Study report to DSMC

CTN Study #: CTNPT 031

Study Title: Vedolizumab treatment in antiretroviral drug treated chronic HIV infection

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CURRENT STUDY STATUS ☒ Open to enrolment ☐ Ongoing (Closed to enrolment; participant visits/follow-up ongoing) ☐ Study visits completed; Date of LPLV_____ ☐ Other, specify:	
ENROLMENT	
Target Enrolment	12
Number of participants enrolled/randomized in the last 6 months	0
Total number of participants enrolled/randomized since study start	9
Number of participants enrolled/randomized at each study site, if applicable	N/A
Date of FPFV (first participant first visit)	**JN: 17 Nov 2017**
Projected date of LPLV (last participant last visit) if study is ongoing	31 Dec 2025
STUDY THERAPY	
Number of participants started therapy	9
Number of participants currently on therapy	0
Number of participants discontinued therapy	0
• Number of participants discontinued therapy early, if applicable	N/A
• Therapy discontinuation related to adverse drug reaction?	☐ Yes ☐ No ☒ N/A
• If yes, specify:	
PROTOCOL COMPLETION	
Number of participants completing protocol	9
EARLY DISCONTINUATIONS (Enter number of participants for each discontinuation)	
• Inadvertent enrolment – participant not eligible	0
• Participant withdrew consent	0
• Qualified investigator's request	0
• Non-compliance with study procedures	0
• Safety reasons	0
• Non-compliance with study procedures	0
• Lost to follow up	0
• Death	0

• Other, specify:	
• Other, specify:	
PARTICIPANT CHARACTERISTICS (key characteristics only) (means, medians or proportions)	
• Age	48.5
• Sex	M
• Other specify:	
• Other specify:	
• Other specify:	
SERIOUS ADVERSE EVENTS	
Any SAEs?	☐ Yes ☒ No
• If yes, number of SAEs in the past 6 months	
• If yes, total number of SAEs	
• If yes, attach the SAE form (include: Study ID, Type of event (death, life-threatening, hospitalization, disability), date of event, date of first dose of study drug, judged causal relationship between event and study drug, description of event (text), explained by other etiology? action taken with study drug, if hospitalized for event, date of admission and discharge, current status (e.g., resolved, ongoing, died)	

COMMENTS	
Description of any issues (e.g. reasons for study delays, low enrolment; enrolment suspension)	
Other comments	We have a 10th patient consented. We are waiting to enrol the patient.