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Moderna finalizing protocol for Ph 3 study of COVID-19 vaccine

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Announces First Participants in Each Age Cohort Dosed in Phase 2 Study of mRNA Vaccine

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 that the first participants in each age cohort have been dosed in the Company's Phase 2 study of its mRNA vaccine candidate (mRNA-1273) against the novel coronavirus (SARS-CoV-2).

This Phase 2 study, being conducted by Moderna under its own Investigational New Drug (IND) application, will evaluate the safety, reactogenicity and immunogenicity of two vaccinations of mRNA-1273 given 28 days apart.

The Company intends to enroll 600 healthy participants across two cohorts of adults ages 18-55 years (n=300) and older adults ages 55 years and above (n=300). Each participant will be assigned to receive placebo, a 50 ?g or a 100 ?g dose at both vaccinations. Participants will be followed through 12 months after the second vaccination. Given the 25 ?g and 100 ?g dose levels in the Phase 1 study showed neutralizing antibody titers at or above convalescent sera and were generally well tolerated, the Company has decided not to pursue the 250 ?g dose level in the Phase 2 study.

On May 6, the U.S. Food and Drug Administration (FDA) completed its review of the Company's Investigational New Drug (IND) application for mRNA-1273 and on May 12, the FDA granted it Fast Track designation. On May 18, Moderna announced initial data from the Phase 1 study of mRNA-1273 led by the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH). The NIH will be submitting the Phase 1 data to a peer-reviewed clinical publication. Moderna anticipates collaborating with NIAID to implement the Phase 3 study. The dose for the Phase 3 study is expected to be between 25 µg and 100 µg and expects Phase 3 trial initiation in July, subject to finalization of the clinical trial protocol.

Funding from the Biomedical Advanced Research and Development Authority (BARDA), a division of the Office of the Assistant Secretary for Preparedness and Response (ASPR) within the U.S. Department of Health and Human Services (HHS), supported the planning for these studies and will also support the late-stage clinical development programs, as well as the scale-up of mRNA-1273 manufacturing both at the Company's facilities and that of its strategic collaborator, Lonza Ltd.