1. Trial Subjects and Compliance With Trial Protocol
   1. DISPOSITION OF SUBJECTS

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Laekna | | Page 1 of 2 | | | | |
|  | | | | | | |
|  | | | | | | |
|  |
| Table 14.3.1.1 Overview of Adverse Events - Phase I Safety Analysis Set | | | | | |
| Description | | | Cohort 1 (N=X) n (%) | Cohort 2 (N=X) n (%) | Total (N=X) n (%) |
|  | | |  |  |  |
| Any Adverse Events | | |  |  |  |
|  | | |  |  |  |
| Any TEAE | | |  |  |  |
|  | | |  |  |  |
| Any TEAEs related to study drug | | |  |  |  |
| LAE001 | | |  |  |  |
| afuresertib | | |  |  |  |
| prednisone | | |  |  |  |
|  | | |  |  |  |
| Severity of TEAEs | | |  |  |  |
| Mild/ Grade 1 | | |  |  |  |
| Moderate/ Grade 2 | | |  |  |  |
| Severe/ Grade 3 | | |  |  |  |
| Life-threatening/ Grade 4 | | |  |  |  |
| Death/ Grade 5 | | |  |  |  |
|  | | |  |  |  |
| Any TEAEs with ≥ grade 3 toxicity | | |  |  |  |
|  | | |  |  |  |
| Any TEAEs with ≥ grade 3 toxicity and related to any study drug | | |  |  |  |
|  | | |  |  |  |
| Any serious TEAEs | | |  |  |  |
|  | | |  |  |  |
| Any serious TEAEs related to any study drug | | |  |  |  |
|  | | |  |  |  |
| Any TEAEs leading to discontinuation of any study drug | | |  |  |  |
|  | | |  |  |  |
| Data cut-off = 15OCT2022.  Abbreviations: n = Number of patients, AE = Adverse event, AESI = AE of special interest, TEAE = Treatment-Emergent AE  Note: Percentages are based on the total number of patients in the analysis set for each dose cohort and total column.  Note: Adverse Events (AEs) are coded using MedDRA Dictionary, version 22.0.  Note: Severity of AEs are graded using the NCI-CTCAE (Version 5.0) toxicity grades. | | | | | |
|  |
| [Source: LAEKNA\_LIMITED\AFURESERTIB\BZA46559\BIOSTATISTICS\PRODUCTION\TABLES\PHASE\_I\_FINAL\T\_AE.SAS] IQVIA 19JAN2023 | | | | | | |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Laekna | | Page 2 of 2 | | | | |
| LAE201INT2101 | | | | | | |
| LAE001 (CFG920) and Prednisone + Afuresertib (LAE002) | | | | | | |
|  |
| Table 14.3.1.1 Overview of Adverse Events - Phase I Safety Analysis Set | | | | | |
| Description | | | Cohort 1 (N=8) n (%) | Cohort 2 (N=6) n (%) | Total (N=14) n (%) |
|  | | |  |  |  |
| Any TEAEs leading to discontinuation of any study drug and related to any study drug | | |  |  |  |
|  | | |  |  |  |
| Any TEAEs leading to discontinuation of study | | |  |  |  |
|  | | |  |  |  |
| Any TEAEs leading to discontinuation of study and related to any study drug | | |  |  |  |
|  | | |  |  |  |
| Any TEAEs leading to death | | |  |  |  |
|  | | |  |  |  |
| Any TEAEs leading to death and related to any study drug | | |  |  |  |
|  | | |  |  |  |
| Any treatment emergent AESIs | | |  |  |  |
|  | | |  |  |  |
| Any related treatment emergent AESIs | | |  |  |  |
|  | | |  |  |  |
| Data cut-off = 15OCT2022.  Abbreviations: n = Number of patients, AE = Adverse event, AESI = AE of special interest, TEAE = Treatment-Emergent AE  Note: Percentages are based on the total number of patients in the analysis set for each dose cohort and total column.  Note: Adverse Events (AEs) are coded using MedDRA Dictionary, version 22.0.  Note: Severity of AEs are graded using the NCI-CTCAE (Version 5.0) toxicity grades.  Note: Patients with multiple occurrences of TEAEs will have the TEAE with the highest grade included in this summary.  Note: Related = �Unlikely�, �Possible�, �Probable�, �Very Likely/Certain�; Not Related = �Unrelated�. | | | | | |
|  |
| [Source: LAEKNA\_LIMITED\AFURESERTIB\BZA46559\BIOSTATISTICS\PRODUCTION\TABLES\PHASE\_I\_FINAL\T\_AE.SAS] IQVIA 19JAN2023 | | | | | | |

* 1. DATASETS ANALYSED
  2. PROTOCOL DEVIATIONS
  3. DEMOGRAPHIC AND OTHER BASELINE CHARACTERISTICS
     1. Demographic characteristics
     2. Medical history and concomitant therapies
  4. EXTENT OF EXPOSURE
  5. MEASUREMENTS OF TREATMENT COMPLIANCE

1. Pharmacokinetic, Pharmacodynamic, and Immunogenicity Evaluation
   1. Data Sets Analyzed
   2. Demographic and Other Baseline Characteristics

* 1. Measurements of Treatment Compliance
  2. Pharmacokinetic Results
     1. Statistical/Analysis Issues
     2. Pharmacokinetic Conclusions
  3. Pharmacodynamic Results
     1. Statistical/Analysis Issues
     2. Pharmacodynamic Conclusions
  4. Immunogenicity Results
     1. Analysis of Immunogenicity
     2. Immunogenicity Conclusions

1. SAFETY EVALUATION
   1. ADVERSE EVENTS
      1. Brief summary of adverse events
      2. Display of adverse events
         1. Treatment-emergent adverse events
         2. Adverse events that led to premature discontinuation of trial drug
         3. Drug-related adverse events
   2. SERIOUS ADVERSE EVENTS INCLUDING DEATHS
   3. CLINICAL LABORATORY EVALUATION
   4. VITAL SIGNS - PHYSICAL FINDINGS AND OTHER OBSERVATIONS RELATED TO SAFETY
      1. Vital signs
      2. Electrocardiograms
   5. SAFETY RESULTS SUMMARY
2. Discussion and Overall Conclusions
   1. Discussion
      1. Pharmacodynamics
      2. Pharmacokinetics
      3. Immunogenicity
      4. Safety1
   2. Conclusions
      1. Pharmacodynamics
      2. Pharmacokinetics
      3. Immunogenicity
      4. Safety2
3. Tables, Figures, and Graphs Referred to But Not Included in the Text
   1. Disposition, Demographic, and Exposure Data
      1. Disposition
      2. Demographics
      3. Exposure
   2. Pharmacokinetic Data
   3. Pharmacodynamic Data
   4. Immunogenicity Data
   5. Safety Data
      1. Adverse Events
      2. Listing of Deaths and Other Serious Adverse Events
      3. Narratives of Deaths and Other Serious Adverse Events
      4. Clinical Laboratory
      5. Other Safety Parameters
4. References

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1. Appendices

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