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Moderna begins Ph 1 study for COVID-19 vaccine

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Announces First Participant Dosed in NIH-led Phase 1 Study of mRNA Vaccine (mRNA-1273) Against Novel Coronavirus



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 participant has been dosed in the Phase 1 study of the Company's mRNA vaccine (mRNA-1273) against the novel coronavirus (SARS-CoV-2). This Phase 1 study is being conducted by the National Institutes of Health (NIH) under its own Investigational New Drug (IND) application.

mRNA-1273 is an mRNA vaccine against SARS-CoV-2 encoding for a prefusion stabilized form of the Spike (S) protein, which was selected by Moderna in collaboration with investigators from the Vaccine Research Center (VRC) at the National Institute of Allergy and Infectious Diseases (NIAID), a part of NIH. Manufacture of the first clinical batch was funded by the Coalition for Epidemic Preparedness Innovations (CEPI).

The Phase 1 study is evaluating the safety and immunogenicity of three dose levels of mRNA-1273 (25, 100, 250 ?g) administered on a two-dose vaccination schedule, given 28 days apart. A total of 45 healthy adults will be enrolled in the study. Participants will be followed through 12 months after the second vaccination. The primary objective is to evaluate the safety and reactogenicity of a two-dose vaccination schedule of mRNA-1273. The secondary objective is to evaluate the immunogenicity to the SARS-CoV-2 S protein.

The Company is actively preparing for a potential Phase 2 study under its own IND to build on data from the ongoing Phase 1 study being conducted by the NIH. In order to continue to progress this potential vaccine during the ongoing global public health emergency, Moderna intends to work with the FDA and other government and non-government organizations to be ready for a Phase 2 and any subsequent trials.