R Consortium R Submission Pilot 1 - Summary Tables and Figures

Note: In this pilot, different open-source packages were used when generating each of the 4 analysis outputs to test wider use case scenarios. The outputs were formatted differently intentionally to cover different company specific formatting choices.

Table 14-2.01

Summary of Demographic and Baseline Characteristics

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Protocol: CDISCPILOT01
Population: Intent-to-Treat

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                                    Placebo      Xanomeline Low Dose  Xanomeline High Dose
                                    (N=86)             (N=84)              (N=84)
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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
Pooled Age Group 1
  <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
Baseline Height (cm)
  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
Baseline Weight (kg)
  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
Baseline BMI (kg/m^2)
  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
MMSE Total
  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
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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.

Table 14-3.02

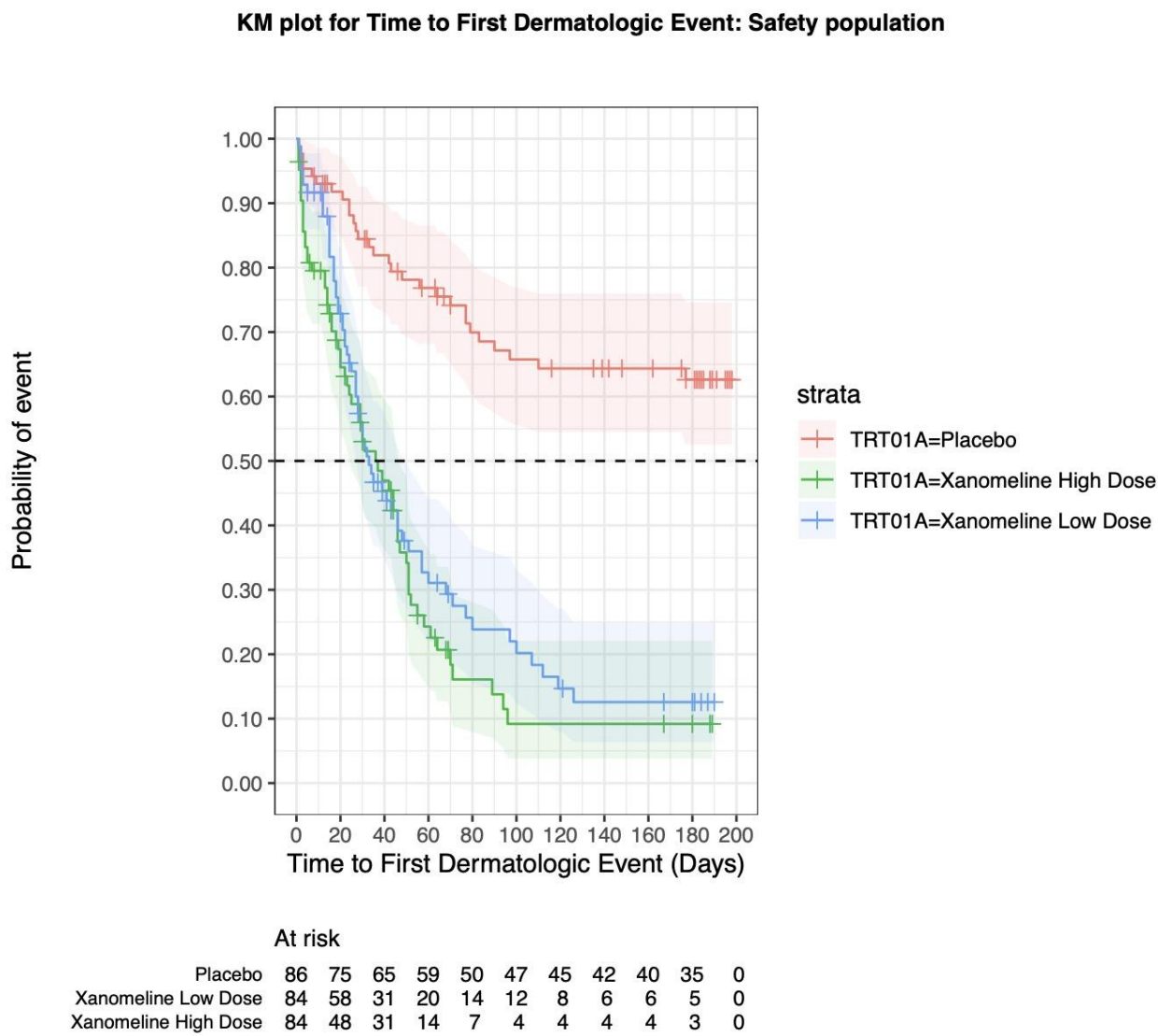**Primary Endpoint Analysis: CIBIC+ - Summary at Week 24 - LOCF**

ANCOVA of Change from Baseline at Week 20
LOCF
ITT Population

Treatment	Baseline		Week 20		Change from Baseline		
	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

KM plot for Time to First Dermatologic Event: Safety population

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