

Online Supplementary Table S6

Table S6. Reason for exclusion from the PK analysis set/subset

Analysis set/subset/ Reasons for exclusion from set/subset	GP2013 N=133 n (%)	RTX-US N=92 n (%)	RTX-EU N=89 n (%)	Total N=312 n (%)
PK Analysis Set (PAS+A)	131 (98.5)	89 (96.7)	86 (98.9)	306 (98.1)
Treated with commercially available drug	0	0	1 (1.1)	1 (0.3)
Patients excluded from AUC_{0-inf} analysis	7 (5.3)	9 (9.8)	7 (8.0)	23 (7.4)
Incomplete first treatment as confirmed by site	0	1 (1.1)	1 (1.1)	2 (0.6)
Unmet 2mg/ml drug concentration for infusion	1 (0.8)	1 (1.1)	1 (1.1)	3 (1.0)
Missing data such that parameter cannot be derived	6 (4.5)	7 (7.6)	5 (5.7)	18 (5.8)
Patients excluded from AUEC_{0-14d} analysis	21 (15.8)	9 (9.8)	10 (11.5)	40 (12.8)
Incomplete first treatment as confirmed by site	0	0	1 (1.1)	1 (0.3)
Unmet 2mg/ml drug concentration for infusion	1 (0.8)	1 (1.1)	1 (1.1)	3 (1.0)
Missing data such that parameter cannot be derived	20 (15.0)	8 (8.7)	8 (9.2)	36 (11.5)
Patients excluded from C_{max} (1st infusion) analysis	11 (8.3)	7 (7.6)	8 (9.2)	26 (8.3)
ADA PK assay interference	0	0	1 (1.1)	1 (0.3)
C _{max_1} sample missing	1 (0.8)	0	0	1 (0.3)
Incomplete first treatment as confirmed by site	0	0	1 (1.1)	1 (0.3)
Unmet 2mg/ml drug concentration for infusion	1 (0.8)	0	1 (1.1)	2 (0.6)
First infusion interrupted by >1 hour	0	1 (1.1)	3 (3.4)	4 (1.3)
Missing data such that parameter cannot be derived	2 (1.5)	2 (2.2)	1 (1.1)	5 (1.6)
Post-infusion sample not within 15 minutes of end of infusion	7 (5.3)	4 (4.3)	1 (1.1)	12 (3.8)