

Online Supplementary Table S7

Table S7. (A) Summary of PK and PD results (PK analysis set)

PK parameter (unit)	Treatment	n	Adj. geom. mean	Comparison	Treatment Comparison	
					Geom. mean ratio	90% CI of mean ratio*
Primary endpoint						
AUC _{0-inf} (day*mcg/mL)	GP2013	124	7627.44	RTX-US vs RTX-EU	1.093	(0.989, 1.208)
	RTX-US	80	7536.89	GP2013 vs RTX-US	1.012	(0.925, 1.108)
	RTX-EU	79	6896.97	GP2013 vs RTX-EU	1.106	(1.010, 1.210)
Secondary endpoints						
AUC _{0-14d} (day*mcg/mL)	GP2013	127	2109.11	RTX-US vs RTX-EU	1.058	(0.970, 1.156)
	RTX-US	84	2013.87	GP2013 vs RTX-US	1.047	(0.967, 1.134)
	RTX-EU	82	1902.64	GP2013 vs RTX-EU	1.109	(1.024, 1.200)
AUC _{0-12w} (day*mcg/mL)	GP2013	125	7318.98	RTX-US vs RTX-EU	1.121	(1.015, 1.239)
	RTX-US	81	7223.71	GP2013 vs RTX-US	1.013	(0.926, 1.109)
	RTX-EU	81	6442.28	GP2013 vs RTX-EU	1.136	(1.036, 1.245)
AUC _{0-24w} (day*mcg/mL)	GP2013	125	7563.81	RTX-US vs RTX-EU	1.120	(1.009, 1.242)
	RTX-US	80	7506.53	GP2013 vs RTX-US	1.008	(0.917, 1.107)
	RTX-EU	80	6702.97	GP2013 vs RTX-EU	1.128	(1.026, 1.241)
C _{max} 1 st inf. (mcg/mL)	GP2013	120	361.53	RTX-US vs RTX-EU	1.050	(0.946, 1.167)
	RTX-US	82	335.88	GP2013 vs RTX-US	1.076	(0.979, 1.184)
	RTX-EU	78	319.80	GP2013 vs RTX-EU	1.131	(1.027, 1.244)
C _{max} 2 nd inf. (mcg/mL)	GP2013	116	423.12	RTX-US vs RTX-EU	1.006	(0.915, 1.106)
	RTX-US	82	393.07	GP2013 vs RTX-US	1.076	(0.988, 1.172)
	RTX-EU	75	390.73	GP2013 vs RTX-EU	1.083	(0.996, 0.177)
T _{max} 1 st inf. (hours)	GP2013	120	4.35	-	-	-
	RTX-US	82	4.42	-	-	-

PK parameter (unit)	Treatment	n	Adj. geom. mean	Comparison	Treatment Comparison	
					Geom. mean ratio	90% CI of mean ratio*
	RTX-EU	78	4.33	-	-	-
T _{max} 2nd inf. (hours)	GP2013	116	3.48	-	-	-
	RTX-US	82	3.49	-	-	-
	RTX-EU	75	3.45	-	-	-
PD parameter (unit)						
AUEC _{0-14d} (%*day)	GP2013	110	1226.53	RTX-US vs RTX- EU	1.033	(1.016, 1.050)
	RTX-US	80	1240.57	GP2013 vs RTX-US	0.989	(0.974, 1.004)
	RTX-EU	76	1201.15	GP2013 vs RTX- EU	1.021	(1.003, 1.040)

Table S7. (B) Summary of primary PK and secondary PK and PD results (PK analysis set) - Study Part 1 data only

PK parameter (unit)	Treatment	n	Adj. geom. mean	Comparison	Treatment Comparison	
					Geom. mean ratio	90% CI of mean ratio*
Primary endpoint						
AUC _{0-inf} (day*mcg/mL)	GP2013	75	6738.51	GP2013 vs RTX-EU	1.064	(0.968, 1.169)
	RTX-EU	70	6334.41			
Secondary endpoints						
AUC _{0-14d} (day*mcg/mL)	GP2013	78	1955.45	GP2013 vs RTX-EU	1.106	(1.010, 1.210)
	RTX-EU	74	1768.78			
AUC _{0-12w} (day*mcg/mL)	GP2013	76	6575.23	GP2013 vs RTX-EU	1.091	(0.988, 1.205)
	RTX-EU	72	6024.81			
AUC _{0-24w} (day*mcg/mL)	GP2013	73	6696.36	GP2013 vs RTX-EU	1.087	(0.980, 1.206)
	RTX-EU	72	6159.42			
C _{max} 1 st inf. (mcg/mL)	GP2013	79	341.67	GP2013 vs RTX-EU	1.133	(1.017, 1.262)
	RTX-EU	77	301.62			
C _{max} 2 nd inf. (mcg/mL)	GP2013	76	386.22	GP2013 vs RTX-EU	1.036	(0.944, 1.138)
	RTX-EU	75	372.63			
T _{max} 1 st inf.	GP2013	79	4.42	-	-	-
	RTX-EU	77	4.33	-	-	-
T _{max} 2 nd inf.	GP2013	76	3.43	-	-	-
	RTX-EU	75	3.45	-	-	-
PD parameter (unit)						
AUEC _{0-14d} (%*day)	GP2013	72	1223.71	GP2013 vs RTX-EU	1.019	(0.997, 1.042)
	RTX-EU	75	1200.49			