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Virological responses of treatment-naïve stage CDC-2 HIV-1 positive subjects receiving VGV-1 injections in a blinded, placebo-controlled, multi-centre clinical trial

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Background

A blinded, placebo-controlled, multi-center study was completed in South Africa to determine virological response of treatment-naïve CDC-2 HIV-1 infected subjects receiving VGV-1 injections. The primary endpoint was the proportion of subjects with >0.5 log decrease in HIV-RNA.

Methods

138 subjects with mean CD4 of 336 cells/ul and mean HIV-RNA of 4.9 log were enrolled in this GCP, ICH-compliant study. Subjects were randomized to receive either VGV-1 monotherapy (bovine-derived thymus nuclear protein in alum, presumable immune modulator) or control via 16 biweekly i.m. injections and followed to 240 days. Effects of antiretrovirals, provided to disease progressors, were excluded from analysis.

Results

Statistically significant antiviral responses were observed in treated subjects versus placebo (22.2% vs. 6.25%, p = 0.024) 100 days after dosing (day 150). Effects waned (15.6% vs. 6.25%, p = 0.128) 190 days after dosing (day 240). Antiviral responses were more common in immune-compromised (baseline CD4<300 cells/ul) subjects at day 150 (35.7%, p = 0.019) and day 240 (25%, p = 0.0479) compared to placebo. There were no serious adverse events observed in relation with the VGV-1 injections.

Conclusion

Bioactivity of VGV-1 was confirmed and it was well tolerated without apparent safety concerns vs. control. Further study to optimize dosing and clarify mechanism is warranted.