

Table 14.2.1.1.1

Summary of Binding Antibody Levels

ADSL.PPBABL=Y Per-Protocol Set for SARS-CoV-2-specific bAb

Antibody: Parameter #1 (unit) (LLOQ: xxxx, ULOQ: xxxx)

ADIS.PARAM ADIS.ISLLOQ ADIS.ULOQ

Timepoint Statistic	Overall				Total (N=xxx)
	Placebo (N=xxx)	ADSL.TRT01A	50 µg (N=xxx)	mRNA-1273 100 µg (N=xxx)	
Baseline ADIS.AVISIT					xxx
n[1] ADIS.AVAL NOT MISSING	xxx		xxx	xxx	xx.xx
GM Level	xx.xx		xx.xx	xx.xx	xx.xx, xx.xx
95% CI [2]	xx.xx, xx.xx		xx.xx, xx.xx	xx.xx, xx.xx	xx.xx
Median	xx.xx		xx.xx	xx.xx	xx.x, xx.x
Min, Max	xx.x, xx.x		xx.x, xx.x	xx.x, xx.x	xxx
Day xx					
n[3]	xxx		xxx	xxx	xxx
GM Level	xx.xx		xx.xx	xx.xx	xx.xx
95% CI [2]	xx.xx, xx.xx		xx.xx, xx.xx	xx.xx, xx.xx	xx.xx, xx.xx
Median	xx.xx		xx.xx	xx.xx	xx.xx
Min, Max	xx.x, xx.x		xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
GM Fold-Rise	xx.xx		xx.xx	xx.xx	xx.xx
95% CI [2]	xx.xx, xx.xx		xx.xx, xx.xx	xx.xx, xx.xx	xx.xx, xx.xx

Including all visits and Binding Antibodies

ADIS.AVISIT ADIS.PARAM where ADIS.PARCAT1='Serum SARS-CoV-2

bAb = Binding antibody. GM = Geometric Mean. CI = Confidence intervals.

Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

For visit Day 29, visit window (-3/+7 days) is used to define per-protocol. If the visit (Day 29) is disrupted and cannot be completed at Day 29 (-3/+7 days) as a result of the COVID-19 pandemic, the window is extended to Day 29 + 21 days.

[1] Number of subjects with non-missing baseline.

[2] 95% CI is calculated based on the t-distribution of the log-transformed values or the difference in the log-transformed values for GM value and GM fold-rise, respectively, then back transformed to the original scale for presentation.

[3] Number of subjects in the Per-Protocol Set for SARS-CoV-2-specific bAb at the corresponding visit.

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