

America's biopharmaceutical companies are committed to developing solutions to help diagnose and treat those with COVID-19, a disease caused by a novel strain of coronavirus that originated in Wuhan, China. In addition to applying their scientific expertise to find ways to diagnose, treat and prevent infections from the virus, the biopharmaceutical industry is providing financial support and in-kind donations to organizations and collaborating with U.S., Chinese and global health authorities to combat this global public health emergency.

More than half of PhRMA members have R&D efforts underway or are providing donations of medicines and critical medical supplies as well as providing financial donations to support patients and first responders in addressing this evolving crisis.

## Here are just a few ways America's research-based biopharmaceutical companies are working to combat the novel coronavirus:



### DEVELOPING POTENTIAL NEW TREATMENTS AND VACCINES

As part of its commitment to finding solutions for patients with coronavirus and preventing others from becoming infected, PhRMA members have been donating investigational compounds that may have potential to treat coronavirus for emergency use and clinical trials, including compounds formerly tested on other viral pathogens such as Ebola and HIV. Other members are researching vaccine candidates for prevention and undertaking inventories of existing research portfolio libraries to identify additional potential treatments for research and development. Companies are also exploring ways to leverage existing technologies that provide the ability to rapidly upscale production once a potential vaccine candidate is identified.



### PARTNERSHIPS

PhRMA member companies are collaborating with relevant U.S. and global public health authorities including the U.S. Food and Drug Administration (FDA), National Institutes of Health (NIH) and Centers for Disease Control and Prevention (CDC), as well as the World Health Organization (WHO), China public health authorities including the Chinese Center for Disease Control and Prevention and the European Medicines Agency, among many others to address this public health crisis. These collaborations are focused on all areas of research and development, including evaluating how pandemic preparedness platforms can potentially be tailored to address the coronavirus emergency, leveraging existing R&D partnerships to accelerate development of antiviral agents against COVID-19 and contribute both resources and expertise to various R&D consortia to address the outbreak.



### MONETARY & IN-KIND SUPPORT

Millions of dollars of direct monetary and in-kind contributions are being used to support organizations at the heart of the crisis who are able to have an immediate impact for infected patients and communities in China. PhRMA member companies acted immediately on the ground in China to donate a variety of crucial supplies including advanced surgical equipment, antibiotics, disinfection equipment, batch virus testing devices (e.g., throat swabs), vitamins, protective clothing, goggles, masks, gloves and more.



### SUPPLY CHAIN INTEGRITY

As the situation evolves, PhRMA companies are continuing to prioritize the continuity of their supply chains and are working proactively to prevent and mitigate any potential shortages through close coordination with the FDA and other global stakeholders.

**Below is a snapshot of on-going PhRMA member company efforts to support the detection, prevention and treatment of the coronavirus outbreak. The below only represents a portion of the more than 50% of PhRMA's members who are engaged in this effort.**

## **ABBVIE**

The company is collaborating with select health authorities and institutions globally to determine antiviral activity as well as efficacy and safety of lopinavir/ritonavir against COVID-19. AbbVie is supporting clinical studies and basic research with lopinavir/ritonavir, working closely with European health authorities and the FDA, CDC, NIH and BARDA to coordinate on these efforts. Along with industry partners, the company has joined the Innovative Medicines Initiative to support research and discovery of targeted medicines against COVID-19. The company previously donated approximately \$2 million (USD) of Aluvia as an experimental option to help address the growing health crisis. AbbVie is also working with the WHO to ensure a coordinated global effort.

## **ASTRAZENECA**

Through its scientific expertise in infectious disease and proprietary antibody discovery technology, AstraZeneca has rapidly mobilized its research efforts to discovering novel coronavirus-neutralising antibodies as a treatment to prevent COVID-19 disease. The company is currently tailoring its Pandemic Prevention Platform (P3) program, funded in part by the U.S. government, to address the 2019-nCoV outbreak and AstraZeneca's teams are now focused on identifying monoclonal antibodies to progress into clinical trial evaluation. The company looks forward to providing more updates on its research soon.

## **BAYER**

Bayer has made substantial financial donations as well as donations of several medicines including an antibiotic to support those affected by the outbreak of COVID-19 in China. The donations have been made to the Chinese Red Cross, which is working with Chinese health authorities to coordinate the deployment of aid measures.

## **BOEHRINGER INGELHEIM**

Boehringer Ingelheim (BI) is standing together with all parties to support the fight against the epidemic, making every effort to protect employees' health and safety. BI has made a number of donations totaling more than \$1 million (USD) to support the forefront fight against the epidemic in China including: A donation to the China Red Cross Foundation to purchase medical protective materials for hospitals in Wuhan and other cities in Hubei. This helps local frontline medical staff involved in their fight against the epidemic to treat patients more safely. The headquarters of BI also purchased 100,000 protective masks from Germany, which are donated to provide protection for medical staff in hospitals where the patients with the new pneumonia are treated. BI has also donated medicines to help treat patients with new pneumonia in Wuhan.

## **GENENTECH, A MEMBER OF THE ROCHE GROUP**

Roche and Genentech are providing scientific expertise and advice to the WHO and other relevant stakeholders given infectious disease is a key R&D focus area for them. The company is working with Chinese health authorities and the government to help provide screening and health care, including supporting local health officials and hospitals in the Hubei Province. They recently donated diagnostic tests, medical supplies and financial support for the affected region.

## GILEAD SCIENCES

Gilead is committed to collaborating with global health organizations to support pandemic responses. The company is working with government and non-government organizations and regulatory authorities to develop a strategy to provide its investigational compound, remdesivir, to patients with COVID-19 for emergency treatment in the absence of any approved treatment options, and to support clinical trials to determine whether it can safely and effectively be used to treat COVID-19. Together with health authorities in China, Gilead has initiated two clinical trials in patients who have been infected with COVID-19 to determine the safety and efficacy of remdesivir as a potential treatment for the coronavirus. Both trials are now enrolling participants. The company is also working with regulatory authorities to provide remdesivir to physicians for compassionate use to treat a small number of severely ill patients with confirmed COVID-19 infection and severe clinical symptoms. In anticipation of potential future needs, Gilead has accelerated manufacturing timelines to increase its available supply of remdesivir as rapidly as possible. This is being done before knowing whether remdesivir will be determined to be safe and effective to treat patients with COVID-19.

## GLAXOSMITH-KLINE

GlaxoSmithKline (GSK) and the Coalition for Epidemic Preparedness Innovations, formed a new collaboration aimed at helping the global effort to develop a vaccine for the 2019-nCoV virus. In this new move, GSK will make its established pandemic vaccine adjuvant platform technology available to enhance the development of an effective vaccine against 2019-nCoV. GSK is a leader in the development of innovative vaccines using different adjuvant systems. An adjuvant is added to some vaccines to enhance the immune response, thereby potentially creating a stronger and longer lasting immunity against infections than the vaccine alone. The use of an adjuvant can be of particular importance in a pandemic situation since it can reduce the amount of antigen required per dose, allowing more vaccine doses to be produced and made available to more people.

## JOHNSON & JOHNSON

Johnson & Johnson (J&J) is seeking to further expedite its investigational coronavirus vaccine program through an expanded collaboration with the Biomedical Advanced Research and Development Authority (BARDA), part of the Office of the Assistant Secretary for Preparedness and Response (ASPR) at the U.S. Department of Health & Human Services. Additionally, J&J initiated a review of known pathways in coronavirus pathophysiology to determine whether previously tested medicines can be used to help patients survive a COVID-19 infection and reduce the severity of disease in non-lethal cases. Johnson & Johnson has also announced that its Janssen Pharmaceutical Companies have entered a collaboration with the Beth Israel Deaconess Medical Center (BIDMC) to support the development of a preventive vaccine candidate for COVID-19. The parties have commenced preclinical testing of multiple vaccine prospects, with the aim to identify by the end of the month a COVID-19 vaccine candidate for clinical trials.

## NOVARTIS

Novartis will make available a set of compounds from its libraries that it considers suitable for in vitro antiviral testing. In addition, the company is evaluating its existing products to see if any could be repurposed beyond their approved indications.

## PFIZER

The company has recently completed a preliminary assessment of certain antiviral compounds that were previously in development and that inhibited the replication of coronaviruses similar to the one causing COVID-19 in cultured cells. Pfizer is engaging with a third party to screen these compounds under an accelerated timeline and currently expects to have the results back by the end of March. Upon completion of such screening, the company could be in a position to move forward with development depending on the results. Toxicology studies would then need to be completed prior to any clinical development, but if successful, Pfizer hopes to be in the clinic by no later than the end of 2020.

## SANOFI

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 2019 novel coronavirus vaccine candidate. The recombinant technology produces an exact genetic match to proteins found on the surface of the virus. The DNA sequence encoding this antigen will be combined into the DNA of the baculovirus expression platform, the basis of Sanofi's licensed recombinant influenza product, and used to rapidly produce large quantities of the coronavirus antigen which will be formulated to stimulate the immune system to protect against the virus.

## TAKEDA

Takeda is developing an anti-SARS-CoV-2 polyclonal hyperimmune globulin (H-IG) with the potential to treat high-risk individuals with COVID-19, which is being referred to as TAK-888. Hyperimmune globulins are plasma derived-therapies that have previously been shown to be effective in the treatment of severe acute viral respiratory infections. Takeda is currently in discussions with multiple national health and regulatory agencies and health care partners in the US, Asia and Europe to expeditiously move the research into TAK-888 forward. In addition, Takeda is exploring whether select marketed therapies and molecules in its drug library could be viable candidates for the effective treatment of COVID-19. These efforts are at an early stage but being given a high priority within the company.

**The biopharmaceutical industry has the capacity and expertise to find and scale solutions to prevent and treat infection of the coronavirus and we will continue to provide updates on the response to the outbreak, and our member companies' contributions, as the situation evolves.**