

MTN 001 – Phase II Adherence and Pharmacokinetic Study of Oral and Vaginal Preparations of Tenofovir

Data as of: November 10, 2009

– Visit Adherence: Number of Days Between Target and Actual Visit Date

	Total	South Africa Durban Bothas Hill	South Africa Durban Umkomaas	Uganda Kampala	United States Birmingham	United States Bronx	United States Cleveland	United States Pittsburgh
<b>Week 3 Visit</b>								
N	127	12	24	22	13	2	27	27
Mean (STD)	0.1 (2.2)	0.2 (0.6)	0.3 (1.8)	0.4 (1.3)	-0.4 (1.2)	-0.5 (3.5)	0.1 (3.6)	-0.3 (1.8)
Median	0.0	0.0	0.0	0.0	0.0	-0.5	0.0	0.0
Min, Max	-7.0, 10.0	0.0, 2.0	-3.0, 7.0	0.0, 6.0	-3.0, 1.0	-3.0, 2.0	-7.0, 10.0	-6.0, 5.0
25th, 75th %tile	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0	-1.0, 0.0	-3.0, 2.0	-1.0, 1.0	-1.0, 0.0
<b>Week 6 Visit</b>								
N	106	11	22	14	12	--	19	28
Mean (STD)	-0.6 (2.3)	-0.6 (2.2)	0.1 (0.8)	-0.1 (0.5)	0.1 (1.5)	--	-2.4 (3.5)	-0.6 (2.5)
Median	0.0	0.0	0.0	0.0	0.0	--	0.0	0.0
Min, Max	-9.0, 3.0	-5.0, 3.0	-1.0, 3.0	-1.0, 1.0	-3.0, 2.0	--	-9.0, 1.0	-9.0, 3.0
25th, 75th %tile	-1.0, 0.0	-2.0, 1.0	0.0, 0.0	0.0, 0.0	-1.0, 1.5	--	-6.0, 0.0	-2.0, 1.0
<b>Week 7 Visit</b>								
N	104	11	22	10	12	--	22	27
Mean (STD)	1.2 (2.7)	1.2 (1.9)	0.8 (1.9)	1.1 (3.1)	0.5 (1.2)	--	2.9 (3.7)	0.6 (2.6)
Median	0.0	0.0	0.0	0.0	0.0	--	1.0	0.0
Min, Max	-3.0, 10.0	0.0, 6.0	-1.0, 7.0	0.0, 10.0	-1.0, 2.0	--	-1.0, 10.0	-3.0, 7.0
25th, 75th %tile	0.0, 2.0	0.0, 2.0	0.0, 1.0	0.0, 0.0	0.0, 2.0	--	0.0, 6.0	-1.0, 1.0
<b>Week 10 Visit</b>								
N	100	11	22	7	12	--	21	27
Mean (STD)	0.4 (2.1)	0.2 (1.0)	0.5 (1.8)	0.1 (0.4)	0.3 (1.4)	--	0.9 (2.8)	0.4 (2.6)
Median	0.0	0.0	0.0	0.0	0.0	--	0.0	0.0
Min, Max	-3.0, 10.0	-2.0, 2.0	-1.0, 7.0	0.0, 1.0	-3.0, 3.0	--	-3.0, 10.0	-3.0, 8.0
25th, 75th %tile	0.0, 1.0	0.0, 1.0	0.0, 0.0	0.0, 0.0	0.0, 0.5	--	0.0, 1.0	-1.0, 1.0
<b>Week 13 Visit</b>								
N	89	11	18	3	12	--	18	27
Mean (STD)	-0.7 (2.2)	-0.4 (2.4)	-0.3 (1.6)	0.3 (0.6)	0.1 (1.0)	--	-1.2 (3.1)	-1.1 (2.1)
Median	0.0	0.0	0.0	0.0	0.0	--	0.0	-1.0
Min, Max	-7.0, 3.0	-6.0, 3.0	-3.0, 3.0	0.0, 1.0	-1.0, 2.0	--	-7.0, 2.0	-6.0, 3.0
25th, 75th %tile	-1.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 1.0	-1.0, 1.0	--	-1.0, 1.0	-2.0, 0.0

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	Total	South Africa Durban Bothas Hill	South Africa Durban Umkomaas	Uganda Kampala	United States Birmingham	United States Bronx	United States Cleveland	United States Pittsburgh
<b>Week 14 Visit</b>								
N	90	10	21	1	12	--	19	27
Mean (STD)	1.0 (2.8)	-0.7 (1.9)	1.4 (2.9)	0.0 (.)	1.0 (2.7)	--	2.0 (3.0)	0.6 (2.9)
Median	0.0	0.0	1.0	0.0	0.0	--	1.0	0.0
Min, Max	-3.0, 10.0	-3.0, 2.0	-3.0, 8.0	0.0, 0.0	-1.0, 9.0	--	-1.0, 8.0	-3.0, 10.0
25th, 75th %tile	0.0, 1.0	-3.0, 0.0	0.0, 1.0	0.0, 0.0	0.0, 1.0	--	0.0, 2.0	-1.0, 1.0
<b>Week 17 Visit</b>								
N	73	7	12	--	12	--	16	26
Mean (STD)	0.6 (2.5)	-0.1 (0.4)	1.3 (3.7)	--	0.9 (2.0)	--	1.3 (3.1)	0.0 (1.6)
Median	0.0	0.0	0.0	--	0.0	--	0.0	0.0
Min, Max	-5.0, 8.0	-1.0, 0.0	-3.0, 8.0	--	-2.0, 6.0	--	-5.0, 7.0	-3.0, 4.0
25th, 75th %tile	0.0, 1.0	0.0, 0.0	-1.0, 3.5	--	0.0, 1.5	--	0.0, 3.0	-1.0, 1.0
<b>Week 20 Visit</b>								
N	52	1	4	--	10	--	11	26
Mean (STD)	-0.6 (2.4)	0.0 (.)	0.0 (0.0)	--	0.6 (1.3)	--	-2.5 (3.9)	-0.3 (1.8)
Median	0.0	0.0	0.0	--	0.5	--	0.0	0.0
Min, Max	-7.0, 3.0	0.0, 0.0	0.0, 0.0	--	-2.0, 2.0	--	-7.0, 2.0	-3.0, 3.0
25th, 75th %tile	-2.0, 1.0	0.0, 0.0	0.0, 0.0	--	0.0, 2.0	--	-7.0, 1.0	-2.0, 1.0
<b>Week 21 Visit</b>								
N	49	1	1	--	11	--	10	26
Mean (STD)	0.3 (1.4)	0.0 (.)	0.0 (.)	--	0.5 (1.4)	--	0.4 (1.5)	0.3 (1.4)
Median	0.0	0.0	0.0	--	1.0	--	0.0	0.0
Min, Max	-3.0, 4.0	0.0, 0.0	0.0, 0.0	--	-3.0, 2.0	--	-3.0, 2.0	-3.0, 4.0
25th, 75th %tile	0.0, 1.0	0.0, 0.0	0.0, 0.0	--	0.0, 1.0	--	0.0, 2.0	0.0, 1.0

**MTN 001 – Phase II Adherence and Pharmacokinetic Study of Oral and Vaginal Preparations of Tenofovir**

**Data as of: November 10, 2009  
– Visit Adherence: Duration of Washout Period**

	<b>Total</b>	<b>South Africa Durban Bothas Hill</b>	<b>South Africa Durban Umkomaas</b>	<b>Uganda Kampala</b>	<b>United States Birmingham</b>	<b>United States Bronx</b>	<b>United States Cleveland</b>	<b>United States Pittsburgh</b>
<b>Duration of First Washout Period</b>								
N	104	11	22	10	12	--	22	27
Mean (STD)	8.7 (3.1)	8.8 (2.7)	7.6 (1.9)	7.1 (0.3)	7.4 (0.9)	--	11.7 (4.5)	8.4 (2.6)
Median	7.0	8.0	7.0	7.0	7.0	--	13.0	8.0
Min, Max	4.0, 22.0	6.0, 13.0	6.0, 14.0	7.0, 8.0	6.0, 9.0	--	6.0, 22.0	4.0, 15.0
25th, 75th %tile	7.0, 9.0	7.0, 12.0	7.0, 7.0	7.0, 7.0	7.0, 8.0	--	7.0, 15.0	7.0, 9.0
<b>Duration of Second Washout Period</b>								
N	90	10	21	1	12	--	19	27
Mean (STD)	8.6 (3.7)	6.7 (3.1)	8.5 (3.9)	6.0 (.)	7.9 (2.2)	--	10.3 (4.8)	8.7 (3.2)
Median	7.0	6.0	7.0	6.0	7.0	--	8.0	8.0
Min, Max	4.0, 21.0	4.0, 13.0	4.0, 18.0	6.0, 6.0	6.0, 14.0	--	5.0, 21.0	5.0, 20.0
25th, 75th %tile	7.0, 9.0	4.0, 9.0	6.0, 10.0	6.0, 6.0	7.0, 8.5	--	7.0, 13.0	7.0, 9.0
<b>Duration of Third Washout Period</b>								
N	49	1	1	--	11	--	10	26
Mean (STD)	8.0 (2.5)	7.0 (.)	7.0 (.)	--	6.9 (1.2)	--	10.1 (3.8)	7.6 (1.9)
Median	7.0	7.0	7.0	--	7.0	--	9.0	7.0
Min, Max	4.0, 16.0	7.0, 7.0	7.0, 7.0	--	4.0, 8.0	--	6.0, 16.0	4.0, 14.0
25th, 75th %tile	7.0, 8.5	7.0, 7.0	7.0, 7.0	--	7.0, 8.0	--	7.0, 14.0	7.0, 8.0

**MTN 001 – Phase II Adherence and Pharmacokinetic Study of Oral and Vaginal Preparations of Tenofovir**

**Data as of: November 10, 2009  
– Visit Adherence: Completion of Procedures**

	<b>Total</b>	<b>South Africa Durban Bothas Hill</b>	<b>South Africa Durban Umkomaas</b>	<b>Uganda Kampala</b>	<b>United States Birmingham</b>	<b>United States Bronx</b>	<b>United States Cleveland</b>	<b>United States Pittsburgh</b>
Participant-visits at Which Study Product Adherence and Behavior Assessment Are Required and Expected	316	16	26	0	50	0	72	152
Completed	315 (100%)	16 (100%)	26 (100%)	--	49 (98%)	--	72 (100%)	152 (100%)
Participant-visits at Which the Last Three Doses of Study Product Are Required and Expected	305	16	26	0	48	0	71	144
Completed	303 (99%)	14 (88%)	26 (100%)	--	48 (100%)	--	71 (100%)	144 (100%)
Participant-visits at Which Acceptability Assessment Are Required and Expected	112	6	10	0	19	0	25	52
Completed	112 (100%)	6 (100%)	10 (100%)	--	19 (100%)	--	25 (100%)	52 (100%)
Participant-visits at Which Final Acceptability Assessment Are Required and Expected	33	0	0	0	2	0	8	23
Completed	33 (100%)	--	--	--	2 (100%)	--	8 (100%)	23 (100%)
Participant-visits (Weeks 3, 10, 17) at Which PK Blood Draw Is Required and Expected	166	10	16	0	27	0	39	74
Completed	166 (100%)	10 (100%)	16 (100%)	--	27 (100%)	--	39 (100%)	74 (100%)
Participant-visits (Weeks 6, 13, 20) at Which Non-intensive PK Blood Draws Are Required and Expected	16	6	10	0	0	0	0	0
Completed	16 (100%)	6 (100%)	10 (100%)	--	--	--	--	--
Participant-visits (Weeks 6, 13, 20) at Which Non-intensive PK CVL Are Required and Expected	16	6	10	0	0	0	0	0
Completed	16 (100%)	6 (100%)	10 (100%)	--	--	--	--	--
Participant-visits (Weeks 6, 13, 20) at Which Intensive PK Blood Draws Are Required and Expected	126	0	0	0	21	0	33	72
Completed	124 (98%)	--	--	--	20 (95%)	--	33 (100%)	71 (99%)
Participant-visits (Weeks 6, 13, 20) at Which Intensive PK Genital Specimens Are Required and Expected	126	0	0	0	21	0	33	72
Completed	124 (98%)	--	--	--	20 (95%)	--	33 (100%)	71 (99%)

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Participant-visits at Which Pregnancy Tests Are Required and Expected	531	33	47	14	75	1	110	251
Completed	503 (95%)	25 (76%)	37 (79%)	12 (86%)	75 (100%)	1 (100%)	106 (96%)	247 (98%)
Participant-visits at Which Follow-up Pelvic Exams Are Required and Expected	427	17	32	0	68	0	96	214
Completed	427 (100%)	17 (100%)	32 (100%)	--	68 (100%)	--	96 (100%)	214 (100%)
Participant-visits at Which HIV Tests Are Required and Expected	103	1	6	0	18	0	24	54
Completed	102 (99%)	1 (100%)	6 (100%)	--	18 (100%)	--	24 (100%)	53 (98%)
Participant-visits at Which Hemogram Tests Are Required and Expected	103	1	6	0	18	0	24	54
Completed	103 (100%)	1 (100%)	6 (100%)	--	18 (100%)	--	24 (100%)	54 (100%)
Participant-visits at Which Chemistries Tests Are Required and Expected	427	17	32	0	68	0	96	214
Completed	427 (100%)	17 (100%)	32 (100%)	--	68 (100%)	--	96 (100%)	214 (100%)
Participant-visits at Which Product Sharing Assessments Are Required and Expected	147	6	10	0	22	0	33	76
Completed	147 (100%)	6 (100%)	10 (100%)	--	22 (100%)	--	33 (100%)	76 (100%)