

Table 14.2.20 Summary of MRI / MRS - by timepoint - FAS

Parameter Timepoint	Actual value	Absolute change from baseline	% Change from baseline	t-Test results			
				Change from baseline	t-value (df)	p-value	95% CI
Numerical Mannose Complex Index (White)							
Baseline							
n	8						
Mean (SD)	1.0( 0.4)						
Median	0.8						
Min; Max	0; 2						
Month 6							
n	9	8	8	Absolute change	0.7 ( 7)	0.503	( -0.2, 0.3)
Mean (SD)	1.0( 0.3)	0.1( 0.3)	19.4( 53.1)	% Change	1.0 ( 7)	0.335	(-24.9, 63.8)
Median	0.9	0.0	2.4				
Min; Max	1; 2	-0; 1	-21; 144				
Month 12							
n	8	7	7	Absolute change	-0.4 ( 6)	0.727	( -0.3, 0.2)
Mean (SD)	1.0( 0.4)	-0.0( 0.3)	1.5( 42.7)	% Change	0.1 ( 6)	0.931	(-38.1, 41.0)
Median	0.9	-0.0	-4.8				
Min; Max	0; 2	-0; 0	-52; 86				
Month 18							
n	8	7	7	Absolute change	0.4 ( 6)	0.733	( -0.2, 0.3)
Mean (SD)	1.0( 0.4)	0.0( 0.3)	15.0( 49.7)	% Change	0.8 ( 6)	0.453	(-30.9, 61.0)
Median	0.9	0.1	7.0				
Min; Max	1; 2	-0; 1	-33; 122				
Month 48							
n	9	8	8	Absolute change	-1.2 ( 7)	0.287	( -0.4, 0.1)
Mean (SD)	0.8( 0.2)	-0.1( 0.3)	-2.9( 33.7)	% Change	-0.2 ( 7)	0.813	(-31.1, 25.3)
Median	0.8	-0.1	-10.6				
Min; Max	1; 1	-1; 0	-40; 63				

Note 1: FAS=Full Analysis Set. n=Number of subjects with data. Parameters only valid for 9 subjects from rhLAMANO2.

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Parameter Timepoint	Actual value	Absolute change from baseline	% Change from baseline	t-Test results			
				Change from baseline	t-value (df)	p-value	95% CI
Numerical Mannose Complex Index							
(White) Last Observation							
n	9	8	8	Absolute change	-1.2 ( 7)	0.287	( -0.4, 0.1)
Mean (SD)	0.8( 0.2)	-0.1( 0.3)	-2.9( 33.7)				
Median	0.8	-0.1	-10.6	% Change	-0.2 ( 7)	0.813	(-31.1, 25.3)
Min; Max	1; 1	-1; 0	-40; 63				

Note 1: FAS=Full Analysis Set. n=Number of subjects with data. Parameters only valid for 9 subjects from rhLAMANO2.