

HPTN 076 - Phase II Safety and Acceptability of an Investigational Injectable Product, TMC278 LA, for Pre Exposure Prophylaxis (PrEP)

Report January 17, 2018

Visit Cutoff Date: January 16, 2018

Table B - Retention by Visit and Site

Oral Phase

	Overall	Bronx Prevention Center CRS Site ID 253	New Jersey Medical School CRS Site ID 254	Emavundleni CRS Site ID 255	Spilhaus CRS Site ID 256
Number Enrolled	136	19	17	48	52
Week 1					
Evaluated ¹	136	19	17	48	52
Visit Completed	94% (128/136)	100% (19/19)	94% (16/17)	85% (41/48)	100% (52/52)
Early	0% (0/136)	0% (0/19)	0% (0/17)	0% (0/48)	0% (0/52)
On time	91% (124/136)	100% (19/19)	94% (16/17)	85% (41/48)	92% (48/52)
Late	3% (4/136)	0% (0/19)	0% (0/17)	0% (0/48)	8% (4/52)
Visit Not Completed	6% (8/136)	0% (0/19)	6% (1/17)	15% (7/48)	0% (0/52)
Visit Missed	6% (8/136)	0% (0/19)	6% (1/17)	15% (7/48)	0% (0/52)
Terminated early	0% (0/136)	0% (0/19)	0% (0/17)	0% (0/48)	0% (0/52)
Week 2					
Evaluated ¹	136	19	17	48	52
Visit Completed	93% (126/136)	95% (18/19)	100% (17/17)	81% (39/48)	100% (52/52)
Early	0% (0/136)	0% (0/19)	0% (0/17)	0% (0/48)	0% (0/52)
On time	93% (126/136)	95% (18/19)	100% (17/17)	81% (39/48)	100% (52/52)
Late	0% (0/136)	0% (0/19)	0% (0/17)	0% (0/48)	0% (0/52)
Visit Not Completed	7% (10/136)	5% (1/19)	0% (0/17)	19% (9/48)	0% (0/52)
Visit Missed	7% (10/136)	5% (1/19)	0% (0/17)	19% (9/48)	0% (0/52)
Terminated early	0% (0/136)	0% (0/19)	0% (0/17)	0% (0/48)	0% (0/52)
Week 4 (Injection 1)					
Evaluated ¹	136	19	17	48	52
Visit Completed	92% (125/136)	95% (18/19)	88% (15/17)	83% (40/48)	100% (52/52)
Early	0% (0/136)	0% (0/19)	0% (0/17)	0% (0/48)	0% (0/52)
On time	85% (116/136)	95% (18/19)	88% (15/17)	67% (32/48)	98% (51/52)
Late	7% (9/136)	0% (0/19)	0% (0/17)	17% (8/48)	2% (1/52)
Visit Not Completed	8% (11/136)	5% (1/19)	12% (2/17)	17% (8/48)	0% (0/52)
Visit Missed	7% (10/136)	5% (1/19)	12% (2/17)	15% (7/48)	0% (0/52)
Terminated early	1% (1/136)	0% (0/19)	0% (0/17)	2% (1/48)	0% (0/52)

¹Evaluated number of participants includes those who have not died as of the visit, 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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Injection Phase

	Overall	Bronx Prevention Center CRS Site ID 253	New Jersey Medical School CRS Site ID 254	Emavundleni CRS Site ID 255	Spilhaus CRS Site ID 256
Participants in Injection Phase	122	18	15	38	51
Week 4 (Injection 1)					
Evaluated ¹	122	18	15	38	51
Visit Completed	100% (122/122)	100% (18/18)	100% (15/15)	100% (38/38)	100% (51/51)
Early	0% (0/122)	0% (0/18)	0% (0/15)	0% (0/38)	0% (0/51)
On time	93% (113/122)	100% (18/18)	100% (15/15)	79% (30/38)	98% (50/51)
Late	7% (9/122)	0% (0/18)	0% (0/15)	21% (8/38)	2% (1/51)
Visit Not Completed	0% (0/122)	0% (0/18)	0% (0/15)	0% (0/38)	0% (0/51)
Visit Missed	0% (0/122)	0% (0/18)	0% (0/15)	0% (0/38)	0% (0/51)
Terminated early	0% (0/122)	0% (0/18)	0% (0/15)	0% (0/38)	0% (0/51)
Week 6					
Evaluated ¹	122	18	15	38	51
Visit Completed	99% (121/122)	100% (18/18)	100% (15/15)	97% (37/38)	100% (51/51)
Early	0% (0/122)	0% (0/18)	0% (0/15)	0% (0/38)	0% (0/51)
On time	94% (115/122)	94% (17/18)	93% (14/15)	89% (34/38)	98% (50/51)
Late	5% (6/122)	6% (1/18)	7% (1/15)	8% (3/38)	2% (1/51)
Visit Not Completed	1% (1/122)	0% (0/18)	0% (0/15)	3% (1/38)	0% (0/51)
Visit Missed	1% (1/122)	0% (0/18)	0% (0/15)	3% (1/38)	0% (0/51)
Terminated early	0% (0/122)	0% (0/18)	0% (0/15)	0% (0/38)	0% (0/51)
Week 12 (Injection 2)					
Evaluated ¹	122	18	15	38	51
Visit Completed	99% (121/122)	100% (18/18)	100% (15/15)	97% (37/38)	100% (51/51)
Early	0% (0/122)	0% (0/18)	0% (0/15)	0% (0/38)	0% (0/51)
On time	98% (120/122)	100% (18/18)	100% (15/15)	95% (36/38)	100% (51/51)
Late	1% (1/122)	0% (0/18)	0% (0/15)	3% (1/38)	0% (0/51)
Visit Not Completed	1% (1/122)	0% (0/18)	0% (0/15)	3% (1/38)	0% (0/51)
Visit Missed	1% (1/122)	0% (0/18)	0% (0/15)	3% (1/38)	0% (0/51)
Terminated early	0% (0/122)	0% (0/18)	0% (0/15)	0% (0/38)	0% (0/51)

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	Overall	Bronx Prevention Center CRS Site ID 253	New Jersey Medical School CRS Site ID 254	Emavundleni CRS Site ID 255	Spilhaus CRS Site ID 256
Week 14					
Evaluated ¹	122	18	15	38	51
Visit Completed	96% (117/122)	94% (17/18)	100% (15/15)	89% (34/38)	100% (51/51)
Early	0% (0/122)	0% (0/18)	0% (0/15)	0% (0/38)	0% (0/51)
On time	93% (113/122)	94% (17/18)	93% (14/15)	84% (32/38)	98% (50/51)
Late	3% (4/122)	0% (0/18)	7% (1/15)	5% (2/38)	2% (1/51)
Visit Not Completed	4% (5/122)	6% (1/18)	0% (0/15)	11% (4/38)	0% (0/51)
Visit Missed	4% (5/122)	6% (1/18)	0% (0/15)	11% (4/38)	0% (0/51)
Terminated early	0% (0/122)	0% (0/18)	0% (0/15)	0% (0/38)	0% (0/51)
Week 20 (Injection 3)					
Evaluated ¹	122	18	15	38	51
Visit Completed	98% (120/122)	100% (18/18)	100% (15/15)	95% (36/38)	100% (51/51)
Early	0% (0/122)	0% (0/18)	0% (0/15)	0% (0/38)	0% (0/51)
On time	95% (116/122)	89% (16/18)	93% (14/15)	92% (35/38)	100% (51/51)
Late	3% (4/122)	11% (2/18)	7% (1/15)	3% (1/38)	0% (0/51)
Visit Not Completed	2% (2/122)	0% (0/18)	0% (0/15)	5% (2/38)	0% (0/51)
Visit Missed	2% (2/122)	0% (0/18)	0% (0/15)	5% (2/38)	0% (0/51)
Terminated early	0% (0/122)	0% (0/18)	0% (0/15)	0% (0/38)	0% (0/51)
Week 28 (Injection 4)					
Evaluated ¹	122	18	15	38	51
Visit Completed	99% (121/122)	100% (18/18)	100% (15/15)	97% (37/38)	100% (51/51)
Early	0% (0/122)	0% (0/18)	0% (0/15)	0% (0/38)	0% (0/51)
On time	99% (121/122)	100% (18/18)	100% (15/15)	97% (37/38)	100% (51/51)
Late	0% (0/122)	0% (0/18)	0% (0/15)	0% (0/38)	0% (0/51)
Visit Not Completed	1% (1/122)	0% (0/18)	0% (0/15)	3% (1/38)	0% (0/51)
Visit Missed	0% (0/122)	0% (0/18)	0% (0/15)	0% (0/38)	0% (0/51)
Terminated early	1% (1/122)	0% (0/18)	0% (0/15)	3% (1/38)	0% (0/51)

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Week 36 (Injection 5)					
Evaluated ¹	122	18	15	38	51
Visit Completed	98% (119/122)	100% (18/18)	93% (14/15)	95% (36/38)	100% (51/51)
Early	2% (2/122)	6% (1/18)	0% (0/15)	3% (1/38)	0% (0/51)
On time	94% (115/122)	94% (17/18)	93% (14/15)	87% (33/38)	100% (51/51)
Late	2% (2/122)	0% (0/18)	0% (0/15)	5% (2/38)	0% (0/51)
Visit Not Completed	2% (3/122)	0% (0/18)	7% (1/15)	5% (2/38)	0% (0/51)
Visit Missed	2% (2/122)	0% (0/18)	7% (1/15)	3% (1/38)	0% (0/51)
Terminated early	1% (1/122)	0% (0/18)	0% (0/15)	3% (1/38)	0% (0/51)
Week 44 (Injection 6)					
Evaluated ¹	122	18	15	38	51
Visit Completed	98% (120/122)	100% (18/18)	100% (15/15)	95% (36/38)	100% (51/51)
Early	0% (0/122)	0% (0/18)	0% (0/15)	0% (0/38)	0% (0/51)
On time	94% (115/122)	89% (16/18)	93% (14/15)	89% (34/38)	100% (51/51)
Late	4% (5/122)	11% (2/18)	7% (1/15)	5% (2/38)	0% (0/51)
Visit Not Completed	2% (2/122)	0% (0/18)	0% (0/15)	5% (2/38)	0% (0/51)
Visit Missed	1% (1/122)	0% (0/18)	0% (0/15)	3% (1/38)	0% (0/51)
Terminated early	1% (1/122)	0% (0/18)	0% (0/15)	3% (1/38)	0% (0/51)
Week 52					
Evaluated ¹	122	18	15	38	51
Visit Completed	98% (120/122)	100% (18/18)	100% (15/15)	95% (36/38)	100% (51/51)
Early	0% (0/122)	0% (0/18)	0% (0/15)	0% (0/38)	0% (0/51)
On time	98% (120/122)	100% (18/18)	100% (15/15)	95% (36/38)	100% (51/51)
Late	0% (0/122)	0% (0/18)	0% (0/15)	0% (0/38)	0% (0/51)
Visit Not Completed	2% (2/122)	0% (0/18)	0% (0/15)	5% (2/38)	0% (0/51)
Visit Missed	1% (1/122)	0% (0/18)	0% (0/15)	3% (1/38)	0% (0/51)
Terminated early	1% (1/122)	0% (0/18)	0% (0/15)	3% (1/38)	0% (0/51)

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Week 64					
Evaluated ¹	121	17	15	38	51
Visit Completed	99% (120/121)	100% (17/17)	100% (15/15)	97% (37/38)	100% (51/51)
Early	0% (0/121)	0% (0/17)	0% (0/15)	0% (0/38)	0% (0/51)
On time	99% (120/121)	100% (17/17)	100% (15/15)	97% (37/38)	100% (51/51)
Late	0% (0/121)	0% (0/17)	0% (0/15)	0% (0/38)	0% (0/51)
Visit Not Completed	1% (1/121)	0% (0/17)	0% (0/15)	3% (1/38)	0% (0/51)
Visit Missed	0% (0/121)	0% (0/17)	0% (0/15)	0% (0/38)	0% (0/51)
Terminated early	1% (1/121)	0% (0/17)	0% (0/15)	3% (1/38)	0% (0/51)
Week 76					
Evaluated ¹	121	17	15	38	51
Visit Completed	98% (118/121)	94% (16/17)	100% (15/15)	95% (36/38)	100% (51/51)
Early	0% (0/121)	0% (0/17)	0% (0/15)	0% (0/38)	0% (0/51)
On time	98% (118/121)	94% (16/17)	100% (15/15)	95% (36/38)	100% (51/51)
Late	0% (0/121)	0% (0/17)	0% (0/15)	0% (0/38)	0% (0/51)
Visit Not Completed	2% (3/121)	6% (1/17)	0% (0/15)	5% (2/38)	0% (0/51)
Visit Missed	1% (1/121)	6% (1/17)	0% (0/15)	0% (0/38)	0% (0/51)
Terminated early	2% (2/121)	0% (0/17)	0% (0/15)	5% (2/38)	0% (0/51)

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