Table 15.3.2.3
MAKE60a - logistic regressions
Full analysis set

Imputed values

		Treatment		
		Placebo (N=95)	**Ilofotase Alfa (N=109)**	**Total (N=204)**
MAKE60a	n	95	109	204
No	n (%)	80.34 (84.6)	92.48 (84.8)	172.82 (84.7)
Yes	n (%)	14.66 (15.4)	16.52 (15.2)	31.18 (15.3)
RRT Up To and Including Day 61	n	95	109	204
No	n (%)	89 (93.7)	105 (96.3)	194 (95.1)
Yes	n (%)	6 (6.3)	4 (3.7)	10 (4.9)
Decrease in eGFR >= 25% on Day 61 Compared to Pre-operative Baseline	n	95	109	204
No	n (%)	83.96 (88.4)	94.05 (86.3)	178.01 (87.3)
Yes	n (%)	11.04 (11.6)	14.95 (13.7)	25.99 (12.7)

Major adverse kidney events 60a (MAKE60a) include: any RRT up to and including Day 61, or a decrease in eGFR >= 25% at Day 61 compared to pre-operative Baseline.
For more detail on the used imputation method see SAP. For the imputation, events death and RRT were combined. Averages are based on 100 imputations.

Table 15.3.2.3
MAKE60a - logistic regressions
Full analysis set

Raw values

		Treatment		
		Placebo (N=95)	**Ilofotase Alfa (N=109)**	**Total (N=204)**
MAKE60a	n	83	94	177
No	n (%)	71 (85.5)	80 (85.1)	151 (85.3)
Yes	n (%)	12 (14.5)	14 (14.9)	26 (14.7)
RRT Up To and Including Day 61	n	92	104	196
No	n (%)	86 (93.5)	100 (96.2)	186 (94.9)
Yes	n (%)	6 (6.5)	4 (3.8)	10 (5.1)
Decrease in eGFR >= 25% on Day 61 Compared to Pre-operative Baseline	n	81	93	174
No	n (%)	73 (90.1)	81 (87.1)	154 (88.5)
Yes	n (%)	8 (9.9)	12 (12.9)	20 (11.5)

Major adverse kidney events 60a (MAKE60a) include: any RRT up to and including Day 61, or a decrease in eGFR >= 25% at Day 61 compared to pre-operative Baseline.

Table 15.3.2.3
MAKE60a - logistic regressions
Full analysis set

Adjusted odds ratios for MAKE60a

Parameter	Adjusted Odds Ratio	95% Wald Confidence Interval	P-Value (Two-Sided)
Treatment: Ilofotase Alfa vs Placebo	0.889	[0.392; 2.018]	0.7794
Pre-operative baseline sCreat value	0.972	[0.950; 0.995]	0.0182
Baseline eGFR: > 45 mL/min/1.73m2 vs <= 45 mL/min/1.73m2	0.233	[0.059; 0.927]	0.0386
Type of surgery: CABG with 3 or more distal anastomoses vs CABG combined with valve surgery	0.683	[0.300; 1.554]	0.3636

For statistical testing imputed values are used only.
An adjusted odds ratio > 1 indicates a higher risk for a MAKE60a event for 'Ilofotase Alfa' vs 'Placebo' while keeping the other covariates constant, an adjusted odds ratio < 1 indicates a lower risk for a MAKE60a event.
The p-value indicates whether the adjusted odds ratio differs from 1.

Table 15.3.2.3
MAKE60a - logistic regressions
Full analysis set

Adjusted odds ratios for RRT up to and including Day 61

Parameter	Adjusted Odds Ratio	95% Wald Confidence Interval	P-Value (Two-Sided)
Treatment: Ilofotase Alfa vs Placebo	0.515	[0.134; 1.976]	0.3336
Pre-operative baseline sCreat value	1.025	[0.992; 1.059]	0.1388
Baseline eGFR: > 45 mL/min/1.73m2 vs <= 45 mL/min/1.73m2	0.924	[0.114; 7.481]	0.9412
Type of surgery: CABG with 3 or more distal anastomoses vs CABG combined with valve surgery	0.282	[0.072; 1.107]	0.0697

For statistical testing imputed values are used only.
An adjusted odds ratio > 1 indicates a higher risk for an RRT event for 'Ilofotase Alfa' vs 'Placebo' while keeping the other covariates constant, an adjusted odds ratio < 1 indicates a lower risk for an RRT event.
The p-value indicates whether the adjusted odds ratio differs from 1.

Table 15.3.2.3
MAKE60a - logistic regressions
Full analysis set

Adjusted odds ratios for decrease in eGFR >= 25% on Day 61 compared to pre-operative Baseline

Parameter	Adjusted Odds Ratio	95% Wald Confidence Interval	P-Value (Two-Sided)
Treatment: Ilofotase Alfa vs Placebo	1.035	[0.405; 2.641]	0.9431
Pre-operative baseline sCreat value	0.950	[0.923; 0.977]	0.0004
Baseline eGFR: > 45 mL/min/1.73m2 vs <= 45 mL/min/1.73m2	0.125	[0.025; 0.623]	0.0112
Type of surgery: CABG with 3 or more distal anastomoses vs CABG combined with valve surgery	0.738	[0.291; 1.875]	0.5233

For statistical testing imputed values are used only.
An adjusted odds ratio > 1 indicates a higher risk for an eGFR decrease >= 25% event for 'Ilofotase Alfa' vs 'Placebo' while keeping the other covariates constant, an adjusted odds ratio < 1 indicates a lower risk for an eGFR decrease >= 25% event.
The p-value indicates whether the adjusted odds ratio differs from 1.