Medicines Control Authority of Zimbabwe

Clinical Trials Registry

PUBLIC TITLE/ACRONYM	An open-label, single-arm study to provide continued access to study drug to participants who have completed pediatric clinical studies involving Gilead HIV treatments: GS-US-380-6684
Scientific Title	An open-label, single-arm study to provide continued access to study drug to participants who have completed pediatric clinical studies involving Gilead HIV treatments

Primary Sponsor Details

Sponsors *	Gilead Sciences Inc

Secondary Sponsor Details

Contact for Public Queries

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Countries of Recruitment *

Argentina, Panama, South Africa, Thailand, Uganda and Zimbabwe

Source of Funds	Gilead Sciences
Health Condition(s) or Problem(s) Studied *	HIV
Medicine Name *	B/F/TAF (Biktarvy®), F/TAF (Descovy®), E/C/F/TAF (Genvoya®), Cobicistat (Tybost®)..
Quantity of medicine required *	As stated in table below

7.0 PRINCIPAL INCLUSION CRITERIA *

Inclusion Criteria:

Participants who meet all of the following inclusion criteria are eligible for participation in this study:

- **Completed an applicable parent study: GS-US-292-0106, GS-US-380-1474, GS-US-311-1269, GS-US-216-0128, or CO-US-380-5578.**
- **Parent or legal guardian or participant ≥ 18 years of age and able to provide written informed consent. Participants < 18 years of age will provide written assent if they are able per investigator assessment, and if applicable, per their local institutional guidelines and local country regulations.**

7.1 PRINCIPAL EXCLUSION CRITERIA *

Exclusion Criteria

Participants who meet *any* of the following exclusion criteria are not eligible to be enrolled in this study:

- Participants planning to switch to B/F/TAF on Day 1 cannot have plasma HIV RNA ≥ 50 copies/mL during the last parent study visit prior to screening/Day 1 visit.

Note: participants planning to switch after Day 1 must not have plasma HIV RNA ≥ 50 copies/mL (or detectable HIV-1 RNA level according to the local assay being used if the limit of detection is ≥ 50 copies/mL).

- Participants planning to switch to B/F/TAF must not have any ongoing Grade 3 or 4 drug-related AE or clinically relevant Grade 3 or 4 drug-related laboratory abnormality (confirmed on repeat) related to any component of B/F/TAF prior to treatment switch.
- For those on B/F/TAF or planning to switch to B/F/TAF: previous treatment discontinuation of any component of B/F/TAF due to toxicity or intolerance.
- For those planning to switch to B/F/TAF: known hypersensitivity to any component of the study drug, its metabolites, or formulation excipients.
- Ongoing treatment with or prior use of any prohibited medications.

7.2 PRIMARY END POINTS *

Primary Endpoint:

Number of eligible participants who have received access to the study drug(s) in the study

9.0 DESIGN OF THE TRIAL

Type of trial *	Opened
If controlled	
Randomised	No
Single Blind	No
Double Blind	No
Parallel group	No
Cross over	No
Other	Yes
If yes to other, specify	Single arm study
If controlled, specify the comparator	
Other medicinal product(s)	No
Placebo	No
Other	No
If yes to other, specify	
Other	Yes

Expected Number of participants in Zimbabwe *	70

Total enrolment in each site: (if competitive enrolment, state minimum and maximum number per site.) *	All participants who are on parent study medication and have completed a designated Gilead parent study evaluating drugs for HIV treatment per country are eligible to enroll in this study.
Total participants worldwide *	350

Time period for the trial * UP TO 10 YEARS