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Moderna's COVID-19 vaccine enters Ph 2 trial

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Moderna receives FDA fast track designation for mRNA Vaccine (mRNA-1273) against Novel Coronavirus SARS-CoV-2

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, on 12 May 2020 announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation for the Company's mRNA vaccine candidate (mRNA-1273) against the novel coronavirus (SARS-CoV-2).

"Fast Track designation underscores the urgent need for a vaccine against the novel coronavirus," said Tal Zaks, M.D., Ph.D., Chief Medical Officer at Moderna. "As we await the full set of clinical data from the NIAID-led Phase 1 study, we are actively preparing for our Phase 2 and Phase 3 clinical studies to continue learning about the potential of mRNA-1273 to protect against SARS-CoV-2."

Fast Track is designed to facilitate the development and expedite the review of therapies and vaccines for serious conditions and fill an unmet medical need. Programs with Fast Track designation may benefit from early and frequent communication with the FDA, in addition to a rolling submission of the marketing application.

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 allowing it to proceed to a Phase 2 study, which is expected to begin shortly. Moderna is finalizing the protocol for a Phase 3 study, expected to begin in early summer of 2020.

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 Vaccine Research Center (VRC) at the National Institute of Allergy and Infectious Diseases (NIAID), a part of the NIH. The first clinical batch, which was funded by CEPI, was completed on February 7, 2020 and underwent analytical testing; it was shipped to NIH on February 24, 42 days from sequence selection. The first participant in the NIAID-led Phase 1 study of mRNA-1273 was dosed on March 16, 63 days from sequence selection to Phase 1 study dosing.