

Table 15.3.1.1.1
Ratio between the highest value post-surgery and baseline for serum creatinine - subgroup analysis
Full analysis set

		Treatment			
Baseline eGFR			Placebo (N=17)	Ilofotase Alfa (N=19)	Total (N=36)
<= 45 mL/min/1.73m ²	Highest sCreat Value Post-surgery [umol/L]	n	17	19	36
		Mean (SD)	208.479 (85.529)	223.766 (89.754)	216.547 (86.873)
		Median	167.960	194.480	185.170
		Q ₁ , Q ₃	156.470, 231.000	165.000, 323.550	161.500, 275.065
		Min, Max	96.00, 409.00	105.20, 433.17	96.00, 433.17
	Baseline sCreat Value [umol/L]	n	17	19	36
		Mean (SD)	157.266 (24.957)	160.446 (27.278)	158.944 (25.884)
		Median	159.120	157.000	157.500
		Q ₁ , Q ₃	144.090, 169.000	141.000, 190.000	142.545, 174.500
		Min, Max	113.15, 209.00	113.15, 208.63	113.15, 209.00
	Ratio Highest sCreat Value / Baseline sCreat Value	n	17	19	36
		Mean (SD)	1.309 (0.435)	1.397 (0.518)	1.355 (0.476)
		Median	1.130	1.160	1.150
		Q ₁ , Q ₃	1.060, 1.470	1.070, 1.630	1.060, 1.540
		Min, Max	0.79, 2.42	0.75, 2.61	0.75, 2.61

Highest sCreat value post-surgery of Day 1, 2, 3, 4, and 5.

The subgroups 'Baseline eGFR <= 45 mL/min/1.73m²' and 'Baseline eGFR > 45 mL/min/1.73m²' are based on the reported baseline eGFR values, not on the eGFR randomization stratum.

Table 15.3.1.1.1
Ratio between the highest value post-surgery and baseline for serum creatinine - subgroup analysis
Full analysis set

		Treatment			
Baseline eGFR			Placebo (N=78)	Ilofotase Alfa (N=90)	Total (N=168)
> 45 mL/min/1.73m ²	Highest sCreat Value Post-surgery [umol/L]	n	77	90	167
		Mean (SD)	141.453 (62.092)	129.241 (46.693)	134.871 (54.510)
		Median	125.000	121.995	123.000
		Q ₁ , Q ₃	110.000, 152.050	102.000, 140.000	106.080, 143.000
		Min, Max	75.14, 466.76	70.72, 336.00	70.72, 466.76
	Baseline sCreat Value [umol/L]	n	78	90	168
		Mean (SD)	112.337 (15.506)	110.501 (17.379)	111.354 (16.513)
		Median	112.270	110.000	111.195
		Q ₁ , Q ₃	104.000, 125.000	96.360, 123.760	100.780, 123.880
		Min, Max	64.53, 139.67	66.00, 147.00	64.53, 147.00
	Ratio Highest sCreat Value / Baseline sCreat Value	n	78	90	168
		Mean (SD)	1.261 (0.518)	1.171 (0.391)	1.213 (0.455)
		Median	1.110	1.065	1.080
		Q ₁ , Q ₃	0.990, 1.290	0.960, 1.240	0.970, 1.250
		Min, Max	0.84, 3.62	0.74, 3.09	0.74, 3.62

Highest sCreat value post-surgery of Day 1, 2, 3, 4, and 5.

Patient 4100010008 died after the second IP administration and prior to Day 5, therefore the 'Ratio Highest sCreat Value / Baseline sCreat Value' was imputed with 1.25 (ICE 3) and no 'Highest sCreat Value Post-surgery' is given.

The subgroups 'Baseline eGFR ≤ 45 mL/min/1.73m²' and 'Baseline eGFR > 45 mL/min/1.73m²' are based on the reported baseline eGFR values, not on the eGFR randomization stratum.

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Full analysis set

ANCOVA

Individual least squares means

Baseline eGFR	Treatment	N	LS Means	Standard Error	95% Wald Confidence Interval
<= 45 mL/min/1.73m2	Placebo	17	1.384	0.119	[1.142; 1.626]
	Ilofotase Alfa	19	1.455	0.111	[1.229; 1.682]
> 45 mL/min/1.73m2	Placebo	78	1.266	0.052	[1.163; 1.370]
	Ilofotase Alfa	90	1.176	0.049	[1.078; 1.273]

Difference in least squares means

Baseline eGFR	Treatment	Difference in LS Means	95% Wald Confidence Interval	P-Value (Two-Sided)
<= 45 mL/min/1.73m2	Ilofotase Alfa - Placebo	0.071	[-0.246; 0.389]	0.6511
> 45 mL/min/1.73m2	Ilofotase Alfa - Placebo	-0.091	[-0.230; 0.049]	0.2025

Parameter estimates

Baseline eGFR	Parameter	Estimate	Standard Error	P-Value (Two-Sided)
<= 45 mL/min/1.73m2	Intercept	1.081	0.493	0.0356
	Treatment: Ilofotase Alfa	0.071	0.156	0.6511
	Pre-operative baseline sCreat value	0.003	0.003	0.3462
	Type of surgery: CABG with 3 or more distal anastomoses	-0.341	0.172	0.0563
> 45 mL/min/1.73m2	Intercept	1.389	0.252	<.0001
	Treatment: Ilofotase Alfa	-0.091	0.071	0.2025
	Pre-operative baseline sCreat value	-0.001	0.002	0.6606
	Type of surgery: CABG with 3 or more distal anastomoses	-0.035	0.073	0.6280

Covariates = pre-operative baseline sCreat value and planned type of surgery (reference = CABG combined with valve surgery).

The subgroups 'Baseline eGFR <= 45 mL/min/1.73m2' and 'Baseline eGFR > 45 mL/min/1.73m2' are based on the reported baseline eGFR values, not on the eGFR randomization stratum.