# GUIDE TO THE CORONAVIRUS DRUG PIPELINE:

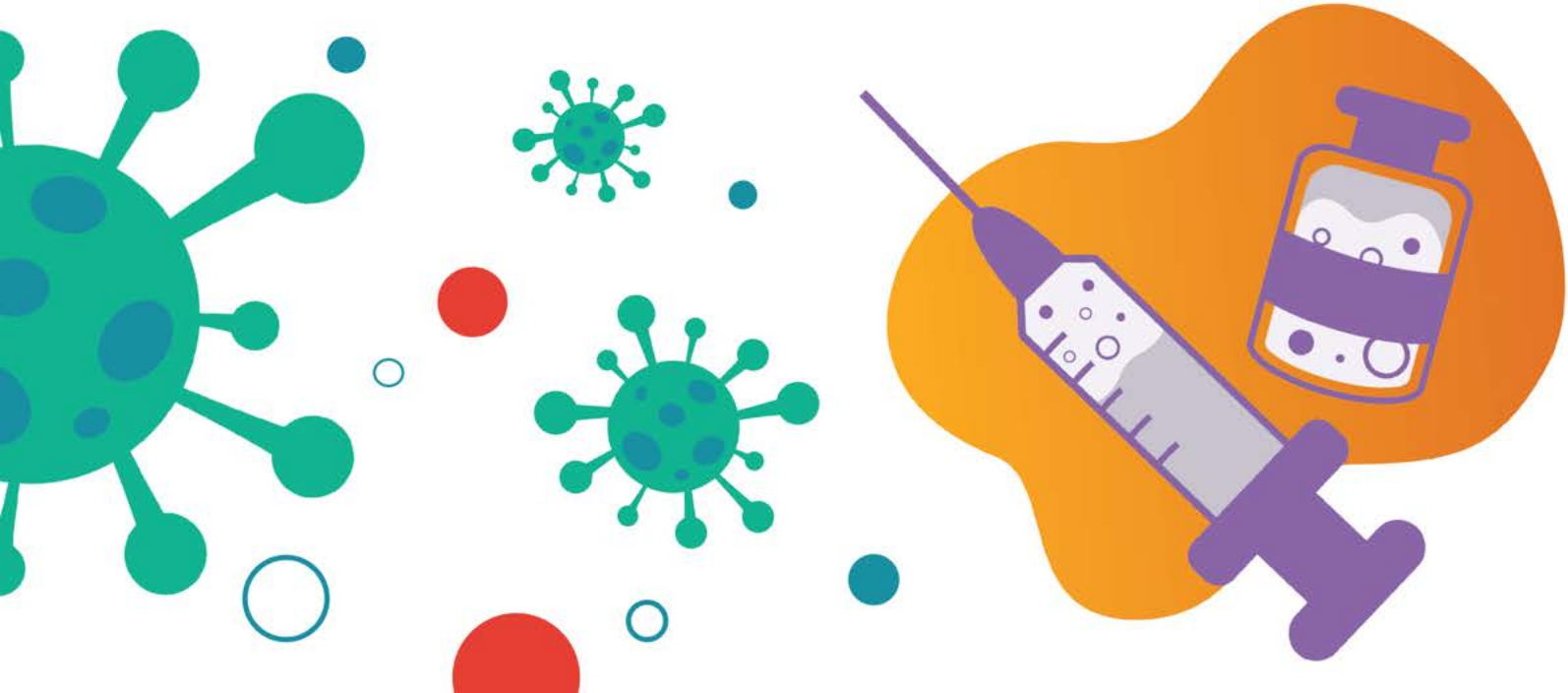
## The Latest On Treatment and Vaccine Trials

# Coronavirus Pandemic:

## Updates on vaccines in the pipelines of leading pharmaceutical companies

Since the World Health Organization (WHO) declared the coronavirus a pandemic in March 2020, hundreds of trials began to understand the disease, find viable treatments and vaccines to protect the public. The Food and Drug Administration (FDA) created a special emergency program for possible coronavirus therapies, the Coronavirus Treatment Acceleration Program (CTAP). The program is designed to move new treatments to patients quickly while studying if it is helpful or harmful. As of Sept. 30, 2020, five COVID-19 treatments were authorized for emergency use by the FDA. In October, the FDA issued guidance on an emergency use authorization for COVID-19 vaccines. There are 44 candidate vaccines in clinical evaluation as of Oct. 19, 2020, according to the WHO.

In our previous Guide to the Coronavirus Drug Pipeline, we identified nine potential vaccine and treatment candidates dating from January to March of 2020. The list included Moderna Therapeutics, Altimmune, Inc. Inovio Pharmaceuticals, Novavax, Tonix Pharmaceuticals, Johnson & Johnson, and Gilead Sciences. This guide will provide an update of those vaccines and treatments previously mentioned.



# UPDATES:

## Moderna Therapeutics

In February, Moderna announced the release of the mRNA-1273 vaccine in hopes of combatting COVID-19. By July 27, the biotechnology company said Phase 3 of the study began dosing participants. The Phase 3 study includes approximately 30,000 participants in the United States. The study is being conducted in collaboration with the National Institute of Allergy and Infectious Diseases, part of the National Institutes of Health and the Biomedical Advanced Research and Development Authority, part of the Office of the Assistant Secretary for Preparedness and Response at the U.S. Department of Health and Human Services. The CEO of Moderna told CNBC that it could have enough data from the late-stage trial by October or November to evaluate its efficacy.

## Altimmune, Inc

Altimmune, Inc, said in an October press release that it anticipates filing an Investigational New Drug (IND) application with the FDA and beginning a Phase 1 safety and immunogenicity trial of AdCOVID in the fourth quarter of this year. Altimmune said AdCOVID is a single-dose, intranasal vaccine candidate designed to protect against COVID-19. The company is following the same platform vaccine technology as its more developed vaccine, known as NasoVax.

## INOVIO Pharmaceuticals

In September, INOVIO Pharmaceuticals announced its Phase 2/ 3 trial is on hold due to questions from the FDA. The company said it "is actively working to address the FDA's questions and plans to respond in October, after which the FDA will have up to 30 days to notify INOVIO of its decision as to whether the trial may proceed." The company also said the partial hold is not due to the occurrence of any adverse events related to INOVIO's ongoing expanded Phase 1 study of its vaccine, INO-4800.

## Novavax

Novavax announced that it has initiated its first Phase 3 study for NVX-CoV2373, a COVID-19 vaccine, at the end of September. The trial is taking place in the United Kingdom and is expected to immunize 10,000 participants. Novavax described the vaccine as a stable, perfusion protein made using the company's recombinant protein nanoparticle technology that includes Novavax's proprietary Matrix-M.

## Tonix Pharmaceuticals

Tonix Pharmaceuticals is developing potential COVID-19 vaccines. According to a recent press release, the company said four potential vaccines in development are based on the horsepox vector and two potential vaccines are based on the bovine parainfluenza vector. Tonix Pharmaceuticals said before the end of 2020 it expects to report results from an efficacy study of TNX-1800, a lead vaccine candidate for the company.

## Johnson & Johnson

Johnson & Johnson announced in October that it temporarily paused further dosing in all COVID-19 vaccine candidate clinical trials because of unexplained illness in a study participant. Previously, Johnson & Johnson announced the launch of its Phase 3 trial, ENSEMBLE, for its COVID-19 vaccine JNJ-78436735. The vaccine is being developed by Janssen Pharmaceutical Companies.

## Gilead Sciences

Gilead Sciences received approval from the U.S. FDA to use remdesivir for treatment of hospitalized COVID-19 patients, the company announced on Oct. 22. The antiviral drug "works to stop replication of SARS-CoV-2, the virus that causes COVID-19," the company said in a press release. Remdesivir was previously authorized for emergency use to treat COVID-19 but it is now the first and only approved treatment in the U.S. Approximately 50 countries have approved or authorized the temporary use of remdesivir.

## Sanofi, GSK & BARDA

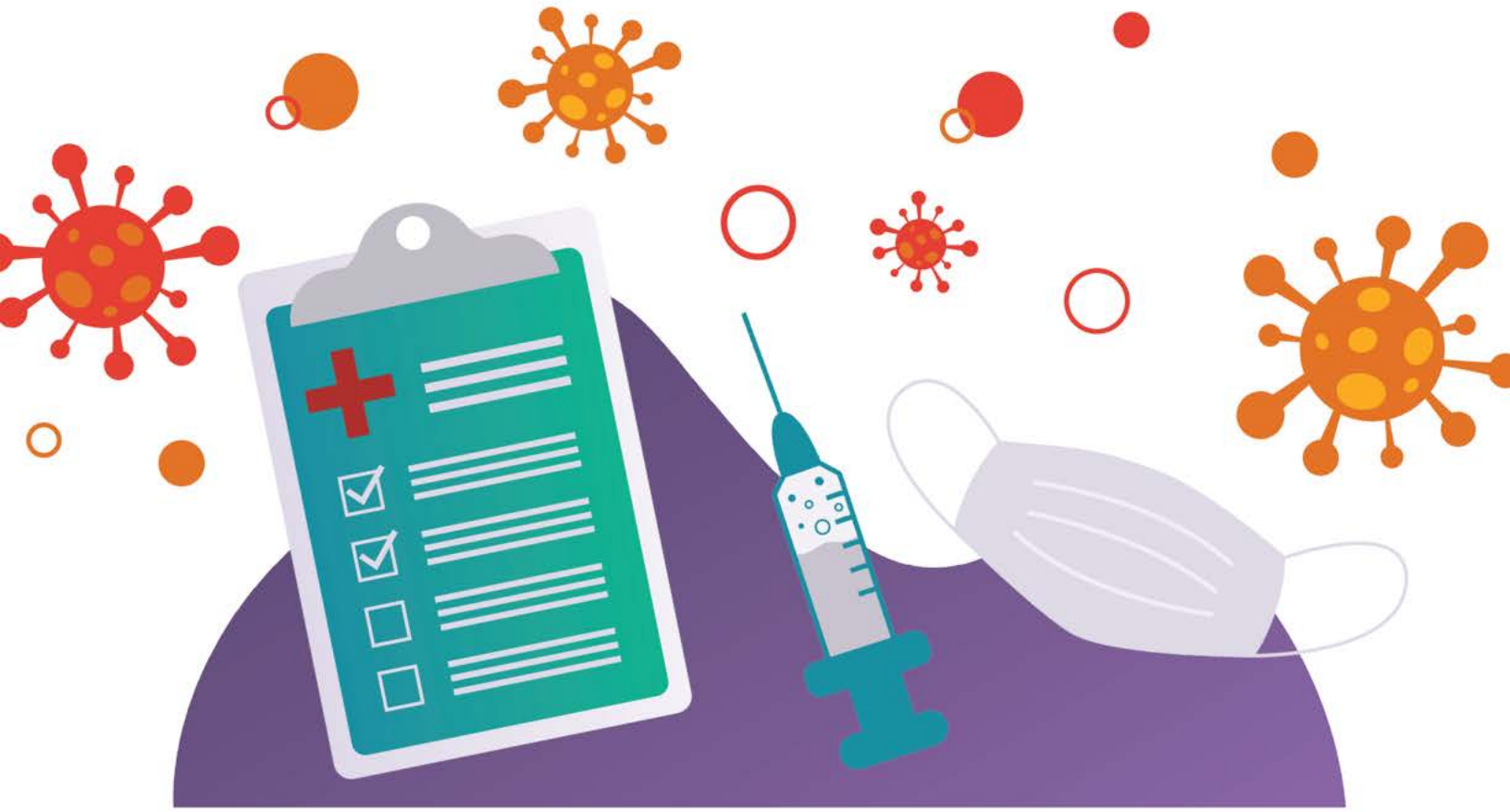
Sanofi and GSK started the Phase 1/ 2 clinical trial for their adjuvanted COVID-19 vaccine, according to a press release issued in September of this year. Sanofi and GSK partnered together to develop the vaccine using the same recombinant protein-based technology as one of Sanofi's seasonal influenza vaccines with GSK's established pandemic adjuvant technology. The development of the vaccine is supported through funding and collaboration with the Biomedical Advanced Research and Development Authority (BARDA). Sanofi and GSK said they anticipate the first results of the trial in early December 2020, supporting the initiation of a Phase 3 trial in December this year. The companies would seek regulatory approval in the first half of 2021 if data is sufficient.

## Algernon Pharmaceuticals

Algernon Pharmaceuticals announced in September it enrolled 75 patients for its multinational Phase 2b/3 human trial of NP-120 (Ifenprodil), a potential treatment for coronavirus. The company said Ifenprodil is a drug they have been investigating for repurposing as a candidate treatment for idiopathic pulmonary fibrosis, acute lung injury and chronic cough. Ifenprodil is a generic drug developed by Sanofi in the 1970s. Algernon Pharmaceuticals said they hope Ifenprodil "may offer a new and efficacious treatment option that limits inflammatory infiltrates and the resulting fibrotic responses."

## Vaxart

In mid-October, Vaxart announced its first subject was dosed in the Phase 1 study of its oral tablet vaccine candidate, VXA-CoV2-1. The Phase 1 trial will examine the safety and immunogenicity of two doses of the vaccine and up to 48 healthy adult volunteers. The company said enrollment is expected to be complete by early November of this year, and assessments will be performed at set times. The CEO of Vaxart said they "are looking forward to receiving the first clinical data in the next few weeks."



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San Francisco
Las Vegas

800-987-6007
contact@clincapture.com
www.clincapture.com