Tables of Antibody Marker Data

Table 1. Demographic and Clinical Characteristics at Baseline in the baseline SARS-CoV-2 negative per-protocol cohort

Characteristics	Vaccine (N = 904)	Placebo (N = 155)	Total (N = 1059)
Age			
Age $\geq$ 65	472 (52.2%)	76 (49.0%)	548 (51.7%)
Age < 65	432 (47.8%)	79 (51.0%)	511 (48.3%)
Mean (Range)	58.7 (18.0, 85.0)	58.3 (18.0, 85.0)	58.7 (18.0, 85.0)
BMI			
Mean $\pm$ SD	29.9 $\pm$ 7.0	29.9 $\pm$ 7.8	29.9 $\pm$ 7.1
Sex			
Female	511 (56.5%)	85 (54.8%)	596 (56.3%)
Male	393 (43.5%)	70 (45.2%)	463 (43.7%)
Race			
White Non-Hispanic	389 (46.0%)	66 (45.8%)	455 (46.0%)
Black or African American	186 (22.0%)	30 (20.8%)	216 (21.8%)
Asian	72 (8.5%)	11 (7.6%)	83 (8.4%)
American Indian or Alaska Native	23 (2.7%)	4 (2.8%)	27 (2.7%)
Native Hawaiian or Other Pacific Islander	17 (2.0%)	3 (2.1%)	20 (2.0%)
Multiracial	50 (5.9%)	12 (8.3%)	62 (6.3%)
Other	26 (3.1%)	2 (1.4%)	28 (2.8%)
Not reported and unknown	82 (9.7%)	16 (11.1%)	98 (9.9%)
Communities of Color	401 (50.8%)	65 (49.6%)	466 (50.6%)
Hispanic or Latino ethnicity			
Hispanic or Latino	112 (12.4%)	20 (12.9%)	132 (12.5%)
Not Hispanic or Latino	723 (80.0%)	119 (76.8%)	842 (79.5%)
Not reported and unknown	69 (7.6%)	16 (10.3%)	85 (8.0%)
Risk for Severe Covid-19			
At-risk	460 (50.9%)	78 (50.3%)	538 (50.8%)
Not at-risk	444 (49.1%)	77 (49.7%)	521 (49.2%)

This table summarises the random subcohort, which was randomly sampled from the per-protocol individuals without a COVID failure event < 7 days post Day 57. The sampling was stratified by the key baseline covariates: assigned treatment arm, baseline SARS-CoV-2 status (defined by serostatus and possibly also NAAT and/or RNA PCR testing), any additional important demographic factors such as the randomization strata (e.g., defined by age and/or co-morbidities).

Table 2. Demographic and Clinical Characteristics at Baseline in the baseline SARS-CoV-2 positive per-protocol cohort

Characteristics	Vaccine (N = 273)	Placebo (N = 270)	Total (N = 543)
Age			
Age $\geq$ 65	128 (46.9%)	121 (44.8%)	249 (45.9%)
Age < 65	145 (53.1%)	149 (55.2%)	294 (54.1%)
Mean (Range)	56.4 (18.0, 85.0)	55.6 (18.0, 85.0)	56.0 (18.0, 85.0)
BMI			
Mean $\pm$ SD	30.0 $\pm$ 7.6	29.7 $\pm$ 7.3	29.8 $\pm$ 7.4
Sex			
Female	149 (54.6%)	149 (55.2%)	298 (54.9%)
Male	124 (45.4%)	121 (44.8%)	245 (45.1%)
Race			
White Non-Hispanic	112 (46.5%)	112 (45.9%)	224 (46.2%)
Black or African American	37 (15.4%)	54 (22.1%)	91 (18.8%)
Asian	24 (10.0%)	22 (9.0%)	46 (9.5%)
American Indian or Alaska Native	8 (3.3%)	9 (3.7%)	17 (3.5%)
Native Hawaiian or Other Pacific Islander	3 (1.2%)	4 (1.6%)	7 (1.4%)
Multiracial	16 (6.6%)	12 (4.9%)	28 (5.8%)
Other	12 (5.0%)	12 (4.9%)	24 (4.9%)
Not reported and unknown	29 (12.0%)	19 (7.8%)	48 (9.9%)
Communities of Color	110 (49.5%)	125 (52.7%)	235 (51.2%)
Hispanic or Latino ethnicity			
Hispanic or Latino	38 (13.9%)	45 (16.7%)	83 (15.3%)
Not Hispanic or Latino	208 (76.2%)	198 (73.3%)	406 (74.8%)
Not reported and unknown	27 (9.9%)	27 (10.0%)	54 (9.9%)
Risk for Severe Covid-19			
At-risk	126 (46.2%)	120 (44.4%)	246 (45.3%)
Not at-risk	147 (53.8%)	150 (55.6%)	297 (54.7%)

This table summarises the random subcohort, which was randomly sampled from the per-protocol individuals without a COVID failure event < 7 days post Day 57. The sampling was stratified by the key baseline covariates: assigned treatment arm, baseline SARS-CoV-2 status (defined by serostatus and possibly also NAAT and/or RNA PCR testing), any additional important demographic factors such as the randomization strata (e.g., defined by age and/or co-morbidities).

Table 3. Antibody levels in the baseline SARS-CoV-2 negative per-protocol cohort (vaccine recipients)

| | | | Baseline SARS-CoV-2 Negative Vaccine Recipients | | | | | | |
| | | | Cases* | | | Non-Cases/Control | | | Comparison |
Visit	Marker	N	Resp rate	GMT/GMC	N	Resp rate	GMT/GMC	Resp Rate Difference	GMTR/GMCR
Day 29	Anti N IgG (IU/ml)	10	79.1/79.1 = 100.0% (100.0%, 100.0%)	13161 (3939, 43978)	894	13174.9/13174.9 = 100.0% (100.0%, 100.0%)	24397 (20958, 28399)	0% (0%, 0%)	0.54 (0.16, 1.82)
Day 57	Anti N IgG (IU/ml)	10	79.1/79.1 = 100.0% (100.0%, 100.0%)	93160 (25382, 341924)	894	13174.9/13174.9 = 100.0% (100.0%, 100.0%)	406694 (339027, 487867)	0% (0%, 0%)	0.23 (0.06, 0.85)
Day 29	Anti RBD IgG (IU/ml)	10	79.1/79.1 = 100.0% (100.0%, 100.0%)	13062 (6241, 27336)	894	13174.9/13174.9 = 100.0% (100.0%, 100.0%)	24897 (21711, 28551)	0% (0%, 0%)	0.52 (0.25, 1.11)
Day 57	Anti RBD IgG (IU/ml)	10	79.1/79.1 = 100.0% (100.0%, 100.0%)	335181 (113451, 990270)	894	13174.9/13174.9 = 100.0% (100.0%, 100.0%)	1083605 (942656, 1245630)	0% (0%, 0%)	0.31 (0.10, 0.92)
Day 29	Anti Spike IgG (IU/ml)	10	79.1/79.1 = 100.0% (100.0%, 100.0%)	18276 (10842, 30809)	894	13174.9/13174.9 = 100.0% (100.0%, 100.0%)	46529 (41517, 52145)	0% (0%, 0%)	0.39 (0.23, 0.67)
Day 57	Anti Spike IgG (IU/ml)	10	79.1/79.1 = 100.0% (100.0%, 100.0%)	429724 (169006, 1092644)	894	13174.9/13174.9 = 100.0% (100.0%, 100.0%)	2374666 (2108766, 2674094)	0% (0%, 0%)	0.18 (0.07, 0.46)
Day 29	Pseudovirus-nAb ID50	10	59.4/79.1 = 80.0% (38.2%, 96.3%)	38 (17, 83)	894	11749.1/13174.9 = 89.2% (85.9%, 91.7%)	107 (92, 124)	-9.2% (-51%, 7.4%)	0.35 (0.16, 0.79)
Day 57	Pseudovirus-nAb ID50	10	54.9/79.1 = 80.0% (38.2%, 96.3%)	173 (41, 739)	894	13062.9/13174.9 = 99.1% (98.1%, 99.6%)	1812 (1505, 2181)	-19.1% (-61%, -2.8%)	0.10 (0.02, 0.41)
Day 29	Pseudovirus-nAb ID80	10	79.1/79.1 = 100.0% (100.0%, 100.0%)	241 (112, 520)	894	12537.6/13174.9 = 95.1% (92.8%, 96.7%)	217 (186, 254)	4.9% (3.3%, 7.2%)	1.11 (0.51, 2.43)
Day 57	Pseudovirus-nAb ID80	10	79.1/79.1 = 100.0% (100.0%, 100.0%)	1278 (261, 6252)	894	13143/13174.9 = 99.8% (99.2%, 99.9%)	2912 (2432, 3487)	0.2% (0.1%, 0.8%)	0.44 (0.09, 2.17)

*Cases are baseline negative per-protocol vaccine recipients with the symptomatic infection COVID-19 primary endpoint diagnosed starting 7 days after the Day 57 study visit. Non-cases/Controls are baseline negative per-protocol vaccine recipients sampled into the random subcohort with no evidence of SARS-CoV-2 infection up to the time of data cut.

Table 4. Antibody levels in the baseline SARS-CoV-2 positive per-protocol cohort (vaccine recipients)

| | | Baseline SARS-CoV-2 Positive Vaccine Recipients | | | | | | | |
| | | Cases* | | | Non-Cases/Control | | | Comparison | |
Visit	Marker	N	Resp rate	GMT/GMC	N	Resp rate	GMT/GMC	Resp Rate Difference	GMTR/GMCR
Day 29	Anti N IgG (IU/ml)	1	1.9/1.9 = 100.0%	3787 (3787, 3787)	272	1440.1/1440.1 = 100.0% (100.0%, 100.0%)	38991 (28984, 52454)	0%	0.10 (0.07, 0.13)
Day 57	Anti N IgG (IU/ml)	1	1.9/1.9 = 100.0%	103825 (103825, 103825)	272	1440.1/1440.1 = 100.0% (100.0%, 100.0%)	860725 (615044, 1204543)	0%	0.12 (0.09, 0.17)
Day 29	Anti RBD IgG (IU/ml)	1	1.9/1.9 = 100.0%	26128 (26128, 26128)	272	1440.1/1440.1 = 100.0% (100.0%, 100.0%)	40375 (31120, 52384)	0%	0.65 (0.50, 0.84)
Day 57	Anti RBD IgG (IU/ml)	1	1.9/1.9 = 100.0%	150349 (150349, 150349)	272	1440.1/1440.1 = 100.0% (100.0%, 100.0%)	2688972 (2110320, 3426292)	0%	0.06 (0.04, 0.07)
Day 29	Anti Spike IgG (IU/ml)	1	1.9/1.9 = 100.0%	114815 (114815, 114815)	272	1440.1/1440.1 = 100.0% (100.0%, 100.0%)	80292 (65063, 99085)	0%	1.43 (1.16, 1.76)
Day 57	Anti Spike IgG (IU/ml)	1	1.9/1.9 = 100.0%	8489850 (8489850, 8489850)	272	1440.1/1440.1 = 100.0% (100.0%, 100.0%)	5786742 (4824223, 6941300)	0%	1.47 (1.22, 1.76)
Day 29	Pseudovirus-nAb ID50	1	1.9/1.9 = 100.0%	35 (35, 35)	272	1387.2/1440.1 = 96.3% (91.9%, 98.4%)	173 (132, 227)	3.7%	0.20 (0.16, 0.27)
Day 57	Pseudovirus-nAb ID50	1	1.9/1.9 = 100.0%	845 (845, 845)	272	1437.3/1440.1 = 99.8% (98.6%, 100.0%)	4747 (3353, 6722)	0.2%	0.18 (0.13, 0.25)
Day 29	Pseudovirus-nAb ID80	1	1.9/1.9 = 100.0%	210 (210, 210)	272	1419.8/1440.1 = 98.6% (96.9%, 99.4%)	337 (255, 446)	1.4%	0.62 (0.47, 0.83)
Day 57	Pseudovirus-nAb ID80	1	1.9/1.9 = 100.0%	6552 (6552, 6552)	272	1440.1/1440.1 = 100.0% (100.0%, 100.0%)	7813 (5407, 11289)	0%	0.84 (0.58, 1.21)

*Cases are baseline positive per-protocol vaccine recipients with the symptomatic infection COVID-19 primary endpoint diagnosed starting 7 days after the Day 57 study visit. Non-cases/Controls are baseline negative per-protocol vaccine recipients sampled into the random subcohort with no evidence of SARS-CoV-2 infection up to the time of data cut.

Table 5. Antibody levels in the baseline SARS-CoV-2 positive per-protocol cohort (placebo recipients)

| | | Baseline SARS-CoV-2 Positive Placebo Recipients | | | | | | | |
| | | Cases* | | | Non-Cases/Control | | | Comparison | |
Visit	Marker	N	Resp rate	GMT/GMC	N	Resp rate	GMT/GMC	Resp Rate Difference	GMTR/GMCR
Day 29	Anti N IgG (IU/ml)	1	1.9/1.9 = 100.0%	1924 (1924, 1924)	269	1384.1/1384.1 = 100.0% (100.0%, 100.0%)	12154 (9340, 15817)	0%	0.16 (0.12, 0.21)
Day 57	Anti N IgG (IU/ml)	1	1.9/1.9 = 100.0%	9179 (9179, 9179)	269	1384.1/1384.1 = 100.0% (100.0%, 100.0%)	149599 (107630, 207934)	0%	0.06 (0.04, 0.09)
Day 29	Anti RBD IgG (IU/ml)	1	1.9/1.9 = 100.0%	1056 (1056, 1056)	269	1384.1/1384.1 = 100.0% (100.0%, 100.0%)	11798 (9288, 14986)	0%	0.09 (0.07, 0.11)
Day 57	Anti RBD IgG (IU/ml)	1	1.9/1.9 = 100.0%	20114 (20114, 20114)	269	1384.1/1384.1 = 100.0% (100.0%, 100.0%)	459815 (350257, 603642)	0%	0.04 (0.03, 0.06)
Day 29	Anti Spike IgG (IU/ml)	1	1.9/1.9 = 100.0%	2888 (2888, 2888)	269	1384.1/1384.1 = 100.0% (100.0%, 100.0%)	17917 (14848, 21621)	0%	0.16 (0.13, 0.19)
Day 57	Anti Spike IgG (IU/ml)	1	1.9/1.9 = 100.0%	280285 (280285, 280285)	269	1384.1/1384.1 = 100.0% (100.0%, 100.0%)	715893 (574830, 891572)	0%	0.39 (0.31, 0.49)
Day 29	Pseudovirus-nAb ID50	1	0/1.9 = 0.0%	5 (5, 5)	269	1135.7/1384.1 = 82.1% (74.2%, 87.9%)	51 (39, 65)	-82.1%	0.10 (0.08, 0.13)
Day 57	Pseudovirus-nAb ID50	1	0/1.9 = 0.0%	5 (5, 5)	269	1340.3/1384.1 = 96.8% (90.9%, 99.0%)	517 (358, 746)	-96.8%	0.01 (0.01, 0.01)
Day 29	Pseudovirus-nAb ID80	1	0/1.9 = 0.0%	5 (5, 5)	269	1294.2/1384.1 = 93.5% (87.5%, 96.7%)	151 (114, 200)	-93.5%	0.03 (0.03, 0.04)
Day 57	Pseudovirus-nAb ID80	1	0/1.9 = 0.0%	5 (5, 5)	269	1381.6/1384.1 = 99.8% (98.7%, 100.0%)	1712 (1241, 2361)	-99.8%	0.00 (0.00, 0.00)

*Cases are baseline negative per-protocol vaccine recipients with the symptomatic infection COVID-19 primary endpoint diagnosed starting 7 days after the Day 57 study visit. Non-cases/Controls are baseline negative per-protocol vaccine recipients sampled into the random subcohort with no evidence of SARS-CoV-2 infection up to the time of data cut.