

Table 14.2.14.1 Summary of serum-Immunoglobulin G (g/L) - by timepoint - FAS

Parameter Timepoint	Actual value	Absolute change from baseline	% Change from baseline	Change from baseline	t-Test results		
					t-value (df)	p-value	95% CI
Immunoglobulin G (g/L)							
Baseline							
n	24						
Mean (SD)	8.37 (4.20)						
Median	7.35						
Min; Max	2.6; 22.0						
Month 6							
n	15	15	15	Absolute change	7.16 (14)	<.001	(1.66, 3.08)
Mean (SD)	11.37 (4.99)	2.37 (1.28)	34.03 (23.26)	% Change	5.67 (14)	<.001	(21.15, 46.91)
Median	11.00	2.40	32.94				
Min; Max	4.2; 24.7	0.4; 4.7	4.0; 77.8				
Month 12							
n	22	22	22	Absolute change	9.63 (21)	<.001	(2.65, 4.11)
Mean (SD)	11.76 (4.99)	3.38 (1.65)	47.03 (27.26)	% Change	8.09 (21)	<.001	(34.94, 59.12)
Median	11.15	3.65	44.83				
Min; Max	4.9; 25.7	0.3; 6.4	5.0; 103.7				
Month 18							
n	2	2	2	Absolute change	2.62 (1)	0.232	(-8.06, 12.26)
Mean (SD)	10.35 (2.47)	2.10 (1.13)	31.46 (27.46)	% Change	1.62 (1)	0.352	(-215.3,278.21)
Median	10.35	2.10	31.46				
Min; Max	8.6; 12.1	1.3; 2.9	12.0; 50.9				
Month 24							
n	10	10	10	Absolute change	7.16 (9)	<.001	(2.28, 4.38)
Mean (SD)	12.21 (6.23)	3.33 (1.47)	47.07 (29.87)	% Change	4.98 (9)	<.001	(25.70, 68.43)
Median	11.60	3.00	37.70				
Min; Max	4.8; 27.3	1.8; 6.1	17.8; 113.0				

Note 1: FAS=Full Analysis Set. n=Number of subjects with data.

Note 2: Data for rhLAMANO5 subjects only.

Table 14.2.14.1 Summary of serum-Immunoglobulin G (g/L) - by timepoint - FAS

Parameter Timepoint	Actual value	Absolute change from baseline	% Change from baseline	Change from baseline	t-Test results		
					t-value (df)	p-value	95% CI
Immunoglobulin G							
(g/L) Month 36							
n	4	4	4	Absolute change	2.87 (3)	0.064	(-0.32, 6.22)
Mean (SD)	11.75 (3.37)	2.95 (2.06)	47.62 (33.29)				
Median	10.90	3.65	56.45	% Change	2.86 (3)	0.065	(-5.35,100.58)
Min; Max	8.7; 16.5	0.0; 4.5	0.0; 77.6				
Last Observation							
n	24	24	24	Absolute change	9.59 (23)	<.001	(2.39, 3.71)
Mean (SD)	11.42 (4.52)	3.05 (1.56)	44.07 (27.23)				
Median	11.15	3.00	42.63	% Change	7.93 (23)	<.001	(32.58, 55.57)
Min; Max	4.8; 27.3	0.0; 6.1	0.0; 113.0				

Note 1: FAS=Full Analysis Set. n=Number of subjects with data. Note 2: Data for rhLAMANO5 subjects only.