

1 R Consortium R Submission Pilot 1 - Summary Tables and Figures

2 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.

5 Table 14-2.01

6 Summary of Demographic and Baseline Characteristics

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15

1 R Consortium R Submission Pilot 3 - Summary Tables and Figures

2 Pilot 3 Team

3 2024-04-17

4 Note : In Pilot 3, following the same approach as Pilot1, different open-source packages were used when

5 generating each of the 4 analysis outputs to test wider use case scenarios. The outputs were formatted

6 differently intentionally to cover different company specific formatting choices.

7 1

8 Table 14-2.01

9 Summary of Demographic and Baseline Characteristics

10 Protocol: CDISCPIL0T01

11 Population: Intent-to-Treat

13 Placebo Xanomeline Low Dose Xanomeline High Dose

14 (N=86) (N=84) (N=84)

16 Age

17 Mean (sd) 75.21 (8.59) 75.67 (8.29) 74.38 (7.89)

18 Median 76.00 77.50 76.00

19 Min - Max 52.00 - 89.00 51.00 - 88.00 56.00 - 88.00

20 Pooled Age Group 1

21 <65 14 8 11

22 65-80 42 47 55

23 >80 30 29 18

24 Race

25 WHITE 78 78 74

26 BLACK OR AFRICAN AMERICAN 8 6 9

27 AMERICAN INDIAN OR ALASKA NATIVE 0 0 1

28 Baseline Height (cm)

29 Mean (sd) 162.57 (11.52) 163.43 (10.42) 165.82 (10.13)

30 Median 162.60 162.60 165.10

31 Min - Max 137.20 - 185.40 135.90 - 195.60 146.10 - 190.50

32 Baseline Weight (kg)

33 Mean (sd) 62.76 (12.77) 67.28 (14.12) 70.00 (14.65)

34 Median 60.55 64.90 69.20

- 7 Table 14-3.01  
 8 Primary Endpoint Analysis: ADAS Cog (11) - Change from Baseline to Week 24 - LOCF  
 9 Table 14-3.02  
 10 Primary Endpoint Analysis: Glucose (mmol/L) - Summary at Week 20 - LOCF  
 11 Figure 14-1  
 12 Time to Dermatologic Event by Treatment Group

35 Min - Max 34.00 - 86.20 45.40 - 106.10 41.70 - 108.00  
 36 Baseline BMI (kg/m<sup>2</sup>)  
 37 Mean (sd) 23.64 (3.67) 25.06 (4.27) 25.35 (4.16)  
 38 Median 23.40 24.30 24.80  
 39 Min - Max 15.10 - 33.30 17.70 - 40.10 13.70 - 34.50  
 40 MMSE Total  
 41 Mean (sd) 18.05 (4.27) 17.87 (4.22) 18.51 (4.16)  
 42 Median 19.50 18.00 20.00  
 43 Min - Max 10.00 - 23.00 10.00 - 24.00 10.00 - 24.00

45 Program: tlf-demographic.r  
 46 2024-04-17 20:01:23  
 47 2  
 48 Protocol: CDISCPIL0T01Page 1 of  
 49 Population: Efficacy

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

52 Placebo  
 53 (N=79)  
 54 Xanomeline  
 55 Low Dose  
 56 (N=81)  
 57 Xanomeline  
 58 High Dose  
 59 (N=74)  
 60 [1] Based on Analysis of covariance (ANCOVA) model with treatment and site group as factors and baseline value as a covariate.  
 61 [2] Test for a non-zero coefficient for treatment (dose) as a continuous variable  
 62 [3] Pairwise comparison with treatment as a categorical variable: p-values without adjustment for multiple comparisons.  
 63 Source: <run interactively>20:01 Wednesday, April 17, 2024  
 64 Baseline  
 65 n 79 81 74  
 66 Mean (SD) 24.1 (12.19) 24.4 (12.92) 21.3 (11.74)  
 67 Median (Range) 21.0 ( 5;61) 21.0 ( 5;57) 18.0 ( 3;57)  
 68 Week 24  
 69 n 79 81 74

72 Mean (SD) 26.7 (13.79) 26.4 (13.18) 22.8 (12.48)

73 Median (Range) 24.0 ( 5;62) 25.0 ( 6;62) 20.0 ( 3;62)

74 Change from Baseline

75 n 79 81 74

76 Mean (SD) 2.5 ( 5.80) 2.0 ( 5.55) 1.5 ( 4.26)

77 Median (Range) 2.0 (-11;16) 2.0 (-11;17) 1.0 (-7;13)

78 p-value(Dose Response) [1][2] 0.245

79 p-value(Xan - Placebo) [1][3] 0.569 0.233

80 Diff of LS Means (SE) -0.5 (0.82) -1.0 (0.84)

81 95% CI (-2.1;1.1) (-2.7;0.7)

82 p-value(Xan High - Xan Low) [1][3] 0.520

83 Diff of LS Means (SE) -0.5 (0.84)

84 95% CI (-2.2;1.1)

85 ANCOVA of Change from Baseline at Week 20

86 Baseline Week 20 Change from Baseline

87 Treatment N Mean (SD) N Mean (SD) N Mean (SD) LS Mean (95% CI)b

88 Xanomeline High Dose 84 5.4 ( 1.34) 31 5.8 ( 1.61) 31 0.2 ( 1.47) 0.16 (-0.31, 0.63)

89 Placebo 86 5.6 ( 2.14) 65 5.8 ( 1.50) 65 0.1 ( 2.08) 0.09 (-0.23, 0.42)

90 Pairwise Comparison Difference in LS Mean (95% CI)b p-Value

91 Xanomeline High Dose vs. Placebo 0.07 (-0.50, 0.63) 0.822

92 Root Mean Squared Error of Change = 1.30

93 Table generated on: 2024-04-17 20:01:10

94 Source: [pilot3: adam-adsl; adlbc]

95 1

96 KM plot for Time to First Dermatologic Event: Safety population

97 0.00

98 0.10

99 0.20

100 0.30

101 0.40

102 0.50

103 0.60

104 0.70

105 0.80

106 0.90

107 1.00

108 0 20 40 60 80 100 120 140 160 180 200

109 Time to First Dermatologic Event (Days)

110 Probability of event

111 TRT01A

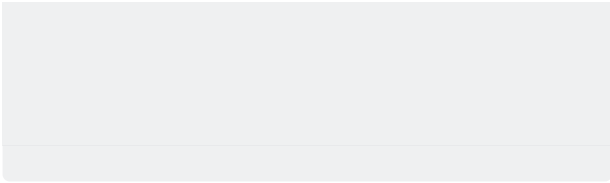
112 Placebo

113 Xanomeline Low Dose

114 Xanomeline High Dose

115 86 75 65 59 50 47 45 42 40 35 0

116 84 58 31 20 14 12 8 6 6 5 0



13

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117 Xanomeline High Dose 84 48 31 14 7 4 4 4 3 0
118 Xanomeline Low Dose
119 Placebo
120 At risk
121 Program: tlf-kmplot.r [2024-04-17 20:01:25]
122
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