COVID-19

The latest drug and vaccine innovations to counter this deadly virus.

The rapidly moving target of the coronavirus is challenging the best of the world's life-sciences innovators, and the landscape changes not only by the day but by the hour. At press time for this issue, these are the most current efforts being made across the industry that show promise for treating and preventing the disease.

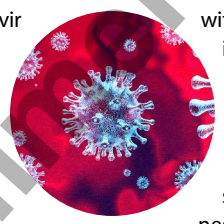
Antiviral Efforts

University of Minnesota

One of the more unprecedented approaches to a clinical trial for an antiviral study comes from the University of Minnesota. At press time, researchers were attempting a virtual post-exposure prophylaxis study of 1,500 healthcare workers who may have been exposed to COVID-19. Study participants are asked to sign up online and the malaria treatment drug hydroxychloroquine is delivered to their door. University of Minnesota is also testing the blood pressure drug losartan. President Donald Trump ordered the FDA to fast-track these two drugs to treat COVID-19.

Gilead Sciences

Next up is remdesivir, the Gilead antiviral, discovered during the 2014 Ebola outbreak. This antiviral has the most traction of all with four clinical trials in Phase III – two in China and two in the United States. Gilead has worked with the FDA to identify pathways to study remdesivir under investigational new drug requirements while simultaneously providing the drug to patients under emergency authorization. In February, the NIH launched a randomized controlled trial to evaluate the drug.



Sanofi

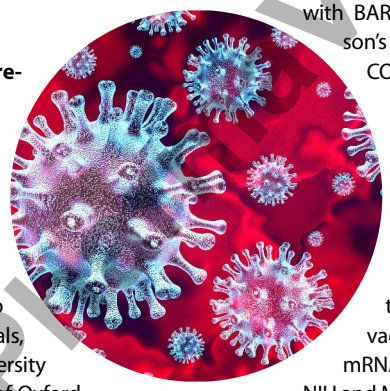
Regeneron Pharmaceuticals and Sanofi are planning an international study trial for the rheumatoid arthritis drug Kevzara to be used in patients infected with coronavirus and suffering from acute respiratory distress syndrome. The trial will start in New York City and expand to a total of 16 U.S. sites, enrolling a total of 400 patients. The companies will study whether Kevzara can reduce fever and the need for supplemental oxygen in patients severely affected by COVID-19.

Takeda

Takeda Pharmaceutical is betting its blood plasma-derived therapy in development will be among the first approved treatments for the deadly pathogen. The treatment involves a process that already has approval from regulators, giving the company a leg up.

The process to manufacture the therapy, using antibodies from recovered patients, is the same as Takeda's other immunoglobulin products, which have approval from regulatory bodies around the world including the FDA.

Vaccines



Coalition for Epidemic Preparedness Innovations

CEPI, the Coalition for Epidemic Preparedness Innovations, at press time had eight COVID-19 vaccine candidates in line through various partnerships. CEPI has provided initial funding to Curevac, Inovio Pharmaceuticals, Moderna, Novavax, The University of Hong Kong, The University of Oxford, The University of Queensland, and the Institut Pasteur-led consortium that includes Themis and the University of Pittsburgh.

These collaborations bring CEPI's total investment in COVID-19 vaccine R&D to $29.2 million.

GlaxoSmithKline

GlaxoSmithKline is a major global supplier of vaccines, but for the coronavirus it is teaming up with others to use its adjuvant technology in combination with vaccines.

Chinese biotech Clover Biopharmaceuticals has joined with GlaxoSmithKline to develop a protein-based vaccine. Clover had already begun designing a vaccine last month after Chinese researchers published the genetic sequence of the novel coronavirus, now known as SARS-CoV-2. GSK is also partnering with the Coalition for Epidemic Preparedness Innovations.

Inovio

Inovio is fast tracking the development of a COVID-19 vaccine, with Phase 1 human trials involving up to 50 healthy people set to begin in April in the U.S. The biotech has received a $5 million grant from the Bill & Melinda Gates Foundation to scale up testing and production of its portable device to deliver a DNA-based COVID-19 vaccine. Inovio's San Diego Device Manufacturing facility will build the initial number of the proprietary vaccine delivery devices — as well as demonstrate how to manufacture them in larger numbers. Work on the vaccine, which was created in Inovio's San Diego lab, is being funded through a $9 million grant from the Coalition for Epidemic Preparedness Innovations, or CEPI.

Johnson & Johnson

Johnson & Johnson is pursuing the development of both antivirals and vaccines to address the needs of those encountering the coronavirus. Janssen Pharmaceutical and the Biomedical Advanced Research and Development Authority (BARDA) have partnered to develop treatment solutions for COVID-19. These efforts, in addition to the ongoing development of a potential vaccine candidate with BARDA, build on Johnson & Johnson's multipronged response to the COVID-19 outbreak.

Moderna

The first potential vaccine, developed by Moderna Therapeutics, went from a lab experiment to human trials in less than three months, a process that commonly takes years. This vaccine candidate, code-named mRNA-1273, was developed by the NIH and Massachusetts-based biotechnology company Moderna Inc.

A Phase I clinical trial has begun at Kaiser Permanente Washington Health Research Institute (KPWHRI) in Seattle. The National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health, is funding the trial. KPWHRI is part of NIAID's Infectious Diseases Clinical Research Consortium. The first participant has already received the investigational vaccine.

Pfizer

Pfizer is partnering with German firm BioNTech to accelerate development of BioNTech's potential first-in-class COVID-19 mRNA vaccine program, BNT162, which is expected to enter clinical testing by the end of April 2020. The rapid advancement of this collaboration stems from the R&D collaboration the two companies entered into in 2018 to develop mRNA-based vaccines for influenza. The companies expect to utilize multiple research and development sites from both companies, including in the United States and Germany, to house the activities identified by the collaboration agreement.

Roche

Roche's Actemra has led to a decrease in fever and oxygen use when tested in Chinese patients. China approved its use in patients with lung complications and high levels of interleukin-6, or IL-6, a protein that mediates inflammatory and immune response. Actemra is also approved in conjunction with cancer cell therapy. PV