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Moderna's COVID-19 vaccine shows positive interim Ph 1 results

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mRNA-1273 provided full protection against viral replication in the lungs in a mouse challenge model

US based Moderna, Inc., a clinical-stage biotechnology company pioneering messenger RNA (mRNA) therapeutics and vaccines to create a new generation of transformative medicines for patients, has announced positive interim clinical data of mRNA-1273, its vaccine candidate against novel coronavirus (SARS-CoV-2), from the Phase 1 study led by the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH).

Immunogenicity data are currently available for the 25 µg and 100 µg dose level (ages 18-55) after two doses (day 43) and at the 250 µg level (ages 18-55) after one dose (day 29). Dose dependent increases in immunogenicity were seen across the three dose levels, and between prime and boost within the 25 µg and 100 µg dose levels. All participants ages 18-55 (n=15 per cohort) across all three dose levels seroconverted by day 15 after a single dose. At day 43, two weeks following the second dose, at the 25 µg dose level (n=15), levels of binding antibodies were at the levels seen in convalescent sera (blood samples from people who have recovered from COVID-19) tested in the same assay. At day 43, at the 100 µg dose level (n=10), levels of binding antibodies significantly exceeded the levels seen in convalescent sera. Samples are not yet available for remaining participants.

At this time, neutralizing antibody data are available only for the first four participants in each of the 25 µg and 100 µg dose level cohorts. Consistent with the binding antibody data, mRNA-1273 vaccination elicited neutralizing antibodies in all eight of these participants, as measured by plaque reduction neutralization (PRNT) assays against live SARS-CoV-2. The levels of neutralizing antibodies at day 43 were at or above levels generally seen in convalescent sera.

mRNA-1273 was generally safe and well tolerated, with a safety profile consistent with that seen in prior Moderna infectious disease vaccine clinical studies.

Preclinical results from a viral challenge study in mice conducted in collaboration with NIAID and its academic partners are also available. In this study, vaccination with mRNA-1273 prevented viral replication in the lungs of animals challenged with SARS-CoV-2. Neutralizing titers in Phase 1 clinical trial participants at the 25 µg and 100 µg dose levels were consistent with

neutralizing titers that were protective in the mouse challenge model.

Based on the interim Phase 1 data, the Moderna-led Phase 2 study will be amended to study two dose levels, 50 µg and 100 µg, with the aim of selecting a dose for pivotal studies. The NIAID-led Phase 1 study is being amended to include a 50 µg dose level cohort across each of the three age groups. Moderna anticipates the dose for the Phase 3 study to be between 25 µg and 100 µg and expects Phase 3 trial initiation in July, subject to finalization of the clinical trial protocol.

“These interim Phase 1 data, while early, demonstrate that vaccination with mRNA-1273 elicits an immune response of the magnitude caused by natural infection starting with a dose as low as 25 µg,” said Tal Zaks, M.D., Ph.D., Chief Medical Officer at Moderna. “When combined with the success in preventing viral replication in the lungs of a pre-clinical challenge model at a dose that elicited similar levels of neutralizing antibodies, these data substantiate our belief that mRNA-1273 has the potential to prevent COVID-19 disease and advance our ability to select a dose for pivotal trials.”