Gilead Sciences, Inc.
Study GS-US-183-0160 (Final Analysis)

Table 37: Statistical Comparisons of Pharmacokinetic Parameter Estimates Between Test and Historical Reference Treatments for EVG
Overall and by EVG Dose (50 mg vs. 85 mg)
Intensive PK Analysis Set: EVG

	Treatment				Statistical Comparison			
	Test		Reference		Ratio		90% Confidence Interval	Model
Parameters	n	GLS Mean	n	GLS Mean	Test/Reference	(%)	(%)	rMSE
Analyte: EVG Pediatric Subjects (50 & 85 mg) in 183-0160 vs. Adults in 183-0145								
Cmax (ng/mL)	14	1942.05	334	1324.01	Test/Reference	146.68	(127.35,168.94)	0.295

GLS Mean = Geometric Least Squares Mean.
PK parameters for the test group were from Study 183-0160 and for the reference group were estimated from population PK modeling in Study 183-0145.
All subjects in Part A, Cohort 2 received atazanavir/r or lopinavir/r as their background regimen.
For subjects receiving atazanavir/r or lopinavir/r, the EVG dose will be 50 mg for subjects >= 17 to < 30 kg and 85 mg for subjects >= 30 kg.
This summary includes Cohort 2 Part A subjects (12 with Screening HIV-1 RNA < 50 copies/mL and 2 with Screening HIV-1 RNA > 1000 copies/mL).
The Model rMSE was chosen as the maximum of the MSE from the test group and the reference group.

Data Extracted: CRF,Lab Data: 17Jan2018 PK Data: 27Jan2017
Source: .../final/version1/prog/t-pkstat-hist-dose.sas v9.4 Output file: t-pkstat-hist-evg-dose.out 19JAN2018:10:48