

HPTN 077 - A Phase IIa Safety, Tolerability and Acceptability Study of an Investigational Injectable HIV Integrase Inhibitor, GSK1265744, for PrEP in HIV Uninfected Men and Women
Report November 16, 2018
Visit Cutoff Date: November 15, 2018
Table D - Injection Summary of Active Participants by Visit and Site

	Overall	UNC AIDS CRS Site ID 257	UCLA CRS Site ID 258	San Francisco Bridge HIV Site ID 259	GWU CRS Site ID 260	Soweto CTU Site ID 261	Vulindlela CRS Site ID 262	Lilongwe UNC Prevention and Treatment Site ID 263	Rio de Janeiro Site ID 264
Week 5 (Injection 1)									
Number of Evaluated Participants	99	24	11	8	12	7	20	1	16
Number of Active Participants	99	24	11	8	12	7	20	1	16
Number of Terminated Participants	0	0	0	0	0	0	0	0	0
Injection Received by Active Participants									
Yes	99/99 (100.0%)	24/24 (100.0%)	11/11 (100.0%)	8/8 (100.0%)	12/12 (100.0%)	7/7 (100.0%)	20/20 (100.0%)	1/1 (100.0%)	16/16 (100.0%)
No	0/99 (0.0%)	0/24 (0.0%)	0/11 (0.0%)	0/8 (0.0%)	0/12 (0.0%)	0/7 (0.0%)	0/20 (0.0%)	0/1 (0.0%)	0/16 (0.0%)

¹Evaluated number of participants includes those whose visit window has closed, plus any participants that have completed the visit even though their visit window has not yet closed.

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Week 17 (Injection 2)									
Number of Evaluated Participants	99	24	11	8	12	7	20	1	16
Number of Active Participants	99	24	11	8	12	7	20	1	16
Number of Terminated Participants	0	0	0	0	0	0	0	0	0
Injection Received by Active Participants									
Yes	88/99 (88.9%)	19/24 (79.2%)	10/11 (90.9%)	7/8 (87.5%)	11/12 (91.7%)	6/7 (85.7%)	18/20 (90.0%)	1/1 (100.0%)	16/16 (100.0%)
No	11/99 (11.1%)	5/24 (20.8%)	1/11 (9.1%)	1/8 (12.5%)	1/12 (8.3%)	1/7 (14.3%)	2/20 (10.0%)	0/1 (0.0%)	0/16 (0.0%)
Reasons Not Received by Active Participants									
Participant Missed Injection Visit	1/11 (9.1%)	0/5 (0.0%)	0/1 (0.0%)	0/1 (0.0%)	0/1 (0.0%)	0/1 (0.0%)	1/2 (50.0%)	-	-
Participant Refused Injection	1/11 (9.1%)	1/5 (20.0%)	0/1 (0.0%)	0/1 (0.0%)	0/1 (0.0%)	0/1 (0.0%)	0/2 (0.0%)	-	-
Injection Schedule Permanently Discontinued	9/11 (81.8%)	4/5 (80.0%)	1/1 (100.0%)	1/1 (100.0%)	1/1 (100.0%)	1/1 (100.0%)	1/2 (50.0%)	-	-
Participant Missed Injection Window	0/11 (0.0%)	0/5 (0.0%)	0/1 (0.0%)	0/1 (0.0%)	0/1 (0.0%)	0/1 (0.0%)	0/2 (0.0%)	-	-
Unknown Reason	0/11 (0.0%)	0/5 (0.0%)	0/1 (0.0%)	0/1 (0.0%)	0/1 (0.0%)	0/1 (0.0%)	0/2 (0.0%)	-	-
Reasons For Missing Visit									
Missing	0/1 (0.0%)	-	-	-	-	-	0/1 (0.0%)	-	-
NA	0/1 (0.0%)	-	-	-	-	-	0/1 (0.0%)	-	-
unable to contact ppt	0/1 (0.0%)	-	-	-	-	-	0/1 (0.0%)	-	-
unable to schedule appts.	0/1 (0.0%)	-	-	-	-	-	0/1 (0.0%)	-	-
participant refused visit	0/1 (0.0%)	-	-	-	-	-	0/1 (0.0%)	-	-
participant incarcerated	0/1 (0.0%)	-	-	-	-	-	0/1 (0.0%)	-	-
ppt. admit to health facility	0/1 (0.0%)	-	-	-	-	-	0/1 (0.0%)	-	-
participant withdrew	0/1 (0.0%)	-	-	-	-	-	0/1 (0.0%)	-	-
participant deceased	0/1 (0.0%)	-	-	-	-	-	0/1 (0.0%)	-	-
other, specify	1/1 (100.0%)	-	-	-	-	-	1/1 (100.0%)	-	-
Reasons For Product Hold									
Missing	0/9 (0.0%)	0/4 (0.0%)	0/1 (0.0%)	0/1 (0.0%)	0/1 (0.0%)	0/1 (0.0%)	0/1 (0.0%)	-	-
NA	0/9 (0.0%)	0/4 (0.0%)	0/1 (0.0%)	0/1 (0.0%)	0/1 (0.0%)	0/1 (0.0%)	0/1 (0.0%)	-	-
product related toxicity	3/9 (33.3%)	3/4 (75.0%)	0/1 (0.0%)	0/1 (0.0%)	0/1 (0.0%)	0/1 (0.0%)	0/1 (0.0%)	-	-
abnormal lab value	1/9 (11.1%)	0/4 (0.0%)	0/1 (0.0%)	1/1 (100.0%)	0/1 (0.0%)	0/1 (0.0%)	0/1 (0.0%)	-	-
clinical reasons	1/9 (11.1%)	0/4 (0.0%)	0/1 (0.0%)	0/1 (0.0%)	0/1 (0.0%)	0/1 (0.0%)	1/1 (100.0%)	-	-
Hep B infection	0/9 (0.0%)	0/4 (0.0%)	0/1 (0.0%)	0/1 (0.0%)	0/1 (0.0%)	0/1 (0.0%)	0/1 (0.0%)	-	-

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QTc>500 ms or change of >60 ms from the	0/9 (0.0%)	0/4 (0.0%)	0/1 (0.0%)	0/1 (0.0%)	0/1 (0.0%)	0/1 (0.0%)	0/1 (0.0%)	-	-
HIV infection suspected	0/9 (0.0%)	0/4 (0.0%)	0/1 (0.0%)	0/1 (0.0%)	0/1 (0.0%)	0/1 (0.0%)	0/1 (0.0%)	-	-
pregnancy or expresses desire to become	0/9 (0.0%)	0/4 (0.0%)	0/1 (0.0%)	0/1 (0.0%)	0/1 (0.0%)	0/1 (0.0%)	0/1 (0.0%)	-	-
use of prohibited con med	0/9 (0.0%)	0/4 (0.0%)	0/1 (0.0%)	0/1 (0.0%)	0/1 (0.0%)	0/1 (0.0%)	0/1 (0.0%)	-	-
request by Ppt to terminate study produc	1/9 (11.1%)	0/4 (0.0%)	0/1 (0.0%)	0/1 (0.0%)	1/1 (100.0%)	0/1 (0.0%)	0/1 (0.0%)	-	-
Ppt unwilling/unable to comply w/procedu	1/9 (11.1%)	0/4 (0.0%)	0/1 (0.0%)	0/1 (0.0%)	0/1 (0.0%)	1/1 (100.0%)	0/1 (0.0%)	-	-
Ppt is currently using or planning to us	0/9 (0.0%)	0/4 (0.0%)	0/1 (0.0%)	0/1 (0.0%)	0/1 (0.0%)	0/1 (0.0%)	0/1 (0.0%)	-	-
CMC decision	1/9 (11.1%)	0/4 (0.0%)	1/1 (100.0%)	0/1 (0.0%)	0/1 (0.0%)	0/1 (0.0%)	0/1 (0.0%)	-	-
other, specify	1/9 (11.1%)	1/4 (25.0%)	0/1 (0.0%)	0/1 (0.0%)	0/1 (0.0%)	0/1 (0.0%)	0/1 (0.0%)	-	-

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Week 29 (Injection 3)									
Number of Evaluated Participants	99	24	11	8	12	7	20	1	16
Number of Active Participants	99	24	11	8	12	7	20	1	16
Number of Terminated Participants	0	0	0	0	0	0	0	0	0
Injection Received by Active Participants									
No	20/99 (20.2%)	9/24 (37.5%)	1/11 (9.1%)	2/8 (25.0%)	2/12 (16.7%)	1/7 (14.3%)	5/20 (25.0%)		
Yes	79/99 (79.8%)	15/24 (62.5%)	10/11 (90.9%)	6/8 (75.0%)	10/12 (83.3%)	6/7 (85.7%)	15/20 (75.0%)	1/1 (100.0%)	16/16 (100.0%)
Reasons Not Received by Active Participants									
Participant Missed Injection Visit	3/20 (15.0%)	0/9 (0.0%)	0/1 (0.0%)	0/2 (0.0%)	0/2 (0.0%)	1/1 (100.0%)	2/5 (40.0%)	-	-
Participant Refused Injection	3/20 (15.0%)	3/9 (33.3%)	0/1 (0.0%)	0/2 (0.0%)	0/2 (0.0%)	0/1 (0.0%)	0/5 (0.0%)	-	-
Injection Schedule Permanently Discontinued	14/20 (70.0%)	6/9 (66.7%)	1/1 (100.0%)	2/2 (100.0%)	2/2 (100.0%)	0/1 (0.0%)	3/5 (60.0%)	-	-
Participant Missed Injection Window	0/20 (0.0%)	0/9 (0.0%)	0/1 (0.0%)	0/2 (0.0%)	0/2 (0.0%)	0/1 (0.0%)	0/5 (0.0%)	-	-
Unknown Reason	0/20 (0.0%)	0/9 (0.0%)	0/1 (0.0%)	0/2 (0.0%)	0/2 (0.0%)	0/1 (0.0%)	0/5 (0.0%)	-	-
Reasons For Missing Visit									
Missing	0/3 (0.0%)	-	-	-	-	0/1 (0.0%)	0/2 (0.0%)	-	-
NA	0/3 (0.0%)	-	-	-	-	0/1 (0.0%)	0/2 (0.0%)	-	-
unable to contact ppt	1/3 (33.3%)	-	-	-	-	0/1 (0.0%)	1/2 (50.0%)	-	-
unable to schedule appts.	0/3 (0.0%)	-	-	-	-	0/1 (0.0%)	0/2 (0.0%)	-	-
participant refused visit	0/3 (0.0%)	-	-	-	-	0/1 (0.0%)	0/2 (0.0%)	-	-
participant incarcerated	0/3 (0.0%)	-	-	-	-	0/1 (0.0%)	0/2 (0.0%)	-	-
ppt. admit to health facility	0/3 (0.0%)	-	-	-	-	0/1 (0.0%)	0/2 (0.0%)	-	-
participant withdrew	0/3 (0.0%)	-	-	-	-	0/1 (0.0%)	0/2 (0.0%)	-	-
participant deceased	0/3 (0.0%)	-	-	-	-	0/1 (0.0%)	0/2 (0.0%)	-	-
other, specify	2/3 (66.7%)	-	-	-	-	1/1 (100.0%)	1/2 (50.0%)	-	-
Reasons For Product Hold									
Missing	0/14 (0.0%)	0/6 (0.0%)	0/1 (0.0%)	0/2 (0.0%)	0/2 (0.0%)	-	0/3 (0.0%)	-	-
NA	0/14 (0.0%)	0/6 (0.0%)	0/1 (0.0%)	0/2 (0.0%)	0/2 (0.0%)	-	0/3 (0.0%)	-	-
product related toxicity	5/14 (35.7%)	3/6 (50.0%)	0/1 (0.0%)	0/2 (0.0%)	0/2 (0.0%)	-	2/3 (66.7%)	-	-
abnormal lab value	3/14 (21.4%)	1/6 (16.7%)	0/1 (0.0%)	2/2 (100.0%)	0/2 (0.0%)	-	0/3 (0.0%)	-	-
clinical reasons	0/14 (0.0%)	0/6 (0.0%)	0/1 (0.0%)	0/2 (0.0%)	0/2 (0.0%)	-	0/3 (0.0%)	-	-
Hep B infection	0/14 (0.0%)	0/6 (0.0%)	0/1 (0.0%)	0/2 (0.0%)	0/2 (0.0%)	-	0/3 (0.0%)	-	-

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QTc>500 ms or change of >60 ms from the	0/14 (0.0%)	0/6 (0.0%)	0/1 (0.0%)	0/2 (0.0%)	0/2 (0.0%)	-	0/3 (0.0%)	-	-
HIV infection suspected	1/14 (7.1%)	0/6 (0.0%)	0/1 (0.0%)	0/2 (0.0%)	0/2 (0.0%)	-	1/3 (33.3%)	-	-
pregnancy or expresses desire to become	1/14 (7.1%)	1/6 (16.7%)	0/1 (0.0%)	0/2 (0.0%)	0/2 (0.0%)	-	0/3 (0.0%)	-	-
use of prohibited con med	0/14 (0.0%)	0/6 (0.0%)	0/1 (0.0%)	0/2 (0.0%)	0/2 (0.0%)	-	0/3 (0.0%)	-	-
request by Ppt to terminate study produc	1/14 (7.1%)	0/6 (0.0%)	0/1 (0.0%)	0/2 (0.0%)	1/2 (50.0%)	-	0/3 (0.0%)	-	-
Ppt unwilling/unable to comply w/procedu	1/14 (7.1%)	0/6 (0.0%)	0/1 (0.0%)	0/2 (0.0%)	1/2 (50.0%)	-	0/3 (0.0%)	-	-
Ppt is currently using or planning to us	0/14 (0.0%)	0/6 (0.0%)	0/1 (0.0%)	0/2 (0.0%)	0/2 (0.0%)	-	0/3 (0.0%)	-	-
CMC decision	1/14 (7.1%)	0/6 (0.0%)	1/1 (100.0%)	0/2 (0.0%)	0/2 (0.0%)	-	0/3 (0.0%)	-	-
other, specify	1/14 (7.1%)	1/6 (16.7%)	0/1 (0.0%)	0/2 (0.0%)	0/2 (0.0%)	-	0/3 (0.0%)	-	-

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