Moderna Runs First Human Trial for Coronavirus Vaccine

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Moderna, Inc., a USA-based biotechnology company specializing in messenger RNA therapeutics, announced that its much-awaited mRNA-based vaccine candidate (mRNA-1273) against the novel coronavirus disease (COVID-19) has just entered Phase 1 study, under the Investigational New Drug (IND) application of the National Institutes of Health (NIH). In this technology, the stretch of RNA which is required for preparing the vaccine is first synthesized and then embedded in lipid nanoparticles.

Moderna, Inc., a clinical stage biotechnology company pioneering messenger RNA (mRNA) therapeutics and vaccines to create a new generation of transformative medicines for patients, today 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).

Nanotechnology in Battle Against Coronavirus ...

The Phase 1 study is evaluating the safety and immunogenicity of three dose levels of mRNA-1273 (25, 100, 250 µg) 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.

“This study is the first step in the clinical development of an mRNA vaccine against SARS-CoV-2, and we expect it to provide important information about safety and immunogenicity. We are actively preparing for a potential Phase 2 study under our own IND,” said Tal Zaks, M.D., Ph.D., Chief Medical Officer at Moderna. “We are grateful to NIH for their ongoing collaboration and to CEPI for funding the initial manufacturing of mRNA-1273 and are proud to be included with the many companies, worldwide health agencies and NGOs working on a possible response to the novel coronavirus outbreak.”

On January 11, 2020, the Chinese authorities shared the genetic sequence of the novel coronavirus. On January 13, 2020 the VRC and Moderna’s infectious disease research team finalized the sequence for the SARS-CoV-2 vaccine and Moderna mobilized toward clinical manufacture. The first clinical batch was completed on February 7, 2020 and underwent analytical testing; it was shipped on February 24, 2020 from Moderna and delivered to NIH from the Company’s manufacturing facility in 42 days from sequence selection.

In 2019, Moderna, Inc., and Harvard University entered into a multi-year research collaboration to develop novel therapeutic approaches, namely mRNA technologies, for use in the treatment of immunological diseases. Additional funding from Moderna to Harvard Medical School (HMS) has established an initiative at HMS called the Alliance for RNA Therapies for the Modulation of the Immune System (ARTiMIS), which enabled basic science research in the field of immunology using Moderna’s mRNA and nanoparticle delivery technology. The mRNA technology commonly includes such carriers as cell penetrating peptides and various nanoparticles, and taking this collaboration between Moderna and Harvard University into account, the recently developed vaccine possibly employs nanoparticles-based drug release approaches.

Next Steps for mRNA-1273

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, which are anticipated to include a larger number of subjects and which will seek to generate additional safety and immunogenicity data. Manufacture of the mRNA-1273 material for the potential Phase 2 trial, which could begin in a few months, is underway. Moderna continues to prepare for rapid acceleration of its manufacturing capabilities that could allow for the future manufacture of millions of doses should mRNA-1273 prove to be safe and effective.

Source

- Moderna Announces First Participant Dosed in NIH-led Phase 1 Study of mRNA Vaccine (mRNA-1273) Against Novel Coronavirus
- Moderna's Work on a Potential Vaccine Against COVID-19
- A Nanotechnology Research Collaboration between Harvard University and Moderna