MTN 026 - Dapivirine Gel Rectal Safety and PK Study
Data as of December 5, 2022

Screen-out Summary by Site

	Birmingham, Al	Pittsburgh, PA	Bangkok, Thailand	All Sites
Participants Screened	12	16	15	43
Participants Enrolled[1, 2]	8 (67%)	10 (63%)	9 (60%)	27 (63%)
Participants not Enrolled	4 (33%)	6 (38%)	6 (40%)	16 (37%)
Participant did not complete all screening procedures[3]	0 (0%)	0 (0%)	4 (67%)	4 (25%)
Participant is eligible but did not enroll	1 (25%)	1 (17%)	1 (17%)	3 (19%)
Reason participant not enrolled is missing	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Participant not eligible[4]	3 (75%)	5 (83%)	1 (17%)	9 (56%)
Age not between 18-45 years (inclusive) at Screening	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Not able and willing to provide written informed consent	0 (0%)	0 (0%)	0 (0%)	0 (0%)
HIV-1/2 infected at Screening and Enrollment and/or not willing to receive HIV test results	0 (0%)	1 (20%)	0 (0%)	1 (11%)
Not able or willing to provide adequate locator information	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Not available to return for all study visits and/or not willing to comply with study requirements	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Not in general good health at Screening and /or Enrollment	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Per participant report, no history of consensual RAI at least once in the past calendar year	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Not willing to not take part in other research studies for the duration of the study	1 (33%)	0 (0%)	0 (0%)	1 (11%)
Not willing to be sexually abstinent when prohibited and as specified per protocol	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Not willing to abstain from inserting any non-study products into the rectum per protocol	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Women over age 21 did not have documentation of satisfactory Pap within the past 3 years	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Women: Not willing to be sexually abstinent for 7 days after biopsy collection per protocol	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Women: Not willing to abstain from inserting non-study products into vagina per protocol	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Women: Not willing to use an effective method of contraception per protocol	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Grade 1 or higher Hemoglobin at Screening	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Grade 1 or higher Platelet at Screening	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Grade 2 or higher White blood count at Screening	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Serum creatinine greater than 1.3x site ULN	0 (0%)	0 (0%)	0 (0%)	0 (0%)
INR greater than 1.5 x ULN	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Grade 1 or higher AST or ALT at Screening	0 (0%)	1 (20%)	0 (0%)	1 (11%)
Positive for hepatitis C antibody	0 (0%)	1 (20%)	0 (0%)	1 (11%)
Positive for hepatitis B surface antigen	0 (0%)	0 (0%)	0 (0%)	0 (0%)
History of inflammatory bowel disease per participant report	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Not willing to abstain from Heparin, including Lovenox, during study participation	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Anticipated use of and/or unwillingness to abstain from Warfarin during study participation	0 (0%)	0 (0%)	0 (0%)	0 (0%)

[1] Number of participants enrolled is based on the Eligibility Criteria eCRF, so could differ from the accrual report, which is instead based on the Randomization eCRF.
[2] Percentage of participants screened.
[3] Percentage of participants not enrolled.
[4] Participants may be ineligible for more than one reason.

Source: SCHARP (Calins) - /trials/mtn/p026/analysis/atlas/9999_99/code/open/screen_out/t_screen_out_main_site.sas, SAS Version 9.4 (06DEC2022,7:02)

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Not willing to abstain from Plavix (clopidogrel bisulfate) during study participation	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Anticipated use of and/or unwillingness to abstain from NSAIDS during study participation	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Not willing to abstain from CYP3A incuder(s) and/or inhibitor(s) during study participation	0 (0%)	0 (0%)	1 (100%)	1 (11%)
Not willing to abstain from Hormone-replacement therapy during study participation	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Known adverse reaction to any of the components of the study products	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Use of PEP for potential HIV exposure within 6 months prior to Enrollment	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Use of PreP for HIV prevention within 6 months prior to or after Enrollment	1 (33%)	0 (0%)	0 (0%)	1 (11%)
Use of systemic immuno modulatory meds within the 6 months prior to or after Enrollment	0 (0%)	0 (0%)	0 (0%)	0 (0%)
RAI or penile-valiginal sex with partner who is known to be HIV-positive in the past 6 months	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Non-therapeutic injection drug use in the 12 months prior to Screening and Enrollment	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Participation in research studies within 45 days of the Enrollment Visit	1 (33%)	0 (0%)	0 (0%)	1 (11%)
At Screening, participation report of treatment for anogenital STI within past 3 months	0 (0%)	0 (0%)	0 (0%)	0 (0%)
At Screening, active anorectal or reproductive tract infection requiring treatment	1 (33%)	1 (20%)	0 (0%)	2 (22%)
At Enrollment, active anorectal or reproductive tract infection requiring treatment or UTI	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Other condition that could preclude informed consent or interfere with study objectives	1 (33%)	1 (20%)	0 (0%)	2 (22%)
Women: Pregnant or breastfeeding or intends to become pregnant during study participation	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Women: Last pregnancy outcome 90 days or less prior to Screening	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Women: Has had a hysterectomy	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Women: At enrollment, has apparent Grade 1 or higher pelvic exam finding per FGGT	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Anticipated use of and/or unwillingness to abstain from Aspirin (greater than 81 mg) during study participation	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Not willing to abstain from any other drugs associated with increased likeklihood of bleeding	0 (0%)	0 (0%)	0 (0%)	0 (0%)

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Listing of Other Reasons for Ineligibility by Site

Obs	Site	Reason
1	Birmingham, Al	THE PARTICIPANT WAS FOUND THE ANAL FISTULA.
2	Pittsburgh, PA	UNABLE TO DRAW BLOOD AFTER MULTIPLE ATTEMPTS.