

Table 15.3.2.4
MAKE60 - win ratio analysis
Full analysis set

		Treatment					
		Placebo (N=95)		Ilofotase Alfa (N=109)		Total (N=204)	
Number of patients with death up to and including Day 61	n (%)	2	(2.1)	2	(1.8)	4	(2.0)
Number of patients with any RRT event up to and including Day 61	n (%)	6	(6.3)	4	(3.7)	10	(4.9)
Number of patients with a decrease in eGFR >= 25% on Day 61 compared to pre-operative baseline	n (%)	8	(9.9)	12	(12.9)	20	(11.5)
Number of pairs (Ilofotase Alfa x Placebo)	n	10355					
Categorization of pairs							
Step 1: Death - Ilofotase Alfa WIN (a)	n (%)	217 (2.1)					
Step 1: Death - Placebo WIN (b)	n (%)	187 (1.8)					
Step 1: Death - TIES	n (%)	9951 (96.1)					
Step 2: RRT - Ilofotase Alfa WIN (c)	n (%)	419 (4.2)					
Step 2: RRT - Placebo WIN (d)	n (%)	274 (2.8)					
Step 2: RRT - TIES	n (%)	9258 (93.0)					
Step 3: eGFR - Ilofotase Alfa WIN (e)	n (%)	481 (5.2)					
Step 3: eGFR - Placebo WIN (f)	n (%)	710 (7.7)					
Step 3: eGFR - TIES	n (%)	8067 (87.1)					
Death comparison: Ratio (a/b)		1.16					
RRT comparison: Ratio (c/d)		1.53					
eGFR decrease comparison: Ratio (e/f)		0.68					
Win ratio estimate $[(a)+(c)+(e)) / ((b)+(d)+(f))]$		0.954					
95% confidence interval		[0.436; 2.089]					
p-value* (two-sided)		0.9060					

* The statistical comparison is based on the procedures described in Pocock (Pocock et al. (2012): The win ratio: a new approach to the analysis of composite endpoints in clinical trials based on clinical priorities, European Heart Journal, 33, 176–182).