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LIST OF INVESTIGATORS

| Investigator               | Institution                        | Location (City, State) |
|----------------------------|------------------------------------|------------------------|
| Laurence Chu, M.D.         | Benchmark Research                 | Austin, TX             |
| Carlos Fierro, M.D.        | Johnson County Clinical Trials     | Lenexa, KS             |
| Howard Schwartz, M.D.      | Research Centers of America        | Hollywood, FL          |
| William Seger, M.D.        | Benchmark Research                 | Fort Worth, TX         |
| Michael Cotugno, M.D.      | Benchmark Research                 | Metairie, LA           |
| Greg Hachigian, M.D.       | Benchmark Research                 | Sacramento, CA         |
| David Ensz, M.D.           | Meridian Clinical Research         | Sioux City, Iowa       |
| Larkin Wadsworth, M.D.     | Sundance Clinical Research         | St. Louis, MO          |

SUPPLEMENTARY METHODS

Immunogenicity assays

SARS-CoV-2 Spike-Pseudotyped Virus Neutralization Assay

The SARS-CoV-2 spike-pseudotyped virus neutralization assay was used to analyze all of the samples from this study as well as the historical control group (Phase 3 COVE trial). This is a validated assay that quantifies SARS-CoV-2 neutralizing antibodies by using lentivirus particles that express SARS-CoV-2 full-length spike proteins (Wuhan-Hu-1 isolate including the amino acid change of D614G in the spike protein; the Delta variant [B.1.617.2; AY.3; Wuhan-Hu-1 isolate containing spike mutations T19R, G142D, Δ156-157, R158G, L452R, T478K, D614G, P681R, D950N] on their surface and contain a firefly luciferase reporter gene for quantitative measurements of infection by relative luminescence units (RLU). The Omicron variant (B.1.1.529) assay and results are described elsewhere\(^{12}\).

SARS-CoV-2 Meso-Scale Discovery (MSD) assay

The validated Meso-Scale Discovery (MSD) assay uses an indirect, quantitative, electrochemiluminescence method to detect SARS-CoV-2 binding IgG antibodies to the SARS-
CoV-2 full-length spike (Wuhan-Hu-1 ancestral isolate including D614G; Beta [B.1.351] with the following amino acid changes in the spike protein [L18F, D80A, D215G, Δ242-244, R246I, K417N, E484K, N501Y, D614G, and A701V]) in human serum. The assay is based on the MSD technology which employs capture molecule MULTI-SPOT® microtiter plates fitted with a series of electrodes.

Statistical analysis

Study analysis populations included the Safety Set, comprising all enrolled participants who received the 100 µg mRNA-1273 booster injection; the Immunogenicity Set, consisting all participants who received the booster dose and had neutralizing antibody data at both pre-booster baseline and Day 29 visit, with no major protocol deviations that could impact data integrity. The Safety Set was used for the safety analyses and the Immunogenicity Set and the analysis of immunogenicity data.

The primary immunogenicity objective for 100 µg mRNA-1273 booster dose was considered to be met if the pre-specified non-inferiority criteria were demonstrated, at a 2-sided alpha of 0.05, based on both GMT and SRR at 28 days after the booster dose compared to GMTs 28 days after the second dose in the historical control arm. For the primary immunogenicity objective, there were two pre-specified hypotheses to be tested: (1) Non-inferiority based on the GMR (GMT post-boost/GMT post-primary series) with a noninferiority margin of 1.5; if the lower bound of the 95% CI of GMR ≥ 0.67 (1/1.5), then non-inferiority was considered met; and (2) noninferiority based on the difference in seroresponse rate (SRR) with a noninferiority margin of 10%; if the lower bound of the 95% CI of SRR difference >-10%, then
SRR non-inferiority was considered met. Seroresponse was defined as: 4-fold rise for participants with baseline ≥ lower limit of quantification (LLOQ) of the neutralizing antibody assay or ≥ 4 times the LLOQ of the assay for those with baseline <LLOQ. Seroresponse was derived based on two types of baselines: pre-vaccination baseline on Day 1 of the primary series (before receiving the first dose), and pre-booster baseline. The seroresponse rate based on the pre-vaccination baseline titers is the primary definition. For participants who received the 100 µg booster of mRNA-1273 in this study and did not have pre-vaccination antibody titers, seroresponse was defined as ≥ 4 times LLOQ for subjects with negative SARS-CoV-2 status at their pre-dose 1 of primary series, and these participant’s antibody titers were deemed <LLOQ at pre-dose 1 of primary series.

Analysis of covariance (ANCOVA) model was used to assess immune response of 100 µg mRNA-1273 booster dose compared to the immune response after the second dose of 100 µg primary series. The model included log-transformed antibody titers at 28 days post-boost and 28 days post-second dose as the dependent variables, treatment groups (100 µg mRNA-1273 booster dose, 100 µg primary series) as explanatory variable and adjusting for age groups (< 65 years; ≥ 65 years). The geometric least squares mean (GLSM) and corresponding 2-sided 95% CI for the antibody titers for each treatment group were calculated. The GLSM, and the corresponding 95% CI results in log-transformed scale estimated from the model were back-transformed to obtain these estimates in the original scale. GMR, estimated by the ratio of GLSM and the corresponding 2-sided 95% CI were used to assess the treatment difference.

To assess noninferiority of immune response based on SRR, the number and percentage (rate) of participants achieving seroresponse at 28 days after the booster or after the second
dose in the historical control group were summarized with 95% CI calculated using the Clopper-Pearson method for each group. The difference of SRRs between 100 µg mRNA-1273 at 28 days after the booster dose and 100 µg mRNA-1273 primary 28 days after the second dose were calculated with 95% CI using Miettinen-Nurminen (score) method.

All analyses were conducted using SAS Version 9.4 or higher.

IMMUNOGENICITY RESULTS

Administration of a booster dose of 100 µg mRNA-1273 to participants who previously received the primary series of 100 µg mRNA-1273 increased neutralizing antibodies (nAbs) (pseudovirus assay) based on the pre-booster baseline to the ancestral SARS-CoV-2 spike protein containing the D614G amino acid substitution and the Delta variant (B.1.617.2) spike protein (Supplementary Table 2). The GMTs (95% CIs) pre-booster for nAbs to the ancestral virus spike protein were 90.0 (76.9, 104.7) and increased to 4039.5 (3592.7, 4541.8) at 28 days after the booster dose. The GMFR was 45.0 (38.9, 52.1) compared to the pre-booster. In comparison, the GMT (95% CI) for the historical control group was 1132.0 (1046.7, 1224.2) at 28 days after the second dose. The seroresponse rates (95% CI) for the ancestral spike protein were 96.5% (93.5, 98.4) for the booster dose and 98.1% (96.7, 99.1) for the historical control group. Testing for nAbs was also performed against the Delta variant (B.1.617.2) spike protein. The Delta-specific GMTs (95% CI) for nAbs was 2164.4 (1915.0, 2446.3) at 28 days after the booster and 383.1 (352.4, 416.4) in the historical control group at 28 days after the second dose.

Administration of a booster dose of 100 µg mRNA-1273 to participants who previously received the primary series of 100 µg mRNA-1273 also increased binding IgG antibodies (MSD
assay) based on the pre-vaccination baseline to the ancestral SARS-CoV-2 spike protein containing the D614G amino acid substitution and the Beta variant (B.1.351) spike protein (Supplementary Table 3). The GMTs (95% CIs) pre-vaccination for binding antibodies to the ancestral virus spike protein were 12 (not estimated [NE], NE) pre-vaccination and increased to 712,284 (577,541-878,464) at 28 days after the booster dose. The GMFR (95% CIs) for the GMTs at 28 days after the booster was 59,469 (48,153-73,444). In comparison, the GMT (95% CI) for the historical control group was 249,485 (229,020-271,779) at 28 days after the second dose. The seroresponse rates (95% CI) for the ancestral spike protein were 98% (96-99) for the booster dose and 99% (98,100) for the historical control group. Testing for binding antibodies was also performed against the Beta variant (B.1.351) spike protein. The Beta-specific GMTs (95% CI) for binding antibodies were 306,816 (247,479-380,379) at 28 days after the booster and 98,520 (90,730-106,980) in the historical control group at 28 days after the second dose. Administration of a booster dose of 100 μg mRNA-1273 to participants who previously received the primary series of 100 μg mRNA-1273 also increased binding IgG antibodies (MSD assay) based on the pre-booster baseline to the ancestral SARS-CoV-2 spike protein containing the D614G amino acid substitution and the Beta variant (B.1.351) spike protein (Supplementary Table 4). The GMTs (95% CIs) pre-booster for binding antibodies to the ancestral virus spike protein were 23,972 (21,116-27,215) and increased to 712,284 (577,541-878,464) at 28 days after the booster dose. The GMFRs (95% CIs) at 28 days after the booster was 29.7 (23.6-37.4) based on pre-booster baseline. In comparison, the GMT (95% CI) for the historical control group was 249,485 (229,020-271,779) at 28 days after the second dose. The seroresponse rates (95%
CI) for the ancestral spike protein were 95% (91-97) for the booster dose and 99% (98,100) for the historical control group.
Supplementary Figure 1: Summary of pseudovirus neutralizing antibodies to SARS-CoV-2 at 28 days after a booster dose of 100 µg of mRNA-1273

Supplementary Figure 1 Legend: GMT=geometric mean titer from participants with non-missing data at the timepoint (pre-booster and 28 days after the booster; CI=confidence interval (95% CI was 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, and then back transformed to the original scale for presentation.)
SUPPLEMENTARY TABLE 1: Solicited local and systemic adverse reactions within 7 days after the booster injection of 100 or 50 µg of mRNA-1273 or the second dose of 100 µg of mRNA-1273

| Adverse Reaction, N (%) | mRNA-1273, 100 µg booster, N=303 | mRNA-1273, 50 µg booster in phase 2 mRNA-P201 study N=167 | mRNA-1273 100 µg primary series in Phase 3 COVE study, N=14691 |
|-------------------------|----------------------------------|-------------------------------------------------|-------------------------------------------------|
| Solicited AR, N1        | 303                              | 167                                             | 14691                                           |
| Any Solicited AR        | 290 (95.7)                       | 151 (90.4)                                      | 13556 (92.3)                                    |
| Grade 1                 | 95 (31.4)                        | 73 (43.7)                                       | 4847 (33.0)                                     |
| Grade 2                 | 144 (47.5)                       | 59 (35.3)                                       | 5800 (39.5)                                     |
| Grade 3                 | 51 (16.8)                        | 18 (10.8)                                       | 2895 (19.7)                                     |
| Grade 4                 | 0                                | 0                                               | 14 (<0.1)                                       |
| Any Solicited Local AR, N1 | 302                          | 167                                             | 14688                                           |
| Any Solicited Local AR  | 280 (92.7)                       | 143 (85.6)                                      | 13029 (88.7)                                    |
| Grade 1                 | 183 (60.6)                       | 108 (64.7)                                      | 8789 (59.8)                                     |
| Grade 2                 | 77 (25.5)                        | 27 (16.2)                                       | 3217 (21.9)                                     |
| Grade 3                 | 20 (6.6)                         | 8 (4.8)                                         | 1023 (7.0)                                      |
| Local AR, Pain, N1      | 302                              | 167                                             | 14688                                           |
| Pain                    | 280 (92.7)                       | 140 (83.8)                                      | 12964 (88.3)                                    |
| Grade 1                 | 201 (66.6)                       | 111 (66.5)                                      | 9508 (64.7)                                     |
| Grade 2                 | 68 (22.5)                        | 23 (13.8)                                       | 2850 (19.4)                                     |
| Grade 3                 | 11 (3.6)                         | 6 (3.6)                                         | 606 (4.1)                                       |
| Erythema, N1            | 302                              | 167                                             | 14687                                           |
| Erythema                | 32 (10.6)                        | 8 (4.8)                                         | 1274 (8.7)                                      |
| Grade 1                 | 14 (4.6)                         | 5 (3.0)                                         | 456 (3.1)                                       |
| Grade 2                 | 14 (4.6)                         | 2 (1.2)                                         | 531 (3.6)                                       |
| Grade 3                 | 4 (1.3)                          | 1 (0.6)                                         | 287 (2.0)                                       |
| Swelling, N1            | 302                              | 167                                             | 14687                                           |
| Swelling                | 43 (14.2)                        | 9 (5.4)                                         | 1807 (12.3)                                     |
|                  | Grade 1 | Grade 2 | Grade 3 |
|------------------|---------|---------|---------|
|                  | 23 (7.6) | 4 (2.4) | 900 (6.1) |
| Axillary Swelling | 23 (7.6) | 4 (2.4) | 900 (6.1) |
| Axillary Swelling or Tenderness, N1 | 302 | 167 | 14687 |
| Grade 1 | 92 (30.5) | 34 (20.4) | 2092 (14.2) |
| Grade 2 | 30 (18.0) | 1735 (11.8) |
| Grade 3 | 652 (4.4) | 289 (2.0) |
| Grade 4 | 68 (0.5) | |
| Any Systemic AR, N1 | 303 | 167 | 14690 |
| Any Systemic AR | 260 (85.8) | 126 (75.4) | 11678 (79.5) |
| Grade 1 | 82 (27.1) | 60 (35.9) | 3717 (25.3) |
| Grade 2 | 140 (46.2) | 53 (31.7) | 5611 (38.2) |
| Grade 3 | 38 (12.5) | 12 (7.2) | 2336 (15.9) |
| Grade 4 | 0 | 0 | 14 (<0.1) |
| Fever, N1 | 303 | 167 | 14682 |
| Fever | 43 (14.2) | 11 (6.6) | 2276 (15.5) |
| Grade 1 | 24 (7.9) | 6 (3.6) | 1363 (9.3) |
| Grade 2 | 16 (5.3) | 3 (1.8) | 697 (4.7) |
| Grade 3 | 3 (1.0) | 2 (1.2) | 203 (1.4) |
| Grade 4 | 0 | 0 | 13 (<0.1) |
| Headache, N1 | 302 | 167 | 14687 |
| Headache | 187 (61.9) | 92 (55.1) | 8637 (58.8) |
| Grade 1 | 105 (34.8) | 61 (36.5) | 4815 (32.8) |
| Grade 2 | 76 (25.2) | 29 (17.4) | 3156 (21.5) |
| Grade 3 | 6 (2.0) | 2 (1.2) | 666 (4.5) |
| Grade 4 | 0 | 0 | 0 |
| Fatigue, N1 | 302 | 167 | 14687 |
| Fatigue | 220 (72.8) | 98 (58.7) | 9607 (65.4) |
| Grade  | N1  | N2  | N3  |
|--------|-----|-----|-----|
| Grade 1 | 81 (26.8) | 47 (28.1) | 3431 (23.4) |
| Grade 2 | 116 (38.4) | 44 (26.3) | 4743 (32.3) |
| Grade 3 | 23 (7.6) | 7 (4.2) | 1433 (9.8) |
| Grade 4 | 0 | 0 | 0 |
| Myalgia, N1 | 302 | 167 | 14687 |
| Myalgia | 204 (67.5) | 82 (49.1) | 8529 (58.1) |
| Grade 1 | 80 (26.5) | 47 (28.1) | 3242 (22.1) |
| Grade 2 | 104 (34.4) | 30 (18.0) | 3966 (27.0) |
| Grade 3 | 20 (6.6) | 5 (3.0) | 1321 (9.0) |
| Grade 4 | 0 | 0 | 0 |
| Arthralgia, N1 | 302 | 167 | 14687 |
| Arthralgia | 147 (48.7) | 69 (41.3) | 6303 (42.9) |
| Grade 1 | 63 (20.9) | 43 (25.7) | 2809 (19.1) |
| Grade 2 | 69 (22.8) | 21 (12.6) | 2719 (18.5) |
| Grade 3 | 15 (5.0) | 5 (3.0) | 775 (5.3) |
| Grade 4 | 0 | 0 | 0 |
| Nausea/ vomiting, N1 | 302 | 167 | 14687 |
| Nausea / vomiting | 59 (19.5) | 19 (11.4) | 2794 (19.0) |
| Grade 1 | 42 (13.9) | 16 (9.6) | 2094 (14.3) |
| Grade 2 | 17 (5.6) | 3 (1.8) | 678 (4.6) |
| Grade 3 | 0 | 0 | 21 (0.1) |
| Grade 4 | 0 | 0 | 1 (<0.1) |
| Chills, N1 | 302 | 167 | 14687 |
| Chills | 133 (44.0) | 59 (35.3) | 6500 (44.3) |
| Grade 1 | 63 (20.9) | 36 (21.6) | 2907 (19.8) |
| Grade 2 | 67 (22.2) | 23 (13.8) | 3402 (23.2) |
| Grade 3 | 3 (1.0) | 0 | 191 (1.3) |
| Grade 4 | 0 | 0 | 0 |

Supplementary Table 2 Legend: AR=adverse reaction. Any=Grade 1 or higher. N1=Number of exposed participants with any information about the adverse event. Percentages based on N1.
Supplementary Table 2. Neutralizing antibody titers (pseudovirus assay; ID50; pre-booster baseline titers) after the 100 µg booster dose of mRNA-1273

|                          | Ancestral SARS-CoV-2 with D614G | Delta (B.1.617.2) |
|--------------------------|----------------------------------|-------------------|
|                          | Recipients of 100 µg mRNA-1273   | Recipients of 100 µg mRNA-1273 |
|                          | Booster Dose N=257                | Booster Dose N=257 |
|                          | Historical control group         | Historical control group |
|                          | 100 µg mRNA-1273 N=584           | 100 µg mRNA-1273 N=584 |
| Pre-booster/Baseline n^a | 257                             | 257               |
| GM titer                 | 90.0                            | 44.4              |
| (95% CI) b               | (76.9-104.7)                    | (37.5-52.6)       |
| 28 days after booster or 2^nd dose n^i | 257                             | 257               |
| GM titer                 | 4039.5                          | 2164.4            |
| (95% CI) b               | (3592.7-4541.8)                 | (1915.0-2446.3)   |
| GMFR                     | 45.0                            | 48.7              |
| (95% CI) b               | (38.9-52.1)                     | (41.4, 57.3)      |
| Seroreponse rate^c       | 248/257 (96.5)                  | 245/257 (95.3)    |
| n/N1 (%) d               | 93.5-98.4                       | (92.0-97.6)       |
| (95% CI) e               |                                 |                   |
| Difference in seroresponse rate after booster compared to Phase 3 COVE [% (95% CI)] | -1.6 | (-4.8, 0.6) |

Supplementary Table 2 Legend: GM=geometric mean, CI=confidence interval, GMFR=geometric mean fold rise, GLSM=geometric least squares mean, GMR=geometric mean ratio. a Number of participants with non-missing data at the corresponding timepoint. b The 95% CI was 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, and then back transformed to the original scale for presentation. c Seroreponse at a participant level was defined as a change from below the LLOQ to equal or above 4 x LLOQ if the baseline was below the LLOQ, or at least a 4-fold rise if the baseline was equal to or above the LLOQ. d The number of participants meeting the criterion at the time point. Percentages are based on N1. e The 95% CI was calculated using the Clopper-Pearson method. f The 95% CI was calculated using the Miettinen-Nurinen (score) confidence limits. For calculation of GMTs and GMFRs, antibody
values reported as below the lower limit of quantification (LLOQ) were replaced by 0.5 times the LLOQ. Values that were greater than the upper limit of quantification (ULOQ) were converted to the ULOQ if actual values were not available. Missing results were not imputed.
### Supplementary Table 3. Binding IgG antibody titers (MSD assay; ID50; Ancestral SARS-CoV-2 with D614G and Beta (B.1.351); pre-vaccination baseline titers) after the 100 µg booster dose of mRNA-1273

|                         | Ancestral SARS-CoV-2 with D614G | Beta (B.1.351) |
|-------------------------|----------------------------------|----------------|
|                         | Recipients of 100 µg mRNA-1273    | Historical control group, 100 µg mRNA-1273 |
|                         | Booster Dose N=257               | Booster Dose N=257 |
|                         |                                   | Booster Dose N=257 |
| Pre-Vaccination         |                                    |                          |
| Baseline n\(^a\)        | 255                               | 255                       |
| GM titer\(^b\)          | 12                                | 9                         |
| (95% CI)\(^c\)          | (NE-NE)                           | (NE-NE)                   |
| 28 days after booster or 2\(^{nd}\) dose n\(^*\) | 257                               | 257                       |
| GM titer\(^b\)          | 712, 284                          | 306,816                   |
| (95% CI)\(^c\)          | (577,541-878,464)                 | (247,479-380,379)         |
| GMFR                    | 59,469                            | 34,123                    |
| (95% CI)\(^c\)          | (48,153-73,444)                   | (27,484-42,365)           |
| Seroresponse rate\(^d\) | 250/255 (98)                      | 249/255 (98)              |
| n/N1 (%\(^e\))          | 96-99                             | 95-99                     |
| (95% CI)\(^f\)          | (98-100)                          | (98-100)                  |

**Supplementary Table 3 Legend:** GM=geometric mean, NE=not estimated, CI=confidence interval, GMFR=geometric mean fold rise. \(^a\) Number of participants with non-missing data at the timepoint (baseline or post-baseline). \(^b\) AU/mL. \(^c\) The 95% CI was calculated based on the t-distribution of the log-transformed values or the difference in the log-transformed values for GM value or GM fold-rise, respectively, then back transformed to the original scale for presentation. \(^d\) Seroresponse at a participant level was defined as a change from below the LLOQ to equal or above 4 x LLOQ if the baseline was below the LLOQ, or at least a 4-fold rise if the baseline was equal to or above the LLOQ. For mRNA1273-P205 subjects without pre-Dose 1 antibody titer information and have corresponding Day 29 post-boost assessment, seroresponse is defined as >= 4*LLOQ for subjects with negative SARS-CoV-2 status at their pre-dose 1 of primary series, and these subjects’ antibody titer are imputed as <LLOQ at pre-dose 1 of primary series. For subjects who are without SARS-CoV-2 status information at pre-dose 1 of primary series, their pre-booster SARS-CoV-2 status is used to impute their SARS-CoV-2 status at their pre-dose 1 of primary series. \(^e\) The number of participants meeting the criterion at the time point. Percentages are based on N1. \(^f\) The 95% CI was calculated using the Clopper-Pearson method.
Supplementary Table 4. Binding IgG antibody titers (MSD assay; ID50; Ancestral SARS-CoV-2 with D614G and Beta (B.1.351); pre-booster baseline titers) after the 100 µg booster dose of mRNA-1273

|                     | Ancestral SARS-CoV-2 with D614G | Beta (B.1.351) |
|---------------------|---------------------------------|----------------|
|                     | Recipients of 100 µg mRNA-1273   |                |
|                     | Booster Dose N=257               |                |
| Pre-booster/Baseline n<sup>a</sup> | 257                             | 257            |
| GM titer<sup>b</sup>  | 23,972                           | 8,973          |
| (95% CI)<sup>c</sup> | (21,116-27215)                   | (7,904-10,185) |
| 28 days 9 after booster or 2<sup>nd</sup> dose n<sup>*</sup> | 257                             | 257            |
| GM titer<sup>b</sup>  | 712,284                          | 306,816        |
| (95% CI)<sup>c</sup> | (577,541-878,464)                | (247,479-380,379) |
| GMFR                | 30                               | 34             |
| (95% CI)<sup>c</sup> | (24-37)                          | (27-43)        |
| Seroresponse rate<sup>d</sup> | 243/257 (95)                     | 244/257 (95)   |
| n/N1 (%)<sup>e</sup> | 243/257 (95)                     | 244/257 (95)   |
| (95% CI)<sup>f</sup> | 91-97 (98-100)                   | (92-97)        |

Supplementary Table 4 Legend: GM=geometric mean, CI=confidence interval, GMFR=geometric mean fold rise.

<sup>a</sup>Number of participants with non-missing data at the timepoint (baseline or post-baseline).

<sup>b</sup>AU/mL.

<sup>c</sup>The 95% CI was calculated based on the t-distribution of the log-transformed values or the difference in the log-transformed values for GM value or GM fold-rise, respectively, then back transformed to the original scale for presentation.

<sup>d</sup>Seroresponse at a participant level was defined as a change from below the LLOQ to equal or above 4 x LLOQ if the baseline was below the LLOQ, or at least a 4-fold rise if the baseline was equal to or above the LLOQ. The number of participants meeting the criterion at the time point. Percentages are based on N1.

<sup>e</sup>The 95% CI was calculated using the Clopper-Pearson method.