

Table 13.2: Statistical Analysis and Comparisons of aGFR (mL/min) Between Visits by Baseline eGFR (< 50 vs. ≥ 50 mL/min) and Overall PD Substudy Analysis Set

Parameters	Treatment				Statistical Comparison				
	Test		Reference		Ratio		90% Confidence Interval (%)	Model	
	n	GLS Mean	n	GLS Mean	Test/Reference	(%)		rMSE	rInter

Analyte: Actual GFR Week 2/4/8 vs Baseline			Group: All Subjects						

aGFR (mL/min)	32	56.59	32	57.20	Week 2/4/8/BL	98.94	(93.71,104.46)	0.130	0.296

Analyte: Actual GFR Week 24 vs Baseline			Group: All Subjects						

aGFR (mL/min)	30	58.72	32	57.20	Week 24/BL	102.66	(97.11,108.53)	0.130	0.296

GLS Mean = Geometric Least Squares Mean.

Mixed model covariance parameter estimates: rMSE = square root of mean square error; rInter = square root of intersubject variance.

Actual GFR (aGFR) using iohexol plasma clearance (mL/min) = iohexol dose / iohexol AUCinf.

All subjects in the PK/PD/PBMC Substudy analysis set are from Cohort 1 (Treatment-experienced).

Data Extracted: CRF Data: 17SEP2014, Lab Data: 19SEP2014, Dexa Data: 18SEP2014

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