

Table 14-5.02

Incidence of Treatment Emergent Serious Adverse Events by Treatment Group

System Organ Class/ Preferred Term	Placebo (N=86)		Xanomeline Low (N=84)		Xanomeline High (N=84)		Fisher's Exact p-values Placebo vs. Placebo vs. High Dose	
	n(%)	[AEs]	n(%)	[AEs]	n(%)	[AEs]	Low Dose	High Dose
ANY BODY SYSTEM	0		1 (1.2%)	[1]	2 (2.4%)	[2]	0.494	0.243
NERVOUS SYSTEM DISORDERS	0		1 (1.2%)	[1]	2 (2.4%)	[2]	0.494	0.243
SYNCOPE	0		1 (1.2%)	[1]	1 (1.2%)	[1]	0.494	0.494
PARTIAL SEIZURES WITH SECONDARY GENERALIZATION	0		0		1 (1.2%)	[1]		0.494

Note: Treatment emergent events are defined as events which start on or after the start of treatment.

Note: Adverse events are coded using MedDRA.

Note: Percentages are based on the number of subjects in the safety population within each treatment group.

Note: P-values are based on Fisher's Exact test for the comparison of placebo versus each active treatment group. An asterisk is appended to p-values that are less than 0.15.

Note: The column [AE] represents the total number of times an event was recorded.

Source: C:\cdisc_pilot\PROGRAMS\DRAFT\TFLs\saetable.sas

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