| 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. | | | |

| 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�. | | | |