

Project Brief: GS-US-380-5578

Full Title of Study	Study Title: A Phase 1b Study to Evaluate the Safety and Pharmacokinetics of Bictegravir/Emtricitabine/Tenofovir Alafenamide (B/F/TAF) in Neonates Exposed to HIV-1 Plain Language Short Title: Study of Bictegravir/Emtricitabine/Tenofovir Alafenamide in Newborns Exposed to HIV.
Technical Focus Area	Research. HIV positive Pregnant women and their newborns – a neonatal pharmacokinetic (PK) study.
Rationale	The availability of antiretrovirals (ARVs) for the treatment and for postnatal prophylaxis of HIV-1 infection in neonates is notably more limited. Treating this pediatric group necessitates the use of distinct drugs in various formulations, and in some cases, the administration of medications on different once-daily and twice-daily schedules. B/F/TAF offers a complete ARV regimen characterized by high potency and favorable tolerability in both adult and pediatric populations. The development of B/F/TAF in a tablet for oral suspension (TOS) formulation provides an option for the pediatric population that is unable to swallow tablets, including neonates. Given the substantial physiological changes occurring during the neonatal period, the safety and PKs of B/F/TAF needs to be evaluated in a clinical study prior to supporting a recommendation and dose for its use in this group.
Primary Objectives	1. To evaluate the safety of B/F/TAF TOS administered along with 1 ARV as SOC postnatal prophylaxis in full-term neonates. 2. To evaluate the plasma PKs of bictegravir (BIC) in full-term neonates exposed to HIV-1 but uninfected, who are administered B/F/TAF TOS along with 1 ARV as SOC postnatal prophylaxis.
Secondary Objectives	1. To evaluate the plasma PK of emtricitabine (FTC), tenofovir alafenamide (TAF), and tenofovir (TFV) in full-term neonates exposed to HIV-1 but uninfected, who are administered B/F/TAF TOS along with 1 ARV as SOC postnatal prophylaxis. 2. To assess the acceptability and palatability of B/F/TAF TOS in full-term neonates exposed to HIV-1 but uninfected.
Primary Endpoint/Outcome	1. Proportion of participants experiencing treatment-emergent adverse events (AEs) through Week 8 after neonate birth 2. Proportion of participants experiencing treatment-emergent laboratory abnormalities through Week 8 after neonate birth PK parameters for BIC: AUC_{inf}, AUC_{last}, AUC_{0-24h}, C_{max}, T_{max}, C_{min}, C_{24h}, $t_{1/2}$, apparent CL/F, and apparent V_z /F.

Secondary Endpoint/Outcome	1. PK parameters for FTC: AUC_{inf}, AUC_{last}, AUC_{0-24h}, C_{max}, T_{max}, C_{min}, C_{24h}, t_{1/2}, apparent CL/F, and apparent Vz/F 2. PK parameters for TAF: AUC_{last}, AUC_{0-24h}, C_{max}, T_{max}, C_{min}, C_{24h}, t_{1/2}, apparent CL/F, and apparent Vz /F 3. PK parameters for TFV: AUC_{inf}, AUC_{last}, AUC_{0-24h}, C_{max}, T_{max}, C_{min}, C_{24h}, and t_{1/2}
Secondary Endpoints	1. PK parameters for FTC: AUC_{inf}, AUC_{last}, AUC_{0-24h}, C_{max}, T_{max}, C_{min}, C_{24h}, t_{1/2}, apparent CL/F, and apparent Vz/F 2. PK parameters for TAF: AUC_{last}, AUC_{0-24h}, C_{max}, T_{max}, C_{min}, C_{24h}, t_{1/2}, apparent CL/F, and apparent Vz /F 3. PK parameters for TFV: AUC_{inf}, AUC_{last}, AUC_{0-24h}, C_{max}, T_{max}, C_{min}, C_{24h}, and t_{1/2}
Study Design (R)	This study is a Phase 1b, multicohort, multicenter, open-label, nonrandomized, and noncomparative investigation designed to evaluate the PK, safety, and tolerability of B/F/TAF TOS in full-term neonates born to mothers with HIV-1. The neonates are exposed to HIV-1 but uninfected, with a birth weight of ≥ 2.5 kg, and receiving 1 ARV as SOC postnatal prophylaxis. The study will enrol participants in sequential cohorts: Cohort 1 and Cohort 2. Cohort 1 will enrol full-term neonates and their mothers. Participants in Cohort 1 will be allocated sequentially into Group A and then Group B. Cohort 1 will assess the safety and PK of B/F/TAF when administered as 2 separate single doses: 1 dose at Visit 1 (within 120 hours of birth), followed by a subsequent dose at Visit 3 (within 10 to 15 days post dose at Visit 1). Cohort 2 will be initiated after Safety Review Team review and will evaluate chronic dosing of B/F/TAF throughout the neonatal period (first 4 weeks of life). This protocol is currently in draft.
Study arms (R)	Arm A and Arm B – each with different time points for the intensive PK
Study population (R)	Cohort 1 will enroll full-term neonates, who are exposed to HIV-1 but uninfected, with a weight of ≥ 2.5 kg at birth and receiving 1 ARV as SOC postnatal prophylaxis at the time of study enrollment, along with their mothers.
Study sample size (R)	Approximately 16 evaluable mother-neonate pairs in Cohort 1.
Follow up/duration	The neonate participants in Cohort 1 will receive 2 separate single doses of B/F/TAF 1.88/7.5/0.94 mg TOS at Visit 1 (within 120 hours of birth) and at Visit 3 (within 10 to 15 days postdose at Visit 1). They will be followed until 8 weeks after birth. The mother will exit the study at Visit 4.
Study/Programme sites	Wits RHI, Multi Site (Worldwide)
Study/Programme duration	Cohort 1 closed to enrolment and follow up
Intervention (R)	Test Product, Dose, and Mode of Administration: Cohort 1: B/F/TAF fixed-dose combination (FDC), 1.88/7.5/0.94 mg TOS
Operations	Pending Cohort 2 protocol finalisation
Investigators	Dr Faezah Patel, Principal Investigator Prof Lee Fairlie, Sub Investigator Dr Elizea Horne, Sub Investigator

	Dr Mrinmayee Dhar, Sub Investigator Dr Jeanne Coetzee, Sub Investigator
Other Partners & Collaborators	BARC, Thermofischer, LabCorp
Sponsors/Donors	Gilead
Linked Sub Studies and post grad projects	Nil
Publications/key presentations to date	Nil at present
Progress Update as at Aug-2025	Study conducted an electronic source data system - Real Time (CTMS) Screened: 08 Screening failure: 03 Enrolled: 5 enrolled into Cohort A, 3 under Schedule A and 2 under schedule B. All participants completed the study Cohort 1 closed to enrollment, pending Cohort 2 protocol finalisation
Frequency of donor narrative report	N/A
Overall Study/Project Contact	Dr Faezaz Patel
Briefing owner and date	Kabelo Mashaba 10 Mar 2026