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Moderna inks pact with Lonza to manufacture COVID-19 vaccine

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Collaboration goal to enable manufacturing of up to 1 billion doses per year

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, and Lonza Ltd. have announced a 10-year strategic collaboration agreement to enable larger scale manufacture of Moderna's mRNA vaccine (mRNA-1273) against the novel coronavirus (SARS-CoV-2) and additional Moderna products in the future.

Under the terms of the agreement, the companies plan to establish manufacturing suites at Lonza's facilities in the United States and Switzerland for the manufacture of mRNA-1273 at both sites. Technology transfer is expected to begin in June 2020, and the companies intend to manufacture the first batches of mRNA-1273 at Lonza U.S. in July 2020.

Over time, the parties intend to establish additional production suites across Lonza's worldwide facilities, ultimately allowing for the manufacture of material equivalent to up to 1 billion doses of mRNA-1273 per year for use worldwide assuming the currently expected dose of 50 µg. The manufacturing facilities at Lonza complement Moderna's ongoing U.S. manufacturing efforts, which continue to ramp up to prepare for the further clinical development and commercialization of mRNA-1273.

On April 27, 2020, Moderna announced that it submitted an Investigational New Drug (IND) application to the U.S. Food and Drug Administration (FDA) for Phase 2 and late stage studies of mRNA-1273 if supported by safety data from the Phase 1 study.

Moderna has received initial feedback from the FDA on the design of the planned Phase 2 study, which is expected to begin in the second quarter of 2020. This study will evaluate the safety, reactogenicity and immunogenicity of two vaccinations of mRNA-1273 given 28 days apart. Each subject will be assigned to receive placebo, a 50 ?g or a 250 ?g dose at both vaccinations. 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). Participants will be followed through 12 months after the second vaccination.