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TNX-355, IN COMBINATION WITH OPTIMIZED BACKGROUND REGIMEN (OBR), ACHIEVES STATISTICALLY SIGNIFICANT VIRAL LOAD REDUCTION AND CD4 CELL COUNT INCREASE WHEN COMPARED WITH OBR ALONE IN PHASE 2 STUDY AT 48 WEEKS

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BACKGROUND: TNX-355 is a novel humanized monoclonal antibody that binds to domain 2 of the CD4 receptor, blocking entry of HIV-1 into target cells. A 48-week randomized, double-blind, placebo-controlled study assessed the safety and efficacy of two dosage regimens of TNX-355 plus OBR versus (vs.) placebo plus OBR. The primary endpoint was mean change in HIV-1 RNA (VL) from baseline (BL) at Week 24; additional assessments of safety and efficacy were conducted through Week 48.

METHODS: Triple-class experienced HIV-infected patients were randomized to receive TNX-355 intravenously: 10mg/kg Q wk for 9 doses followed by 10mg/kg Q 2 wks; 15 mg/kg Q 2 wks, or placebo. All patients received OBR. After virologic failure (< 0.5 log₁₀ drop from BL after week 16), patients received 15 mg/kg open-label TNX-355 Q 2 wks in combination with new OBR. An analysis of the intent-to-treat population was performed, along with statistical tests for immunologic and virologic measurements at 24 and 48-weeks, corrected for multiple comparisons of each TNX-355 arm vs. the placebo arm.

RESULTS: 82 patients (87% male, 46% white) enrolled: mean age 46 years. Summary of Week 48 Data:

TNX-355	15mg/kg+OBR n=28	10mg/kg+OBR n=27	Placebo+OBR n=27
Mean VL change log ₁₀ *	-0.71 (p=0.009)	-0.96 (p<0.001)	-0.14
N (%) ≥1.0 log ₁₀ reduction	9 (32)	10 (37)	3 (11)
N (%) ≥0.5 log ₁₀ reduction	11 (39) (p=0.029)	12 (44) (p=0.014)	3 (11)
% <400 (% <50) copies/mL	7 (4)	4 (0)	0 (0)
Median time loss of virologic response (days)	253 (p=0.003)	230 (p=0.003)	0

Mean change in CD4+ (cells/mL)	51 (p=0.016)	48 (p=0.031)	1
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*Non-completer=mean of last two values

CONCLUSIONS: TNX-355 in combination with OBR resulted in a statistically significant difference in viral load reduction compared to placebo plus OBR at Week 48. Treatment with TNX-355 is associated with durable viral load reductions and clinically meaningful increases in CD4 counts in treatment-experienced patients.

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