

Table 11:
Summary of Viral Load over time
ITT Population

Test Day	Treatment	N	Unadjusted Mean (SE)
Week 1	Active A	xxx	x.xxx (x.xxx)
	Active B	xxx	x.xxx (x.xxx)
Week 4	Active A	xxx	x.xxx (x.xxx)
	Active B	xxx	x.xxx (x.xxx)
Week 8	Active A	xxx	x.xxx (x.xxx)
	Active B	xxx	x.xxx (x.xxx)
Week 12	Active A	xxx	x.xxx (x.xxx)
	Active B	xxx	x.xxx (x.xxx)
Week 16	Active A	xxx	x.xxx (x.xxx)
	Active B	xxx	x.xxx (x.xxx)

Table 12:

Summary of Adjusted Mean of Change from baseline Viral Load at Week 12 and 16

ITT Population

Test Day	Treatment	N	Adjusted Mean (SE)
Week 12	Active A	xxx	x.xxx (x.xxx)
	Active B	xxx	x.xxx (x.xxx)
Week 16	Active A	xxx	x.xxx (x.xxx)
	Active B	xxx	x.xxx (x.xxx)

Adjusted mean is calculated using PROC MIXED stage as factor and treatment.

Table 13:

Best Overall Response per Investigator by Age Category

ITT Subjects

Subgroup: Age Category - < 65

	Number of Subjects (%)		
	Trt A (N=XXX)	Trt B (N=XXX)	Total (N=XXX)
BEST OVERALL RESPONSE COMPLETE RESPONSE (CR)	XX (XX.X)	XX (XX.X)	XX (XX.X)
PARTIAL RESPONSE (PR)	XX (XX.X)	XX (XX.X)	XX (XX.X)
STABLE DISEASE (SD)	XX (XX.X)	XX (XX.X)	XX (XX.X)
PROGRESSIVE DISEASE (PD)	XX (XX.X)	XX (XX.X)	XX (XX.X)
UNABLE TO DETERMINE (UTD)	XX (XX.X)	XX (XX.X)	XX (XX.X)
REASON UTD 1	XX (XX.X)	XX (XX.X)	XX (XX.X)
REASON UTD 2	XX (XX.X)	XX (XX.X)	XX (XX.X)
REASON UTD X	XX (XX.X)	XX (XX.X)	XX (XX.X)
OBJECTIVE RESPONSE RATE (1) (95% CI)	XX/XXX (XX.X%) XX.X, XX.X	XX/XXX (XX.X%) (XX.X, XX.X)	XX/XXX (XX.X%) (XX.X, XX.X)

Subgroup: Age Category - >= 65

	Number of Subjects (%)		
	Trt A (N=XXX)	Trt B (N=XXX)	Total (N=XXX)
BEST OVERALL RESPONSE COMPLETE RESPONSE (CR)	XX (XX.X)	XX (XX.X)	XX (XX.X)
PARTIAL RESPONSE (PR)	XX (XX.X)	XX (XX.X)	XX (XX.X)
STABLE DISEASE (SD)	XX (XX.X)	XX (XX.X)	XX (XX.X)
PROGRESSIVE DISEASE (PD)	XX (XX.X)	XX (XX.X)	XX (XX.X)
UNABLE TO DETERMINE (UTD)	XX (XX.X)	XX (XX.X)	XX (XX.X)
REASON UTD 1	XX (XX.X)	XX (XX.X)	XX (XX.X)
REASON UTD 2	XX (XX.X)	XX (XX.X)	XX (XX.X)
REASON UTD X	XX (XX.X)	XX (XX.X)	XX (XX.X)
OBJECTIVE RESPONSE RATE (1) (95% CI)	XX/XXX (XX.X%) XX.X, XX.X	XX/XXX (XX.X%) (XX.X, XX.X)	XX/XXX (XX.X%) (XX.X, XX.X)

