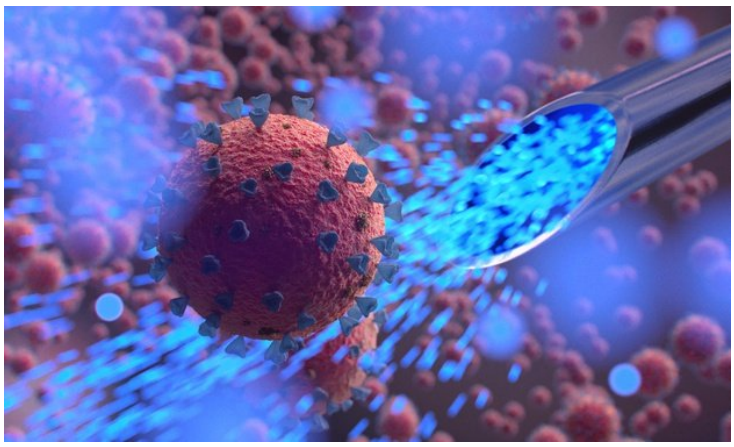
BioSpectrum
the business of Bio & Health Sciences
ASIA EDITION

Moderna advances Late-Stage development of mRNA-1273 Vaccine against COVID-19

June 12, 2020 | News

Phase 3 study of 30,000 subjects expected to begin in July 2020 at 100 Ã?Â¼g dose level



Moderna, Inc. announced on 11 June 2020 about progress on the late-stage development of mRNA-1273, the Company's mRNA vaccine candidate against COVID-19.

Moderna has finalized the Phase 3 study protocol based on feedback from the U.S. FDA. The randomized, 1:1 placebo-controlled trial is expected to include approximately 30,000 participants enrolled in the U.S. and is expected to be conducted in collaboration with the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH). The trial's primary endpoint will be the prevention of symptomatic COVID-19 disease; key secondary endpoints include prevention of severe COVID-19 disease and prevention of infection by SARS-CoV-2. Moderna has completed manufacture of vaccine required to start the Phase 3 study. The Company expects dosing in the Phase 3 study to begin in July.

With the Phase 3 dose being finalized at 100 ?g, the Company remains on track to be able to deliver approximately 500 million doses per year, and possibly up to 1 billion doses per year, beginning in 2021 from the Company's internal U.S. manufacturing site and strategic collaboration with Lonza.

"We look forward to beginning our Phase 3 study of mRNA-1273 with some 30,000 participants in July," said Tal Zaks, M.D., Ph.D., Chief Medical Officer at Moderna. "Moderna is committed to advancing the clinical development of mRNA-1273 as safely and quickly as possible to demonstrate our vaccine's ability to significantly reduce the risk of COVID-19 disease."

On May 6, the U.S. FDA completed its review of the Company's Investigational New Drug (IND) application for mRNA-1273 and on May 11, the FDA granted it Fast Track designation. On May 18, Moderna announced initial data from the Phase 1 study of mRNA-1273 led by NIAID. The Phase 1 study is ongoing with the original cohorts in long-term follow-up and enrollment in 9 of 12 cohorts complete. The NIH will be submitting the Phase 1 data to a peer-reviewed clinical publication.