

Program:C:/packages/reporter/tests/testthat/test-user.R

Study: 0598-CL-0101

Appendix 10.2.6.1.2.1

Draft

Source: ADAE, ADOT

TMP Complete Closure Response - Single Ascending Dose (SAD)

All Randomized Patients

Cohort	Dose Day/ Date/ Treated Ear	Visit Day/Date	Analysis Visit	Observed Response	Imputed Response
Investigator Site = 10003 - Advance ENT, Subject ID=1000310001, Age=22 Years, Sex=Male, Race=White, Weight= 74.84 kg COHORT 1 - Single Dose Escalation - 0.03ug					
	1/ 2020-09-29/ Left	2/2020-09-30	Day 2	No	
		4/2020-10-03	Day 3	No	
		8/2020-10-06	Week 1	No	
		14/2020-10-12	Week 2	No	
		28/2020-10-26	Week 4	No	
		57/2020-11-24	Week 8	No	No
Investigator Site = 10003 - Advance ENT, Subject ID=1000310002, Age=56 Years, Sex=Female, Race=Asian or Pacific Islander, Weight= 60.31 kg COHORT 1 - Single Dose Escalation - 0.03ug					
	1/ 2020-09-29/ Right	2/2020-09-30	Day 2	No	
		4/2020-10-03	Day 3	No	
		8/2020-10-06	Week 1	No	
		14/2020-10-12	Week 2	No	
		28/2020-10-26	Week 4	Yes	
		57/2020-11-24	Week 8	Yes	

Time to First Complete Closure of TMP.

Values flagged with '@' were excluded from the by-visit analysis in tables showing the qualitative test results.

Date: 13SEP2022 05:21:09

Astellas

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