R consortium R submission Pilot 1 - summary tables and outputs

Table 14-2.01

Summary of Demographic and Baseline Characteristics

Protocol: CDISCPILOT01
Population: Intent-to-Treat

	Placebo (N=86)	Xanomeline Low Dose (N=84)	Xanomeline High Dose (N=84)
AGE			
Mean (sd)	75.21 (8.59)	75.67 (8.29)	74.38 (7.89)
Median	76	77.5	76
Min - Max	52 - 89	51 - 88	56 - 88
AGEGR1			
<65	14	8	11
65-80	42	47	55
>80	30	29	18
RACE			
WHITE	78	78	74
BLACK OR AFRICAN AMERICAN	8	6	9
AMERICAN INDIAN OR ALASKA NATIVE	0	0	1
HEIGHTBL			
Mean (sd)	162.57 (11.52)	163.43 (10.42)	165.82 (10.13)
Median	162.6	162.6	165.1
Min - Max	137.2 - 185.4	135.9 - 195.6	146.1 - 190.5
WEIGHTBL			
Mean (sd)	62.76 (12.77)	67.28 (14.12)	70 (14.65)
Median	60.55	64.9	69.2
Min - Max	34 - 86.2	45.4 - 106.1	41.7 - 108
BMIBL			
Mean (sd)	23.64 (3.67)	25.06 (4.27)	25.35 (4.16)
Median	23.4	24.3	24.8
Min - Max	15.1 - 33.3	17.7 - 40.1	13.7 - 34.5
MMSETOT			
Mean (sd)	18.05 (4.27)	17.87 (4.22)	18.51 (4.16)
Median	19.5	18	20
Min - Max	10 - 23	10 - 24	10 - 24

Program: tlf_demographic.Rmd

Table 14-3.01

Primary Endpoint Analysis: ADAS Cog (11) - Change from Baseline to Week 24 - LOCF

Table 14-3.01
Primary Endpoint Analysis: ADAS Cog (11) - Change from Baseline to Week 24 - LOCF

	Placebo (N=79)	Xanomeline Low Dose (N=81)	Xanomeline High Dose (N=74)
Baseline			
n	79	74	81
Mean (SD)	24.1 (12.19)	21.3 (11.74)	24.4 (12.92)
Median (Range)	21.0 (5;61)	18.0 (3;57)	21.0 (5;57)
Week 24			
n	79	74	81
Mean (SD)	26.7 (13.79)	22.8 (12.48)	26.4 (13.18)
Median (Range)	24.0 (5;62)	20.0 (3;62)	25.0 (6;62)
Change from Baseline			
n	79	74	81
Mean (SD)	2.5 (5.80)	1.5 (4.26)	2.0 (5.55)
Median (Range)	2.0 (-11;16)	1.0 (-7;13)	2.0 (-11;17)
p-value(Dose Response) [1][2]		0.245	
p-value(Xan - Placebo) [1][3]		0.233	0.569
Diff of LS Means (SE)		-1.0 (0.84)	-0.5 (0.82)
95% CI		(-2.7;0.7)	(-2.1;1.1)
p-value(Xan High - Xan Low) [1][3]		0.520	
Diff of LS Means (SE)		-0.5 (0.84)	
95% CI		(-2.2;1.1)	

[1] Based on Analysis of covariance (ANCOVA) model with treatment and site group as factors and baseline value as a covariate.
[2] Test for a non-zero coefficient for treatment (dose) as a continuous variable
[3] Pairwise comparison with treatment as a categorical variable: p-values without adjustment for multiple comparisons.
Source: <run interactively> *23:38 Saturday, October 09, 2021*

Table 14-3.02

Primary Endpoint Analysis: CIBIC+ - Summary at Week 24 - LOCF

ANCOVA of Change from Baseline at Week 20
LOCF
ITT Population

	Baseline		Week 20		Change from Baseline		
Treatment	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	LS Mean (95% CI)[a]
Study Drug	31	5.6 (1.44)	31	5.8 (1.61)	31	0.2 (1.47)	0.16 (-0.31, 0.63)
Placebo	65	5.7 (2.44)	65	5.8 (1.50)	65	0.1 (2.08)	0.09 (-0.23, 0.42)
Pairwise Comparison				Difference in LS Mean (95% CI)[a]			p-Value
Study Drug vs. Placebo				0.07 (-0.50, 0.63)			0.822
Root Mean Squared Error of Change = 1.31							
[a] Based on an ANCOVA model. ANCOVA = Analysis of Covariance, CI = Confidence Interval, LS = Least Squares, SD = Standard Deviation							

Source: [study999: adam-adlbc]

Figure 14-1

Time to Dermatologic Event by Treatment Group