Maryam Ali

Writing Sample (Unedited)

Adverse Events report in narrative form based on provided Table 1 and Table 2

Table 1 presents a summary of treatment-emergent adverse events (AEs) occurring in subjects of a clinical trial comparing treatments using DrugX versus Comparator. AEs were experienced by 45 (64.3%) of 70 subjects receiving DrugX and 54 (90%) of 60 subjects receiving Comparator. Of these, the investigator deemed the AEs from 12 (17.1%) subjects receiving DrugX treatment and from 19 (31.7%) subjects receiving Comparator treatment to be drug-related.

The incidence of mild AEs was comparable in DrugX (25 of 70) and Comparator (30 of 60) treatment groups (35.7% vs. 33.3%). However, the Comparator group experienced nearly twice the rate of moderate AEs (10 (14.2%) with DrugX vs. 21 (35.0%) with Comparator) and severe AEs (5 (7.1%) with DrugX vs. 13 (21.7%) with Comparator). Serious Adverse Events (SAEs) were experienced by one (1.4%) DrugX recipient who discontinued treatment, and four (6.7%) Comparator recipients of whom three (5%) discontinued treatment. None of the SAEs were terminal.

Table 2 reports the incidence of treatment-emergent AEs occurring in 3% or more subjects. The most common AEs in the DrugX group were vomiting (8.6%) and headache (7.1%), while the most common in the Comparator group were right ventricular failure (20.0%), palpitations (16.7%), and hypotension (15.0%). While both treatment groups experienced AEs with comparable frequency in the body classes of Nervous System Disorders (8 (11.4%) with DrugX vs. 10 (16.7%) with Comparator) and Vascular Disorders (8 (11.4%) with DrugX vs. 13 (21.7%) with Comparator), subjects treated with DrugX experienced a four-fold lower incidence rate of Cardiac Disorders (6 (8.6%) with DrugX vs. 22 (36.7%) with Comparator). On the other hand, they experienced Gastrointestinal Disorders at a higher incidence rate (8 (11.4%) with DrugX vs. 2 (3.3%) with Comparator).

In conclusion, the group treated with DrugX experienced half the rate of AEs (particularly moderate and severe AEs) and a quarter the rate of SAEs as the group treated with the Comparator. The Drug X group also had a markedly lower rate of Cardiac Disorder AEs but an elevated rate of Gastrointestinal Disorder AEs.

Table 1. Overview of Adverse Events

Number (%) of subjects	**DrugX N=70**	**Comparator N=60**
Subjects with any AE, n (%)	45 (64.3)	54 (90.0)
Subjects with mild AEs, n (%) Subjects with moderate AEs, n (%) Subjects with severe AEs, n (%)	25 (35.7) 10 (14.2) 5 (7.1)	20 (33.3) 21 (35.0) 13 (21.7)
Subjects with drug-Related AE, n (%)	12 (17.1)	19 (31.7)
Subjects with SAEs, n (%)	1 (1.4)	4 (6.7)
Subjects discontinued due to an AE, n (%)	1 (1.4)	3 (5.0)
Subjects who died on study, n (%)	0 (0.0)	0 (0.0)

Table 2. Incidence of Treatment-Emergent Adverse Events Occurring in ≥3% Patients

	DrugX	Comparator
Number of Patients	**70**	**60**
Number of patients experiencing at least 1 AE	45 (64.3)	54 (90.0)
Cardiac Disorders	6 (8.6)	22 (36.7)
Palpitations	4 (5.7)	10 (16.7)
Right ventricular failure	2 (2.9)	12 (20.0)
Ear and labyrinth disorders	4 (5.7)	3 (5.0)
Vertigo	4 (5.7)	3 (5.0)
Gastrointestinal disorders	8 (11.4)	2 (3.3)
Nausea	2 (2.9)	1 (1.7)
Vomiting	6 (8.6)	1 (1.7)
General disorders and administration site conditions	2 (2.9)	7 (11.7)
Edema peripheral	2 (2.9)	7 (11.7)
Nervous system disorders	8 (11.4)	10 (16.7)
Dizziness	3 (4.3)	7 (11.7)
Headache	5 (7.1)	3 (5.0)
Psychiatric disorders	4 (5.7)	2 (3.3)
Insomnia	4 (5.7)	2 (3.3)
Respiratory, thoracic and mediastinal disorders	4 (5.7)	4 (6.7)
Cough	2 (2.9)	2 (3.3)
Dyspnea exacerbated	2 (2.9)	2 (3.3)
Vascular disorders	8 (11.4)	13 (21.7)
Flushing	4 (5.7)	4 (6.7)
Hypotension	4 (5.7)	9 (15.0)

Values are number (%) of patients experiencing an AE. Patients are counted only once at each level of summation.