

Novavax, Fujifilm to manufacture COVID-19 vaccine at large scale

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US based Novavax, Inc., a late-stage biotechnology company developing next-generation vaccines for serious infectious diseases, and FUJIFILM Diosynth Biotechnologies (FDB), a partnership between Japan based FUJIFILM Corporation and Mitsubishi Corporation, have announced an agreement to manufacture bulk drug substance for NVX-CoV2373, Novavax' COVID-19 vaccine candidate. FDB's site in Morrisville, North Carolina has begun production of the first batch of NVX-CoV2373.

This arrangement falls under Novavax' recent \$1.6 billion award by the federal government as part of Operation Warp Speed (OWS), a U.S. government program that aims to begin delivering millions of doses of a safe, effective vaccine for COVID-19 to the U.S. population.

The OWS funding is being used by Novavax to complete late-stage clinical development, including a pivotal Phase 3 clinical trial; establish large-scale manufacturing; and deliver 100 million doses of NVX CoV2373 beginning as early as late 2020.

NVX-CoV2373 consists of a stable, prefusion protein made using Novavax' proprietary nanoparticle technology and includes Novavax' proprietary Matrix M™ adjuvant.

The batches produced at the FDB site in North Carolina will be utilized in a future pivotal Phase 3 clinical trial of up to 30,000 subjects which is expected to begin in the fall of 2020 and which will determine the safety and efficacy of NVX-CoV2373.