

Food and Drug Administration
Antimicrobial Drugs Advisory Committee

Errata for the FDA Briefing Document

Applicant: Gilead Sciences, Inc
NDA 208215/S-012

July 29, 2019

AVAILABLE FOR PUBLIC DISCLOSURE WITHOUT REDACTION

- 1) Page 8: The third sentence in the first paragraph should be changed from:

“However, similarly low rates of adherence among MSM/TGW in the iPrEx trial still resulted in a 42% risk reduction ...”

to:

“However, low rates of adherence among MSM/TGW in the iPrEx trial still resulted in a 42% risk reduction ...”

- 2) Page 13: The fourth sentence in the first paragraph should be changed from:

“Median age was 34 years (range: 18-74 years) ...”

to:

“Median age was 34 years (range: 18-76 years) ...”

- 3) Page 25: Table 12 should be changed from:

	F/TAF (N=2694)				F/TDF (N=2693)			
	<100 (N=720)	100-159 (N=629)	160-190 (N=63)	>190 (N=11)	<100 (N=721)	100-159 (N=656)	160-190 (N=67)	>190 (N=17)
Week 48								
<100	418 (73)	126 (24)	1 (2)	1 (11)	487 (84)	192 (36)	1 (3)	2 (14)
100-159	154 (27)	371 (71)	24 (38)	0	95 (16)	325 (61)	29 (76)	6 (43)
160-190	3 (1)	22 (4)	11 (26)	5 (56)	1 (<1)	17 (3)	7 (18)	3 (21)
>190	1 (<1)	1 (<1)	7 (16)	3 (33)	0	0	1 (3)	3 (21)
Week 96								
<100	202 (76)	81 (29)	2 (10)	0	247 (87)	104 (39)	2 (10)	0

100-159	63 (23)	186 (66)	13 (62)	0	37 (13)	150 (57)	13 (65)	5 (71)
160-190	0	9 (3)	4 (19)	1 (50)	0	10 (4)	5 (25)	2 (29)
>190	0	5 (2)	2 (10)	1 (50)	0	1 (<1)	0	0

to:

	F/TAF (N=2694)				F/TDF (N=2693)			
	<100 (N=720)	100-159 (N=629)	160-190 (N=52)	>190 (N=11)	<100 (N=721)	100-159 (N=656)	160-190 (N=50)	>190 (N=17)
Week 48								
<100	418 (73)	126 (24)	1 (2)	1 (11)	487 (84)	192 (36)	2 (5)	2 (14)
100-159	154 (27)	371 (71)	24 (56)	0	95 (16)	325 (61)	29 (74)	6 (43)
160-190	3 (1)	22 (4)	11 (26)	5 (56)	1 (<1)	17 (3)	7 (18)	3 (21)
>190	1 (<1)	1 (<1)	7 (16)	3 (33)	0	0	1 (3)	3 (21)
Week 96								
<100	202 (76)	79 (29)	2 (10)	0	247 (87)	104 (39)	2 (10)	0
100-159	63 (24)	184 (67)	13 (62)	0	37 (13)	150 (57)	13 (65)	5 (71)
160-190	0	9 (3)	4 (19)	1 (50)	0	10 (4)	5 (25)	2 (29)
>190	0	4 (1)	2 (10)	1 (50)	0	0	0	0