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OA04-05. Safety and viral load changes in HIV-1 infected subjects treated with autologous dendritic immune therapy following ART discontinuation (CTN#239)

J Routy*[1], M Boulassel[2], L Mona[3], V Sylvie[4], T Cécile[5], A Jonathan[6], G John[7], B Jean-Guy[8], S Fiona[9], J Renu[10], H Don[10], T Irina[10], N Charles[10] and RP Sékaly[11]

Address: [1]McGill University and INSERM Unit 743, Montréal, Canada, [2]McGill University health Centre, Montréal, Canada, [3]Maple Leaf Clinic, Toronto, Canada, [4]Clinique Médicale l'Actuel, Montréal, Canada, [5]Centre de recherche du centre Hospitalier de l'Université de Montréal, Montréal, Canada, [6]Ottawa General Hospital, Ottawa, Canada, [7]Southern Alberta Clinic, Calgary, Canada, [8]Medical du Quartier Latin, Montréal, Canada, [9]Hamilton Health Sciences, McMaster University Medical Center, Hamilton, Canada, [10]Argos Therapeutics Inc, Durham, NC, USA and [11]University of Montreal Research Centre, and INSERM Unit 743, Montreal, Canada

* Corresponding author

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Background

We demonstrated in a phase 1 trial that an immunotherapy (AGS-004) consisting of a monocyte-derived dendritic cells (DC) and RNA encoding autologous HIV antigens (Gag, Nef, Rev, Vpr) derived from the patient's own pre-ART plasma induced immunogenicity in most patients. Based on these results a multicenter phase 2 trial was implemented to assess the safety and proportion of patients demonstrating viral load (VL) < 1000, < 5000 and < 10,000 copies/ml during the 12 week ART structured treatment interruption (STI).

Methods

Subjects on their initial ART regimen with VL < 50 copies/ml, CD4 > 450 cells/µl, CD4 nadir > 200 cells/µl and a pre-ART VL > 10,000 to 500,000 copies/ml were eligible. The treatment consists of 4 intradermal AGS-004 doses administered monthly in combination with ART followed by two more doses during the 12 week STI. Subjects who participated in the phase 1 study were included and received a second cycle of AGS-004. Subjects may continue AGS-004 booster administration if VL remains < 10,000 copies/ml.

Results

33 subjects were enrolled from 11 Canadian sites, and AGS-004 successfully manufactured and administered to 21 subjects. 9 subjects have successfully completed 12 weeks of STI. The immunotherapy related AEs were Grade 1 or 2 flu-like, GI symptoms, fatigue, and injection site reactions. During the STI, no reports of autoimmunity or AIDS defining events were observed. After an initial viral rebound, 4 out of 9 subjects had > 2 instances of VL measures < 1000 copies/mL when assessed every 2 weeks during the STI. At week 12 of STI 5 subjects had viral loads < 10,000 copies/ml with CD4 > 350 cells/µl including 4 subjects with viral loads < 5000 copies/ml.

Conclusion

Results from this phase 2 autologous immunotherapy trial demonstrated that this therapy is safe and induced partial control of VL when compared to pre-ART VL during the 12-week STI.