

STATISTICAL ANALYSIS for Percentage of Subjects With at Least 4-fold Rise in Recombinant Lipoprotein 2086 (rLP2086) Specific Serum Bactericidal Assay Using Human Complement (hSBA) Titer: Before vaccination 1 up to 1 month after vaccination 3

Statistical analysis title	[A05] Control-Stage 1 (1 month after vaccination 3)
Statistical analysis description	Strain A05: Response rate was compared with whether greater than (>) 50% of subjects had fold rise ≥ 4 using right one-sided exact test based on binomial distribution. p-value < 0.025 was considered significant.
Comparison groups	Control- Stage 1
Number of subjects included in analysis	119
Analysis specification	Pre-specified
Analysis type	superiority
P-value	> 0.9999
Method	Binomial Distribution
Confidence interval	

Statistical analysis title	[A05] rLP2086 60 mcg- Stage 1 (1 month after vaccination 3)
Statistical analysis description	Strain A05: Response rate was compared with whether greater than (>) 50% of subjects had fold rise ≥ 4 using right one-sided exact test based on binomial distribution. p-value < 0.025 was considered significant.
Comparison groups	rLP2086 60 microgram (mcg)- Stage 1
Number of subjects included in analysis	22
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0004
Method	Binomial Distribution
Confidence interval	

Statistical analysis title	[A05]rLP2086 120 mcg- Stage 1 (1 month after vaccination 3)
Statistical analysis description	Strain A05: Response rate was compared with whether greater than (>) 50% of subjects had fold rise ≥ 4 using right one-sided exact test based on binomial distribution. p-value < 0.025 was considered significant.
Comparison groups	rLP2086 120 mcg- Stage 1
Number of subjects included in analysis	195

Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	Binomial Distribution
Confidence interval	

Statistical analysis title	[A05]rLP2086 200 mcg- Stage 1 (1 month after vaccination 3)
Statistical analysis description	Strain A05: Response rate was compared with whether greater than (>) 50% of subjects had fold rise ≥ 4 using right one-sided exact test based on binomial distribution. p-value < 0.025 was considered significant.
Comparison groups	rLP2086 200 mcg- Stage 1
Number of subjects included in analysis	192
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	Binomial Distribution
Confidence interval	

Statistical analysis title	[B02]Control-Stage 1 (1 month after vaccination 3)
Statistical analysis description	Strain B02: Response rate was compared with whether greater than (>) 50% of subjects had fold rise ≥ 4 using right one-sided exact test based on binomial distribution. p-value < 0.025 was considered significant.
Comparison groups	Control- Stage 1
Number of subjects included in analysis	119
Analysis specification	Pre-specified
Analysis type	superiority
P-value	> 0.9999
Method	Binomial Distribution
Confidence interval	

Statistical analysis title	[B02] rLP2086 60 mcg- Stage 1 (1 month after vaccination 3)
Statistical analysis description	Strain B02: Response rate was compared with whether greater than (>) 50% of subjects had fold rise ≥ 4 using right one-sided exact test based on binomial distribution. p-value < 0.025 was considered significant.
Comparison groups	rLP2086 60 microgram (mcg)- Stage 1

Number of subjects included in analysis	22
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0036
Method	Binomial Distribution
Confidence interval	

Statistical analysis title	[B02] rLP2086 120 mcg- Stage 1 (1 month after vaccination 3)
Statistical analysis description	Strain B02: Response rate was compared with whether greater than (>) 50% of subjects had fold rise ≥ 4 using right one-sided exact test based on binomial distribution. p-value < 0.025 was considered significant.
Comparison groups	rLP2086 120 mcg- Stage 1
Number of subjects included in analysis	195
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	Binomial Distribution
Confidence interval	

Statistical analysis title	[B02] rLP2086 200 mcg- Stage 1 (1 month after vaccination 3)
Statistical analysis description	Strain B02: Response rate was compared with whether greater than (>) 50% of subjects had fold rise ≥ 4 using right one-sided exact test based on binomial distribution. p-value < 0.025 was considered significant.
Comparison groups	rLP2086 200 mcg- Stage 1
Number of subjects included in analysis	192
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	Binomial Distribution
Confidence interval	