

Project Brief: GSK205858

Full Title of Study/Programme	Continued access to etravirine in treatment experienced HIV-1 infected subjects
Technical Focus Area	Research Pediatric
Rationale	The aim of the study is to provide continuous access to ETR for subjects who have completed a clinical study with ETR sponsored by or in collaboration with Janssen Research & Development.
Primary Objectives	The primary objective is to continue the provision of ETR for subjects who previously received ETR in a clinical trial sponsored by or in collaboration with Janssen Research & Development, and who continue to benefit from the use of ETR, in countries where ETR is not commercially available for the subject's indication, is not reimbursed, and cannot be accessed through another source (e.g. access program or government program), or where the subject is not eligible for ongoing trials/programs with ETR.
Secondary Objectives	
Endpoint/Outcome	Incidence and severity of serious adverse events (SAEs) and any clinical or laboratory adverse events leading to discontinuation of IP (Tivicay or ABC/DTG/3TC FDC
Study Design	This is a non-randomized, open-label, multi-center rollover study with two treatment arms. The purpose of this study is to provide continued access to IP for eligible subjects who have completed parent studies P1093 or P2019 and who have tolerated IP in the parent studies without any significant toxicity or signs of virologic failure leading to the permanent discontinuation of IP and withdrawal from the parent study. Continued access to DTG will be provided as follows: • Arm 1: Subjects from the P1093 parent study will continue to receive Tivicay. • Arm 2: Subjects from the P2019 parent study will continue to receive ABC/DTG/3TC. The duration of subject participation in the study will extend until age appropriate formulations of Tivicay or ABC/DTG/3TC receive local (by country) regulatory approval and are available commercially in those countries or other availability occurs from another source (e.g. government programs, aid programs, assistance programs, etc.).

	Patients may be enrolled after all screening procedures have been completed and results are available and documented in the patient's medical records. In most cases, the Screening visit will overlap with the subject's penultimate visit on the parent study (at Week 180 of P1093, or Week 36 of the P2019 study). Patients who meet all entry criteria may enroll and will be seen in the clinic every 12 weeks for a safety evaluation and to receive IP. IP is provided by ViiV Healthcare. Only Tivicay and ABC/DTG/3TC will be made available through this rollover protocol. Provision of other ARVs as part of the background regimen are not considered IP and will not be supplied. It is the responsibility of the investigator to source the ARVs of the background regimen locally
Study Arms	IP will be provided to each subject on this rollover study until any one or more of the following events occur: • Until age-appropriate formulations of Tivicay or ABC/DTG/3TC are available from some other source (e.g. government programs, aid programs, assistance programs etc.) for a subject; OR • Until a subject is no longer deriving benefit from treatment; OR • Until a subject meets a protocol-defined reason for discontinuation • Until development of Tivicay or ABC/DTG/3TC is terminated.
Study Population	All subjects from the P1093 and P2019 studies who meet the screening eligibility criteria and are unable to access age appropriate formulations of IP locally, will be allowed to enroll in this study and will be considered evaluable. Based on the design of the parent studies.
Study Sample Size	No formal sample size calculation is done. Subjects who completed treatment in a clinical study with ETR, and continue to benefit from the use of ETR, may be eligible to continue ETR via this trial
Follow-up/Duration	Once subjects enter this rollover study, they will be seen in clinic every 12 weeks for safety visits until one of the below are met. • Until age-appropriate formulations of Tivicay or ABC/DTG/3TC are available from some other source (e.g. government programs, aid programs, assistance programs etc.) for a subject; OR • Until a subject is no longer deriving benefit from treatment; OR • Until a subject meets a protocol-defined reason for discontinuation • Until development of Tivicay or ABC/DTG/3TC is terminated.

Study/Programme Sites	Wits RHI Shandukani Research Centre (SRC)
Study/Programme Duration	Start Date: November 2017 Estimated End Date: Jul 2024
Intervention	Investigational Product (IP) is defined as Tivicay film coated tablets, Tivicay DT, ABC/DTG/3TC immediate release tablets or ABC/DTG/3TC DT. IP for subject transitioning from parent studies P1093 and P2019 will be provided through the study as per Tivicay and ABC/DTG/3TC dosing tables (Appendix 2). Other ARVs will not be provided by the study and are not considered part of the study. These other ARVs must be supplied locally.
Operations	Study Specific
Investigators	Prof Lee Fairlie: Principal Investigator Dr Elizea Horne: Sub-Investigator Dr Faezaz Patel: Sub-Investigator Dr Mrinmayee Dhar: Sub-Investigator
Other Partners & Collaborators	GSK
Sponsors/Donors	Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc. (hereafter referred to as the Sponsor or MSD)
Publications/Key Presentations to Date	None yet.
Progress Update as of Jun 2025	Screened: 16 Enrolled: 16 Discontinued: 01 Completed Study: 16 Roll on to study: 4 On study: 0
Frequency of Donor Narrative Report	Monthly
Overall Study/Project Contact	Prof Lee Fairlie
Briefing Owner and Date	Rorisang Komane(rkomane@wrhi.ac.za) Jun 2025