Highlight Sheet Study CTNPT 031 **Investigators:** Michaeline McGuinty & Bill Cameron: updated 09 Apr 2024

Title: Vedolizumab treatment in antiretroviral drug treated chronic HIV infection (Havarti study)

Objectives:

- To identify safety and tolerance of standard serial dosage of vedolizumab (300mg) in healthy adults are treated with HIV antiretroviral therapy (HIV- ART).
- To identify whether healthy adults with HIV-ART treated with adjunctive vedolizumab will show a sustained post-treatment remission of PVL/gut viral loads rebound and recurrence after ATI.
- To identify the clinical, therapeutic, and laboratory immunovirological measures that characterize HIV-ART cases treated with vedolizumab before, during and after adjunctive vedolizumab treatment, ATI, and possible remission of PVL.

Study Design: Phase II single-arm 3-group prospective interventional cohort study

Population: Chronically HIV +ve adults (otherwise healthy) receiving ART and followed at Ottawa Hospital HIV clinic. **N=12**

Sites: The Ottawa Hospital

Intervention: Vedolizumab 300mg, 150mg or 75 mg IV at week 0, 2, 6 and every 4 weeks thereafter up to 26 weeks, for a total of up to 7 doses as tolerated

Study Duration: Participants on study for 52 weeks

Enrolment Period: Oct 2017 – Dec 2024

FVFP: 17 Nov 2017; **LVLP:** Projected: 31 Dec 2025

CTN Services: Knowledge Translation and Communications – Press releases and media interaction, community dissemination.

Visit Schedule/Procedures:

Study Visit[2] → / Study Activity ↓	Screening	Baseline	Week 0	Week 2	Week 5	Week 6, 7^	Week 8	Week 12	Week 16	Week 20	Week 24	Weeks 28, 32, 36, 40, 44, 48	Week 52
Informed consent	X												
Eligibility confirmation	X												
Concomitant Meds	X	X	X	X	X		X	X	X	X	X	X	
Pregnancy test if appl.[+]	X												
Safety Labs (CBC, diff WBC, biochem, ESR, CRP)	X[1]	X	X	X			X	X	X	X	X	X	X
Serum (10ml)		X	X	X	X		X	X	X	X	X	X	
Plasma (10ml)		X	X	X	X	X	X	X	X	X	X	X	
PBL**		X			X						X		
PVL	X	X					X	X	X	X	X	X	X
CD4	X	X					X	X	X	X	X	X	X
Vedolizumab IV infusion			X	X	X		X	X	X	X			
History & Physical	X	X	X	X	X		X	X	X	X	X	X	X
Optional CSF Specimen											X		
Optional Rectal Mucosal Biopsy		X									X		X
Optional Stool Sample		X									X		X
AE Assessment		X	X	X	X	X	X	X	X	X	x	X	X

[1] If safety labs have been drawn within 1 year of the screening visit these results may be used for screening purposes.
[2] Study visits may occur ± 1 week from the time points outlined in the table.
^ ATI (analytical treatment interruption) will occur at week 6-7
** 50 -100 ml phlebotomy for separation & cryopreservation[+] Pregnancy testing with urine dip for βHCG may be repeated at any study visit where it is felt to be indicated by the patient or the study investigator.