

America's biopharmaceutical companies are committed to developing solutions to help diagnose, treat and prevent COVID-19, a disease caused by a novel strain of coronavirus that originated in Wuhan, China. The biopharmaceutical industry is uniquely positioned to respond rapidly to COVID-19 and has a long track record of developing solutions to combat a range of infectious diseases and bring deep

scientific expertise from decades of working with similar viruses such as MERS, SARS and influenza. Over the past several decades, PhRMA members have invested billions of dollars in building the advanced manufacturing infrastructure and developing critical technological advances that will allow us to accelerate the development of and quickly manufacture new vaccines and treatments for patients.

RESEARCHING AND DEVELOPING POTENTIAL VACCINES AND TREATMENTS

PhRMA members have been manufacturing thousands of doses of investigational and previously approved medicines that may have potential to treat coronavirus for emergency use and for use in clinical trials around the globe, including compounds formerly tested on other viral pathogens such as Ebola and HIV.

Several members are researching vaccine candidates for prevention and collaborating to share existing technologies that can be leveraged to allow rapid upscale of production once a vaccine candidate is identified. Members are also sharing

technologies that act as an adjuvant that can boost the effectiveness of a potential vaccine.

Across PhRMA's membership, companies are undertaking inventories of existing research portfolio libraries to identify additional potential treatments for investigation and emergency use as well as identifying, manufacturing and donating approved investigational medicines.

Here is a snapshot and a few detailed examples of the types of efforts under way by PhRMA member companies to combat COVID-19.¹

GILEAD

Gilead is supporting phase II and III clinical trials in the U.S., China and other countries with high prevalence of COVID-19 to rapidly evaluate the safety and efficacy of its investigational compound remdesivir as a potential treatment. The company is working with government and non-government organizations and regulatory authorities on these clinical trials as well as on the provision of remdesivir for compassionate use for qualifying cases of confirmed, severe COVID-19 infection in the absence of local clinical trial sites. While the studies to determine the efficacy and safety of remdesivir are ongoing, Gilead has accelerated manufacturing at risk to increase available supply of remdesivir as rapidly as possible, in anticipation of potential future needs.

JOHNSON & JOHNSON

Johnson & Johnson began work on the search for vaccines and therapies in early January 2020, when the viral sequence became publicly available. The company's vaccine program leverages the Janssen AdVac[®] and PER.C6[®] technologies that provide the ability to rapidly upscale production of the optimal vaccine candidate. These are the same technologies that were used in the development and manufacturing of their investigational Ebola vaccine, which is currently deployed in the Democratic Republic of the Congo (DRC) and Rwanda, and were also used to construct our Zika, RSV and HIV vaccine candidates. To accelerate and upscale this effort, Johnson & Johnson expanded its collaboration with the Biomedical Advanced Research and Development Authority (BARDA), part of the U.S. Department of Health & Human Services (HHS).

**SANOFI
PASTEUR**

Sanofi Pasteur, the vaccines global business unit of Sanofi, will leverage previous development work for a SARS vaccine which may unlock a fast path forward for developing a COVID-19 vaccine. Sanofi is collaborating with BARDA, expanding the company's long-standing partnership with the Authority. Sanofi will use its recombinant DNA platform to produce a novel coronavirus vaccine candidate.

MEDICINES IN DEVELOPMENT FOR COVID-19

The chart below provides a snapshot of the potential medicines in development to address COVID-19 based on an analysis of publicly available data from press releases, clinicaltrials.gov and AdisInsight database, as of March 4, 2020.

Because the COVID-19 strand did not exist prior to December 2019, the vaccines in development for this specific strain of coronavirus are in early phases of research. This is because to develop vaccines, the COVID-19 virus first needed to be sequenced, and this was able to be completed by scientists only one month after it had been discovered. Biopharmaceutical companies hope to see this early vaccine research progress to human clinical trials as soon as possible.

While vaccines and small molecule treatments are approved through different regulatory pathways and their development programs vary, they generally both must complete three phases of clinical trials. However, there are differences in the

data required to show the safety of vaccines and the size of clinical trials for vaccines relative to small molecules.

While experts have publicly predicted it will take at least 12 to 18 months before there is a vaccine available, it is important to note that this is a best case estimate that assumes one or two of the first few vaccines that enter development will be successful. Typically, only approximately one in ten experimental vaccines make it all the way through to U.S. Food and Drug Administration (FDA) approval. This is one of the reasons it is important that a variety of companies are taking different approaches to find a vaccine; more "shots on goal" will significantly increase the chances of success.

There currently are companies working on phase I studies for both vaccines and treatments, and one potential treatment that was already tested for another disease is now in Phase III clinical trials. Potential treatments include both antiviral medicines and immunotherapies.

"We always need a pharmaceutical partner. I can't think of a vaccine, even one in which we've put substantial intellectual and resource input, that was brought to the goal line without a partnership with industry. So this is a very natural process that we're doing right now.... I have not seen in my experience situations in which we were involved in the development of a vaccine, particularly for low- and middle-income countries that really needed it, where the pharmaceutical companies priced it out of their reach."

— NIAID Director Anthony Fauci²

According to an analysis of the AdisInsight Database, many of the medicines in development for the specific strand of coronavirus, COVID-19, are in early research phases. To better demonstrate the full portfolio of research that may be effective at preventing or treating COVID-19 we evaluated all medicines that are in development for coronavirus broadly, including those in development for MERS and SARS, which share similar structural characteristics and have the potential to be applicable to COVID-19.

According to an analysis of Clinicaltrials.gov there are hundreds of clinical trials for experimental new treatments and vaccines in development for coronaviruses including COVID-19, Novel Coronavirus Pneumonia, SARS and MERS.

BIOPHARMACEUTICAL INDUSTRIES' LESSONS LEARNED FROM PAST PUBLIC HEALTH EMERGENCIES

Up until the outbreak began, the COVID-19, a disease caused by a novel strain of coronavirus did not exist. The rapid pace at which researchers have been able to understand this strain and get medicines into human clinical trials is a testament to the lessons learned from past public health emergencies.

"The global response to the Ebola virus threat is a case study for what science, partnership and trust in one another as global citizens can accomplish. The collaboration that made progress against Ebola virus disease possible is a shining example of what we are already seeing today with the response to the coronavirus outbreak and should be celebrated and emulated."

— *Dr. Julie Gerberding, M.D., M.P.H. of Merck & Co.*³

The biopharmaceutical industry is committed to developing solutions to address this global public health emergency just as it has in the past. PhRMA member companies not only bring decades of expertise in infectious diseases, including other strains of coronavirus, but bring the infrastructure and technologies to allow us to quickly advance potential vaccine and treatment candidates to clinical trials and have the manufacturing capabilities and expertise to allow for quick scale-up.

¹ https://clinicaltrials.gov/ct2/results?cond=Coronavirus&flds=aby&recrs=b&recrs=a&recrs=f&recrs=d&recrs=e&recrs=m&age_v=&gndr=&type=Intr&rslt=&fund=2&Search=Apply

² <https://www.rollcall.com/2020/02/27/vaccine-prices-a-flashpoint-in-coronavirus-funding-talks/>

³ <https://www.nytimes.com/2020/03/04/opinion/letters/merck-ebola-vaccine.html>