18.5) | -105, 45 |
|  | C15D1 | 3 | 679.7 (16.26) | 674.0 (667.0, 698.0) | 667, 698 |  | 3 | -80.7 (135.07) | -23.0 (-235.0, 16.0) | -235, 16 |
|  | C16D1 | 2 | 795.0 (181.02) | 795.0 (667.0, 923.0) | 667, 923 |  | 2 | -0.5 (20.51) | -0.5 (-15.0, 14.0) | -15, 14 |
|  | C17D1 | 2 | 795.0 (22.63) | 795.0 (779.0, 811.0) | 779, 811 |  | 2 | -0.5 (137.89) | -0.5 (-98.0, 97.0) | -98, 97 |
|  | C18D1 | 1 | 706.0 (NA) | 706.0 (706.0, 706.0) | 706, 706 |  | 1 | -203.0 (NA) | -203.0 (-203.0, -203.0) | -203, -203 |
|  | End of Treatment | 6 | 632.2 (112.32) | 670.5 (588.0, 706.0) | 426, 732 |  | 6 | -57.0 (177.49) | -108.0 (-140.0, 27.0) | -264, 251 |

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 14.3.8.2.2 Summary of Shifts from Baseline in 12-Lead ECG According to Investigator’s Assessment - Phase II part 1 treatment-naive locally-advanced or metastatic NSCLC (Safety Analysis Set)**

|  | | | Post-baseline | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Parameter | Visit | Baseline | Normal | Abnormal, NCS | Abnormal, CS |  | Total |
| ECG Interpretation (N = 33) | Last Post-Baseline | Normal | 5 (15.2) | 10 (30.3) | 1 (3.0) |  | 16 (48.5) |
|  |  | Abnormal, NCS | 4 (12.1) | 2 (6.1) | 4 (12.1) |  | 10 (30.3) |
|  |  | Abnormal, CS | 1 (3.0) | 2 (6.1) | 4 (12.1) |  | 7 (21.2) |
|  |  | Total | 10 (30.3) | 14 (42.4) | 9 (27.3) |  | 33 (100) |
|  | | | | | | | |
|  | Worst Post-Baseline | Normal | 1 (3.0) | 11 (33.3) | 4 (12.1) |  | 16 (48.5) |
|  |  | Abnormal, NCS | 0 | 6 (18.2) | 4 (12.1) |  | 10 (30.3) |
|  |  | Abnormal, CS | 0 | 0 | 7 (21.2) |  | 7 (21.2) |
|  |  | Total | 1 (3.0) | 17 (51.5) | 15 (45.5) |  | 33 (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 14.3.8.3.2 Summary of Abnormal QTcF - Phase II part 1 treatment-naive locally-advanced or metastatic NSCLC (Safety Analysis Set)**

|  | Treatment-naive locally-advanced or metastatic NSCLC (N = 33) n (%) |
| --- | --- |
| Subjects with At Least One Post-baseline Abnormal QTcF | 32 (97.0) |
|  | |
| QTcF |  |
| > 450 msec | 5 (15.2) |
| > 480 msec | 0 |
| > 500 msec | 0 |
| Change from baseline > 30 msec | 10 (30.3) |
| Change from baseline > 60 msec | 3 (9.1) |

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 14.3.9.2 Summary of Shifts from Baseline in Slip Lamp Examination According to Investigator’s Assessment - Phase II part 1 treatment-naive locally-advanced or metastatic NSCLC (Safety Analysis Set)**

|  | | | | Post-baseline | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Parameter | Site | Visit | Baseline | Normal | Abnormal, NCS |  | Abnormal, CS | Missing | Total |
| Outer Eye (N = 33) | Left | Last Post-Baseline | Normal | 28 (84.8) | 0 |  | 0 | 3 (9.1) | 31 (93.9) |
|  |  |  | Abnormal, NCS | 0 | 0 |  | 0 | 0 | 0 |
|  |  |  | Abnormal, CS | 0 | 0 |  | 0 | 0 | 0 |
|  |  |  | Missing | 0 | 0 |  | 0 | 2 (6.1) | 2 (6.1) |
|  |  |  | Total | 28 (84.8) | 0 |  | 0 | 5 (15.2) | 33 (100) |
|  | | | | | | | | | |
|  |  | Worst Post-Baseline | Normal | 28 (84.8) | 0 |  | 0 | 3 (9.1) | 31 (93.9) |
|  |  |  | Abnormal, NCS | 0 | 0 |  | 0 | 0 | 0 |
|  |  |  | Abnormal, CS | 0 | 0 |  | 0 | 0 | 0 |
|  |  |  | Missing | 1 (3.0) | 0 |  | 0 | 1 (3.0) | 2 (6.1) |
|  |  |  | Total | 29 (87.9) | 0 |  | 0 | 4 (12.1) | 33 (100) |
|  | | | | | | | | | |
|  | Right | Last Post-Baseline | Normal | 27 (81.8) | 0 |  | 0 | 3 (9.1) | 30 (90.9) |
|  |  |  | Abnormal, NCS | 0 | 0 |  | 0 | 0 | 0 |
|  |  |  | Abnormal, CS | 1 (3.0) | 0 |  | 0 | 0 | 1 (3.0) |
|  |  |  | Missing | 0 | 0 |  | 0 | 2 (6.1) | 2 (6.1) |
|  |  |  | Total | 28 (84.8) | 0 |  | 0 | 5 (15.2) | 33 (100) |
|  | | | | | | | | | |
|  |  | Worst Post-Baseline | Normal | 27 (81.8) | 0 |  | 0 | 3 (9.1) | 30 (90.9) |
|  |  |  | Abnormal, NCS | 0 | 0 |  | 0 | 0 | 0 |
|  |  |  | Abnormal, CS | 1 (3.0) | 0 |  | 0 | 0 | 1 (3.0) |
|  |  |  | Missing | 1 (3.0) | 0 |  | 0 | 1 (3.0) | 2 (6.1) |
|  |  |  | Total | 29 (87.9) | 0 |  | 0 | 4 (12.1) | 33 (100) |
|  | | | | | | | | | |
| Eyelid Margin (N = 33) | Left | Last Post-Baseline | Normal | 22 (66.7) | 1 (3.0) |  | 1 (3.0) | 2 (6.1) | 26 (78.8) |
|  |  |  | Abnormal, NCS | 1 (3.0) | 1 (3.0) |  | 0 | 0 | 2 (6.1) |
|  |  |  | Abnormal, CS | 0 | 1 (3.0) |  | 0 | 0 | 1 (3.0) |
|  |  |  | Missing | 1 (3.0) | 0 |  | 0 | 3 (9.1) | 4 (12.1) |
|  |  |  | Total | 24 (72.7) | 3 (9.1) |  | 1 (3.0) | 5 (15.2) | 33 (100) |
|  | | | | | | | | | |
|  |  | Worst Post-Baseline | Normal | 22 (66.7) | 1 (3.0) |  | 1 (3.0) | 2 (6.1) | 26 (78.8) |
|  |  |  | Abnormal, NCS | 1 (3.0) | 1 (3.0) |  | 0 | 0 | 2 (6.1) |
|  |  |  | Abnormal, CS | 0 | 0 |  | 1 (3.0) | 0 | 1 (3.0) |
|  |  |  | Missing | 1 (3.0) | 0 |  | 1 (3.0) | 2 (6.1) | 4 (12.1) |
|  |  |  | Total | 24 (72.7) | 2 (6.1) |  | 3 (9.1) | 4 (12.1) | 33 (100) |
|  | | | | | | | | | |
|  | Right | Last Post-Baseline | Normal | 22 (66.7) | 1 (3.0) |  | 1 (3.0) | 2 (6.1) | 26 (78.8) |
|  |  |  | Abnormal, NCS | 1 (3.0) | 1 (3.0) |  | 0 | 0 | 2 (6.1) |
|  |  |  | Abnormal, CS | 0 | 1 (3.0) |  | 0 | 0 | 1 (3.0) |
|  |  |  | Missing | 1 (3.0) | 0 |  | 0 | 3 (9.1) | 4 (12.1) |
|  |  |  | Total | 24 (72.7) | 3 (9.1) |  | 1 (3.0) | 5 (15.2) | 33 (100) |
|  | | | | | | | | | |
|  |  | Worst Post-Baseline | Normal | 22 (66.7) | 1 (3.0) |  | 1 (3.0) | 2 (6.1) | 26 (78.8) |
|  |  |  | Abnormal, NCS | 1 (3.0) | 1 (3.0) |  | 0 | 0 | 2 (6.1) |
|  |  |  | Abnormal, CS | 0 | 0 |  | 1 (3.0) | 0 | 1 (3.0) |
|  |  |  | Missing | 1 (3.0) | 0 |  | 1 (3.0) | 2 (6.1) | 4 (12.1) |
|  |  |  | Total | 24 (72.7) | 2 (6.1) |  | 3 (9.1) | 4 (12.1) | 33 (100) |
|  | | | | | | | | | |
| Bulbar Conjunctiva (N = 33) | Left | Last Post-Baseline | Normal | 21 (63.6) | 3 (9.1) |  | 1 (3.0) | 3 (9.1) | 28 (84.8) |
|  |  |  | Abnormal, NCS | 0 | 2 (6.1) |  | 0 | 0 | 2 (6.1) |
|  |  |  | Abnormal, CS | 0 | 0 |  | 0 | 0 | 0 |
|  |  |  | Missing | 1 (3.0) | 0 |  | 0 | 2 (6.1) | 3 (9.1) |
|  |  |  | Total | 22 (66.7) | 5 (15.2) |  | 1 (3.0) | 5 (15.2) | 33 (100) |
|  | | | | | | | | | |
|  |  | Worst Post-Baseline | Normal | 21 (63.6) | 3 (9.1) |  | 1 (3.0) | 3 (9.1) | 28 (84.8) |
|  |  |  | Abnormal, NCS | 0 | 2 (6.1) |  | 0 | 0 | 2 (6.1) |
|  |  |  | Abnormal, CS | 0 | 0 |  | 0 | 0 | 0 |
|  |  |  | Missing | 2 (6.1) | 0 |  | 0 | 1 (3.0) | 3 (9.1) |
|  |  |  | Total | 23 (69.7) | 5 (15.2) |  | 1 (3.0) | 4 (12.1) | 33 (100) |
|  | | | | | | | | | |
|  | Right | Last Post-Baseline | Normal | 20 (60.6) | 3 (9.1) |  | 1 (3.0) | 3 (9.1) | 27 (81.8) |
|  |  |  | Abnormal, NCS | 0 | 3 (9.1) |  | 0 | 0 | 3 (9.1) |
|  |  |  | Abnormal, CS | 0 | 0 |  | 0 | 0 | 0 |
|  |  |  | Missing | 1 (3.0) | 0 |  | 0 | 2 (6.1) | 3 (9.1) |
|  |  |  | Total | 21 (63.6) | 6 (18.2) |  | 1 (3.0) | 5 (15.2) | 33 (100) |
|  | | | | | | | | | |
|  |  | Worst Post-Baseline | Normal | 20 (60.6) | 3 (9.1) |  | 1 (3.0) | 3 (9.1) | 27 (81.8) |
|  |  |  | Abnormal, NCS | 0 | 3 (9.1) |  | 0 | 0 | 3 (9.1) |
|  |  |  | Abnormal, CS | 0 | 0 |  | 0 | 0 | 0 |
|  |  |  | Missing | 2 (6.1) | 0 |  | 0 | 1 (3.0) | 3 (9.1) |
|  |  |  | Total | 22 (66.7) | 6 (18.2) |  | 1 (3.0) | 4 (12.1) | 33 (100) |
|  | | | | | | | | | |
| Cornea (N = 33) | Left | Last Post-Baseline | Normal | 25 (75.8) | 0 |  | 0 | 3 (9.1) | 28 (84.8) |
|  |  |  | Abnormal, NCS | 1 (3.0) | 0 |  | 0 | 1 (3.0) | 2 (6.1) |
|  |  |  | Abnormal, CS | 0 | 0 |  | 2 (6.1) | 0 | 2 (6.1) |
|  |  |  | Missing | 0 | 0 |  | 0 | 1 (3.0) | 1 (3.0) |
|  |  |  | Total | 26 (78.8) | 0 |  | 2 (6.1) | 5 (15.2) | 33 (100) |
|  | | | | | | | | | |
|  |  | Worst Post-Baseline | Normal | 24 (72.7) | 1 (3.0) |  | 0 | 3 (9.1) | 28 (84.8) |
|  |  |  | Abnormal, NCS | 1 (3.0) | 0 |  | 0 | 1 (3.0) | 2 (6.1) |
|  |  |  | Abnormal, CS | 0 | 0 |  | 2 (6.1) | 0 | 2 (6.1) |
|  |  |  | Missing | 1 (3.0) | 0 |  | 0 | 0 | 1 (3.0) |
|  |  |  | Total | 26 (78.8) | 1 (3.0) |  | 2 (6.1) | 4 (12.1) | 33 (100) |
|  | | | | | | | | | |
|  | Right | Last Post-Baseline | Normal | 24 (72.7) | 1 (3.0) |  | 1 (3.0) | 4 (12.1) | 30 (90.9) |
|  |  |  | Abnormal, NCS | 1 (3.0) | 0 |  | 0 | 0 | 1 (3.0) |
|  |  |  | Abnormal, CS | 0 | 0 |  | 1 (3.0) | 0 | 1 (3.0) |
|  |  |  | Missing | 0 | 0 |  | 0 | 1 (3.0) | 1 (3.0) |
|  |  |  | Total | 25 (75.8) | 1 (3.0) |  | 2 (6.1) | 5 (15.2) | 33 (100) |
|  | | | | | | | | | |
|  |  | Worst Post-Baseline | Normal | 23 (69.7) | 2 (6.1) |  | 1 (3.0) | 4 (12.1) | 30 (90.9) |
|  |  |  | Abnormal, NCS | 1 (3.0) | 0 |  | 0 | 0 | 1 (3.0) |
|  |  |  | Abnormal, CS | 0 | 0 |  | 1 (3.0) | 0 | 1 (3.0) |
|  |  |  | Missing | 1 (3.0) | 0 |  | 0 | 0 | 1 (3.0) |
|  |  |  | Total | 25 (75.8) | 2 (6.1) |  | 2 (6.1) | 4 (12.1) | 33 (100) |
|  | | | | | | | | | |
| Anterior Chamber (N = 33) | Left | Last Post-Baseline | Normal | 27 (81.8) | 0 |  | 0 | 3 (9.1) | 30 (90.9) |
|  |  |  | Abnormal, NCS | 1 (3.0) | 0 |  | 0 | 0 | 1 (3.0) |
|  |  |  | Abnormal, CS | 0 | 0 |  | 0 | 0 | 0 |
|  |  |  | Missing | 0 | 0 |  | 0 | 2 (6.1) | 2 (6.1) |
|  |  |  | Total | 28 (84.8) | 0 |  | 0 | 5 (15.2) | 33 (100) |
|  | | | | | | | | | |
|  |  | Worst Post-Baseline | Normal | 26 (78.8) | 1 (3.0) |  | 0 | 3 (9.1) | 30 (90.9) |
|  |  |  | Abnormal, NCS | 0 | 1 (3.0) |  | 0 | 0 | 1 (3.0) |
|  |  |  | Abnormal, CS | 0 | 0 |  | 0 | 0 | 0 |
|  |  |  | Missing | 1 (3.0) | 0 |  | 0 | 1 (3.0) | 2 (6.1) |
|  |  |  | Total | 27 (81.8) | 2 (6.1) |  | 0 | 4 (12.1) | 33 (100) |
|  | | | | | | | | | |
|  | Right | Last Post-Baseline | Normal | 27 (81.8) | 0 |  | 0 | 3 (9.1) | 30 (90.9) |
|  |  |  | Abnormal, NCS | 1 (3.0) | 0 |  | 0 | 0 | 1 (3.0) |
|  |  |  | Abnormal, CS | 0 | 0 |  | 0 | 0 | 0 |
|  |  |  | Missing | 0 | 0 |  | 0 | 2 (6.1) | 2 (6.1) |
|  |  |  | Total | 28 (84.8) | 0 |  | 0 | 5 (15.2) | 33 (100) |
|  | | | | | | | | | |
|  |  | Worst Post-Baseline | Normal | 26 (78.8) | 1 (3.0) |  | 0 | 3 (9.1) | 30 (90.9) |
|  |  |  | Abnormal, NCS | 0 | 1 (3.0) |  | 0 | 0 | 1 (3.0) |
|  |  |  | Abnormal, CS | 0 | 0 |  | 0 | 0 | 0 |
|  |  |  | Missing | 1 (3.0) | 0 |  | 0 | 1 (3.0) | 2 (6.1) |
|  |  |  | Total | 27 (81.8) | 2 (6.1) |  | 0 | 4 (12.1) | 33 (100) |
|  | | | | | | | | | |
| Iris (N = 33) | Left | Last Post-Baseline | Normal | 27 (81.8) | 0 |  | 0 | 3 (9.1) | 30 (90.9) |
|  |  |  | Abnormal, NCS | 0 | 0 |  | 0 | 0 | 0 |
|  |  |  | Abnormal, CS | 0 | 0 |  | 0 | 0 | 0 |
|  |  |  | Missing | 0 | 0 |  | 0 | 3 (9.1) | 3 (9.1) |
|  |  |  | Total | 27 (81.8) | 0 |  | 0 | 6 (18.2) | 33 (100) |
|  | | | | | | | | | |
|  |  | Worst Post-Baseline | Normal | 27 (81.8) | 0 |  | 0 | 3 (9.1) | 30 (90.9) |
|  |  |  | Abnormal, NCS | 0 | 0 |  | 0 | 0 | 0 |
|  |  |  | Abnormal, CS | 0 | 0 |  | 0 | 0 | 0 |
|  |  |  | Missing | 0 | 0 |  | 0 | 3 (9.1) | 3 (9.1) |
|  |  |  | Total | 27 (81.8) | 0 |  | 0 | 6 (18.2) | 33 (100) |
|  | | | | | | | | | |
|  | Right | Last Post-Baseline | Normal | 27 (81.8) | 0 |  | 0 | 3 (9.1) | 30 (90.9) |
|  |  |  | Abnormal, NCS | 0 | 0 |  | 0 | 0 | 0 |
|  |  |  | Abnormal, CS | 0 | 0 |  | 0 | 0 | 0 |
|  |  |  | Missing | 0 | 0 |  | 0 | 3 (9.1) | 3 (9.1) |
|  |  |  | Total | 27 (81.8) | 0 |  | 0 | 6 (18.2) | 33 (100) |
|  | | | | | | | | | |
|  |  | Worst Post-Baseline | Normal | 27 (81.8) | 0 |  | 0 | 3 (9.1) | 30 (90.9) |
|  |  |  | Abnormal, NCS | 0 | 0 |  | 0 | 0 | 0 |
|  |  |  | Abnormal, CS | 0 | 0 |  | 0 | 0 | 0 |
|  |  |  | Missing | 0 | 0 |  | 0 | 3 (9.1) | 3 (9.1) |
|  |  |  | Total | 27 (81.8) | 0 |  | 0 | 6 (18.2) | 33 (100) |
|  | | | | | | | | | |
| Pupil (N = 33) | Left | Last Post-Baseline | Normal | 25 (75.8) | 0 |  | 1 (3.0) | 3 (9.1) | 29 (87.9) |
|  |  |  | Abnormal, NCS | 0 | 0 |  | 0 | 0 | 0 |
|  |  |  | Abnormal, CS | 0 | 0 |  | 0 | 0 | 0 |
|  |  |  | Missing | 2 (6.1) | 0 |  | 0 | 2 (6.1) | 4 (12.1) |
|  |  |  | Total | 27 (81.8) | 0 |  | 1 (3.0) | 5 (15.2) | 33 (100) |
|  | | | | | | | | | |
|  |  | Worst Post-Baseline | Normal | 25 (75.8) | 0 |  | 1 (3.0) | 3 (9.1) | 29 (87.9) |
|  |  |  | Abnormal, NCS | 0 | 0 |  | 0 | 0 | 0 |
|  |  |  | Abnormal, CS | 0 | 0 |  | 0 | 0 | 0 |
|  |  |  | Missing | 3 (9.1) | 0 |  | 0 | 1 (3.0) | 4 (12.1) |
|  |  |  | Total | 28 (84.8) | 0 |  | 1 (3.0) | 4 (12.1) | 33 (100) |
|  | | | | | | | | | |
|  | Right | Last Post-Baseline | Normal | 24 (72.7) | 0 |  | 2 (6.1) | 3 (9.1) | 29 (87.9) |
|  |  |  | Abnormal, NCS | 0 | 0 |  | 0 | 0 | 0 |
|  |  |  | Abnormal, CS | 0 | 0 |  | 0 | 0 | 0 |
|  |  |  | Missing | 2 (6.1) | 0 |  | 0 | 2 (6.1) | 4 (12.1) |
|  |  |  | Total | 26 (78.8) | 0 |  | 2 (6.1) | 5 (15.2) | 33 (100) |
|  | | | | | | | | | |
|  |  | Worst Post-Baseline | Normal | 24 (72.7) | 0 |  | 2 (6.1) | 3 (9.1) | 29 (87.9) |
|  |  |  | Abnormal, NCS | 0 | 0 |  | 0 | 0 | 0 |
|  |  |  | Abnormal, CS | 0 | 0 |  | 0 | 0 | 0 |
|  |  |  | Missing | 3 (9.1) | 0 |  | 0 | 1 (3.0) | 4 (12.1) |
|  |  |  | Total | 27 (81.8) | 0 |  | 2 (6.1) | 4 (12.1) | 33 (100) |
|  | | | | | | | | | |
| Lens (N = 33) | Left | Last Post-Baseline | Normal | 14 (42.4) | 1 (3.0) |  | 1 (3.0) | 0 | 16 (48.5) |
|  |  |  | Abnormal, NCS | 1 (3.0) | 8 (24.2) |  | 1 (3.0) | 0 | 10 (30.3) |
|  |  |  | Abnormal, CS | 2 (6.1) | 0 |  | 3 (9.1) | 1 (3.0) | 6 (18.2) |
|  |  |  | Missing | 0 | 0 |  | 0 | 1 (3.0) | 1 (3.0) |
|  |  |  | Total | 17 (51.5) | 9 (27.3) |  | 5 (15.2) | 2 (6.1) | 33 (100) |
|  | | | | | | | | | |
|  |  | Worst Post-Baseline | Normal | 13 (39.4) | 2 (6.1) |  | 1 (3.0) | 0 | 16 (48.5) |
|  |  |  | Abnormal, NCS | 0 | 9 (27.3) |  | 1 (3.0) | 0 | 10 (30.3) |
|  |  |  | Abnormal, CS | 1 (3.0) | 0 |  | 4 (12.1) | 1 (3.0) | 6 (18.2) |
|  |  |  | Missing | 0 | 0 |  | 0 | 1 (3.0) | 1 (3.0) |
|  |  |  | Total | 14 (42.4) | 11 (33.3) |  | 6 (18.2) | 2 (6.1) | 33 (100) |
|  | | | | | | | | | |
|  | Right | Last Post-Baseline | Normal | 15 (45.5) | 1 (3.0) |  | 1 (3.0) | 0 | 17 (51.5) |
|  |  |  | Abnormal, NCS | 0 | 8 (24.2) |  | 1 (3.0) | 0 | 9 (27.3) |
|  |  |  | Abnormal, CS | 2 (6.1) | 0 |  | 3 (9.1) | 1 (3.0) | 6 (18.2) |
|  |  |  | Missing | 0 | 0 |  | 0 | 1 (3.0) | 1 (3.0) |
|  |  |  | Total | 17 (51.5) | 9 (27.3) |  | 5 (15.2) | 2 (6.1) | 33 (100) |
|  | | | | | | | | | |
|  |  | Worst Post-Baseline | Normal | 13 (39.4) | 3 (9.1) |  | 1 (3.0) | 0 | 17 (51.5) |
|  |  |  | Abnormal, NCS | 0 | 8 (24.2) |  | 1 (3.0) | 0 | 9 (27.3) |
|  |  |  | Abnormal, CS | 1 (3.0) | 0 |  | 4 (12.1) | 1 (3.0) | 6 (18.2) |
|  |  |  | Missing | 0 | 0 |  | 0 | 1 (3.0) | 1 (3.0) |
|  |  |  | Total | 14 (42.4) | 11 (33.3) |  | 6 (18.2) | 2 (6.1) | 33 (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 14.3.10.2 Summary of Shifts from Baseline in Physical Examination According to Investigator’s Assessment - Phase II part 1 treatment-naive locally-advanced or metastatic NSCLC (Safety Analysis Set)**

|  | | | Post-baseline | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Parameter | Visit | Baseline | Normal | Abnormal, NCS | Abnormal, CS |  | Missing | Total |
| General condition (N = 33) | Last Post-Baseline | Normal | 32 (97.0) | 0 | 0 |  | 1 (3.0) | 33 (100) |
|  |  | Abnormal, NCS | 0 | 0 | 0 |  | 0 | 0 |
|  |  | Abnormal, CS | 0 | 0 | 0 |  | 0 | 0 |
|  |  | Total | 32 (97.0) | 0 | 0 |  | 1 (3.0) | 33 (100) |
|  | | | | | | | | |
|  | Worst Post-Baseline | Normal | 32 (97.0) | 0 | 0 |  | 1 (3.0) | 33 (100) |
|  |  | Abnormal, NCS | 0 | 0 | 0 |  | 0 | 0 |
|  |  | Abnormal, CS | 0 | 0 | 0 |  | 0 | 0 |
|  |  | Total | 32 (97.0) | 0 | 0 |  | 1 (3.0) | 33 (100) |
|  | | | | | | | | |
| Head (N = 33) | Last Post-Baseline | Normal | 30 (90.9) | 0 | 0 |  | 1 (3.0) | 31 (93.9) |
|  |  | Abnormal, NCS | 0 | 0 | 0 |  | 0 | 0 |
|  |  | Abnormal, CS | 0 | 0 | 2 (6.1) |  | 0 | 2 (6.1) |
|  |  | Total | 30 (90.9) | 0 | 2 (6.1) |  | 1 (3.0) | 33 (100) |
|  | | | | | | | | |
|  | Worst Post-Baseline | Normal | 30 (90.9) | 0 | 0 |  | 1 (3.0) | 31 (93.9) |
|  |  | Abnormal, NCS | 0 | 0 | 0 |  | 0 | 0 |
|  |  | Abnormal, CS | 0 | 0 | 2 (6.1) |  | 0 | 2 (6.1) |
|  |  | Total | 30 (90.9) | 0 | 2 (6.1) |  | 1 (3.0) | 33 (100) |
|  | | | | | | | | |
| Neck (N = 33) | Last Post-Baseline | Normal | 32 (97.0) | 0 | 0 |  | 1 (3.0) | 33 (100) |
|  |  | Abnormal, NCS | 0 | 0 | 0 |  | 0 | 0 |
|  |  | Abnormal, CS | 0 | 0 | 0 |  | 0 | 0 |
|  |  | Total | 32 (97.0) | 0 | 0 |  | 1 (3.0) | 33 (100) |
|  | | | | | | | | |
|  | Worst Post-Baseline | Normal | 32 (97.0) | 0 | 0 |  | 1 (3.0) | 33 (100) |
|  |  | Abnormal, NCS | 0 | 0 | 0 |  | 0 | 0 |
|  |  | Abnormal, CS | 0 | 0 | 0 |  | 0 | 0 |
|  |  | Total | 32 (97.0) | 0 | 0 |  | 1 (3.0) | 33 (100) |
|  | | | | | | | | |
| Chest(includes heart and lungs) (N = 33) | Last Post-Baseline | Normal | 24 (72.7) | 0 | 1 (3.0) |  | 1 (3.0) | 26 (78.8) |
|  |  | Abnormal, NCS | 0 | 0 | 1 (3.0) |  | 0 | 1 (3.0) |
|  |  | Abnormal, CS | 0 | 0 | 6 (18.2) |  | 0 | 6 (18.2) |
|  |  | Total | 24 (72.7) | 0 | 8 (24.2) |  | 1 (3.0) | 33 (100) |
|  | | | | | | | | |
|  | Worst Post-Baseline | Normal | 24 (72.7) | 0 | 1 (3.0) |  | 1 (3.0) | 26 (78.8) |
|  |  | Abnormal, NCS | 0 | 0 | 1 (3.0) |  | 0 | 1 (3.0) |
|  |  | Abnormal, CS | 0 | 0 | 6 (18.2) |  | 0 | 6 (18.2) |
|  |  | Total | 24 (72.7) | 0 | 8 (24.2) |  | 1 (3.0) | 33 (100) |
|  | | | | | | | | |
| Abdomen (N = 33) | Last Post-Baseline | Normal | 29 (87.9) | 0 | 0 |  | 1 (3.0) | 30 (90.9) |
|  |  | Abnormal, NCS | 0 | 2 (6.1) | 0 |  | 0 | 2 (6.1) |
|  |  | Abnormal, CS | 0 | 0 | 1 (3.0) |  | 0 | 1 (3.0) |
|  |  | Total | 29 (87.9) | 2 (6.1) | 1 (3.0) |  | 1 (3.0) | 33 (100) |
|  | | | | | | | | |
|  | Worst Post-Baseline | Normal | 27 (81.8) | 1 (3.0) | 1 (3.0) |  | 1 (3.0) | 30 (90.9) |
|  |  | Abnormal, NCS | 0 | 2 (6.1) | 0 |  | 0 | 2 (6.1) |
|  |  | Abnormal, CS | 0 | 0 | 1 (3.0) |  | 0 | 1 (3.0) |
|  |  | Total | 27 (81.8) | 3 (9.1) | 2 (6.1) |  | 1 (3.0) | 33 (100) |
|  | | | | | | | | |
| Spine and extremities (N = 33) | Last Post-Baseline | Normal | 20 (60.6) | 1 (3.0) | 9 (27.3) |  | 1 (3.0) | 31 (93.9) |
|  |  | Abnormal, NCS | 0 | 0 | 0 |  | 0 | 0 |
|  |  | Abnormal, CS | 0 | 0 | 2 (6.1) |  | 0 | 2 (6.1) |
|  |  | Total | 20 (60.6) | 1 (3.0) | 11 (33.3) |  | 1 (3.0) | 33 (100) |
|  | | | | | | | | |
|  | Worst Post-Baseline | Normal | 19 (57.6) | 0 | 11 (33.3) |  | 1 (3.0) | 31 (93.9) |
|  |  | Abnormal, NCS | 0 | 0 | 0 |  | 0 | 0 |
|  |  | Abnormal, CS | 0 | 0 | 2 (6.1) |  | 0 | 2 (6.1) |
|  |  | Total | 19 (57.6) | 0 | 13 (39.4) |  | 1 (3.0) | 33 (100) |
|  | | | | | | | | |
| Neurological system (N = 33) | Last Post-Baseline | Normal | 31 (93.9) | 0 | 1 (3.0) |  | 1 (3.0) | 33 (100) |
|  |  | Abnormal, NCS | 0 | 0 | 0 |  | 0 | 0 |
|  |  | Abnormal, CS | 0 | 0 | 0 |  | 0 | 0 |
|  |  | Total | 31 (93.9) | 0 | 1 (3.0) |  | 1 (3.0) | 33 (100) |
|  | | | | | | | | |
|  | Worst Post-Baseline | Normal | 31 (93.9) | 0 | 1 (3.0) |  | 1 (3.0) | 33 (100) |
|  |  | Abnormal, NCS | 0 | 0 | 0 |  | 0 | 0 |
|  |  | Abnormal, CS | 0 | 0 | 0 |  | 0 | 0 |
|  |  | Total | 31 (93.9) | 0 | 1 (3.0) |  | 1 (3.0) | 33 (100) |
|  | | | | | | | | |
| Skin (N = 33) | Last Post-Baseline | Normal | 25 (75.8) | 0 | 2 (6.1) |  | 0 | 27 (81.8) |
|  |  | Abnormal, NCS | 0 | 4 (12.1) | 0 |  | 1 (3.0) | 5 (15.2) |
|  |  | Abnormal, CS | 0 | 0 | 1 (3.0) |  | 0 | 1 (3.0) |
|  |  | Total | 25 (75.8) | 4 (12.1) | 3 (9.1) |  | 1 (3.0) | 33 (100) |
|  | | | | | | | | |
|  | Worst Post-Baseline | Normal | 22 (66.7) | 0 | 5 (15.2) |  | 0 | 27 (81.8) |
|  |  | Abnormal, NCS | 0 | 4 (12.1) | 0 |  | 1 (3.0) | 5 (15.2) |
|  |  | Abnormal, CS | 0 | 0 | 1 (3.0) |  | 0 | 1 (3.0) |
|  |  | Total | 22 (66.7) | 4 (12.1) | 6 (18.2) |  | 1 (3.0) | 33 (100) |
|  | | | | | | | | |
| lymph node (N = 33) | Last Post-Baseline | Normal | 29 (87.9) | 0 | 0 |  | 1 (3.0) | 30 (90.9) |
|  |  | Abnormal, NCS | 0 | 0 | 0 |  | 0 | 0 |
|  |  | Abnormal, CS | 1 (3.0) | 0 | 2 (6.1) |  | 0 | 3 (9.1) |
|  |  | Total | 30 (90.9) | 0 | 2 (6.1) |  | 1 (3.0) | 33 (100) |
|  | | | | | | | | |
|  | Worst Post-Baseline | Normal | 29 (87.9) | 0 | 0 |  | 1 (3.0) | 30 (90.9) |
|  |  | Abnormal, NCS | 0 | 0 | 0 |  | 0 | 0 |
|  |  | Abnormal, CS | 0 | 0 | 3 (9.1) |  | 0 | 3 (9.1) |
|  |  | Total | 29 (87.9) | 0 | 3 (9.1) |  | 1 (3.0) | 33 (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

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| --- | --- | --- |
| Program: t-pe-shift.sas | DCO: 27APR2024 | Executed: 07JUL2024 20:52 |

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

**Table 14.3.11.1.2 Summary of Echocardiogram Parameters - Phase II part 1 treatment-naive locally-advanced or metastatic NSCLC (Safety Analysis Set)**

|  | | | Observed Value | | | |  | Change from Baseline | | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Parameter |  | Visit | n | Mean (STD) | Median (Q1, Q3) | Min, Max |  | n | Mean (STD) | Median (Q1, Q3) | Min, Max |
| Left Ventricular Ejection Fraction (%) (N = 33) |  | Baseline | 33 | 65.33 (4.608) | 64.00 (62.00, 68.00) | 57.0, 78.0 |  |  |  |  |  |
|  |  | C2D1 | 8 | 62.63 (4.868) | 61.50 (59.00, 66.50) | 57.0, 70.0 |  | 8 | -0.38 (3.889) | -0.50 (-3.00, 2.00) | -6.0, 6.0 |
|  |  | C3D1 | 8 | 63.75 (5.230) | 64.00 (59.50, 68.00) | 56.0, 71.0 |  | 8 | 0.75 (4.268) | 1.50 (-1.00, 4.00) | -8.0, 5.0 |
|  |  | C4D1 | 8 | 63.50 (6.118) | 62.50 (60.00, 67.50) | 55.0, 73.0 |  | 8 | 0.50 (4.440) | 1.00 (-0.50, 3.00) | -9.0, 6.0 |
|  |  | C5D1 | 28 | 64.57 (3.834) | 63.00 (62.00, 68.00) | 58.0, 71.0 |  | 28 | -0.39 (3.814) | 0.00 (-2.00, 1.00) | -11.0, 7.0 |
|  |  | C6D1 | 5 | 64.60 (5.595) | 65.00 (60.00, 69.00) | 58.0, 71.0 |  | 5 | 2.60 (2.702) | 1.00 (1.00, 5.00) | 0.0, 6.0 |
|  |  | C7D1 | 3 | 63.67 (4.041) | 63.00 (60.00, 68.00) | 60.0, 68.0 |  | 3 | 2.33 (3.055) | 3.00 (-1.00, 5.00) | -1.0, 5.0 |
|  |  | C8D1 | 1 | 61.00 (NA) | 61.00 (61.00, 61.00) | 61.0, 61.0 |  | 1 | -3.00 (NA) | -3.00 (-3.00, -3.00) | -3.0, -3.0 |
|  |  | C9D1 | 11 | 64.36 (4.178) | 65.00 (63.00, 67.00) | 56.0, 70.0 |  | 11 | -2.27 (4.714) | -2.00 (-6.00, 2.00) | -11.0, 4.0 |
|  |  | C10D1 | 1 | 62.00 (NA) | 62.00 (62.00, 62.00) | 62.0, 62.0 |  | 1 | -2.00 (NA) | -2.00 (-2.00, -2.00) | -2.0, -2.0 |
|  |  | C11D1 | 1 | 57.00 (NA) | 57.00 (57.00, 57.00) | 57.0, 57.0 |  | 1 | -7.00 (NA) | -7.00 (-7.00, -7.00) | -7.0, -7.0 |
|  |  | C12D1 | 1 | 62.00 (NA) | 62.00 (62.00, 62.00) | 62.0, 62.0 |  | 1 | -2.00 (NA) | -2.00 (-2.00, -2.00) | -2.0, -2.0 |
|  |  | C13D1 | 4 | 63.75 (6.292) | 61.50 (60.00, 67.50) | 59.0, 73.0 |  | 4 | -4.00 (10.000) | -3.00 (-11.00, 3.00) | -17.0, 7.0 |
|  |  | C17D1 | 2 | 63.00 (7.071) | 63.00 (58.00, 68.00) | 58.0, 68.0 |  | 2 | -8.00 (2.828) | -8.00 (-10.00, -6.00) | -10.0, -6.0 |
|  |  | End of Treatment | 3 | 62.67 (6.429) | 60.00 (58.00, 70.00) | 58.0, 70.0 |  | 3 | -2.33 (4.041) | -3.00 (-6.00, 2.00) | -6.0, 2.0 |

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

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| --- | --- | --- |
| Program: t-cv-chg.sas | DCO: 27APR2024 | Executed: 07JUL2024 20:52 |

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

**Table 14.3.11.2.2 Summary of Shifts from Baseline in Echocardiogram According to Investigator’s Assessment - Phase II part 1 treatment-naive locally-advanced or metastatic NSCLC (Safety Analysis Set)**

|  | | | Post-baseline | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Parameter | Visit | Baseline | Normal | Abnormal, NCS | Abnormal, CS |  | Missing | Total |
| Interpretation (N = 33) | Last Post-Baseline | Normal | 2 (6.1) | 1 (3.0) | 0 |  | 0 | 3 (9.1) |
|  |  | Abnormal, NCS | 2 (6.1) | 22 (66.7) | 1 (3.0) |  | 1 (3.0) | 26 (78.8) |
|  |  | Abnormal, CS | 0 | 0 | 3 (9.1) |  | 1 (3.0) | 4 (12.1) |
|  |  | Total | 4 (12.1) | 23 (69.7) | 4 (12.1) |  | 2 (6.1) | 33 (100) |
|  | | | | | | | | |
|  | Worst Post-Baseline | Normal | 1 (3.0) | 2 (6.1) | 0 |  | 0 | 3 (9.1) |
|  |  | Abnormal, NCS | 2 (6.1) | 22 (66.7) | 1 (3.0) |  | 1 (3.0) | 26 (78.8) |
|  |  | Abnormal, CS | 0 | 0 | 3 (9.1) |  | 1 (3.0) | 4 (12.1) |
|  |  | Total | 3 (9.1) | 24 (72.7) | 4 (12.1) |  | 2 (6.1) | 33 (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

|  |  |  |
| --- | --- | --- |
| Program: t-cv-shift.sas | DCO: 27APR2024 | Executed: 07JUL2024 20:54 |