

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.

## AMGEN

Amgen and the Amgen Foundation announced an initial commitment of up to \$12.5 million to support U.S. and global relief efforts to address critical needs in communities impacted by the COVID-19 pandemic. The funds will be used to support emergency response efforts in Amgen's U.S. and international communities, patient-focused organizations that are mounting their own response efforts and international relief efforts by Direct Relief and International Medical Corps. The Amgen Foundation will also match donations made by Amgen staff around the globe who wish to contribute their own funds to the relief efforts.

## 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. AstraZeneca is also donating nine million face masks to support health care workers around the world as they respond to the COVID-19 global pandemic. The company has partnered with the World Economic Forum's COVID Action Platform, created with the support of the World Health Organization, to identify countries in greatest need. Italy will receive the first shipments the week of March 23, with other countries to follow. In addition to these donations, AstraZeneca is accelerating the development of its diagnostic testing capabilities to scale-up screening and is also working in partnership with governments on existing screening programs to supplement testing. To help ensure the continued supply of its medicines to patients, AstraZeneca will screen employees across its manufacturing and supply network. The company's research and development teams have also been working expeditiously to identify monoclonal antibodies to progress towards clinical trial evaluation as a treatment to prevent COVID-19. More than 50 virology, immunology, respiratory and protein engineering experts across research, clinical, regulatory and manufacturing are placing the highest priority on developing a treatment to minimize the global impact of the disease.

## 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.

## BIOGEN

The Biogen Foundation has committed \$10 million to support global response efforts and communities around the world impacted by the COVID-19 pandemic. The funds will be used to address immediate critical needs, with the majority of donations going to support non-profit organizations in the U.S., including Massachusetts and North Carolina, in Italy and in other impacted countries worldwide. This donation will be used to help expand testing options, ease the strain on medical systems, provide training for front line health workers and support access to necessities like food. This adds to the donation made by Biogen China to the Red Cross Society of China. The company has also provided medical equipment and supplies to Partners HealthCare in Massachusetts, to help diagnose COVID-19 in a greater number of people. Partners HealthCare is one of the largest providers of healthcare services in the Boston area. Biogen will also be supporting Massachusetts General Hospital and Brigham and Women's Hospital directly as they work on the front line to treat and contain the virus.

## 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.

## BRISTOL MYERS SQUIBB

Bristol Myers Squibb (BMS) has been proactively taking steps to protect and support its global workforce and the communities where they live and work. In taking these actions, BMS' priorities are to ensure the well-being of its colleagues and to continue delivering the medicines its patients need. Effective March 13, 2020 and until April 1, 2020, Bristol Myers Squibb is strongly encouraging its workforce globally, including employees, contingent workers and contractors, who can do their jobs from home to do so. Accordingly, in the U.S. and certain other markets, our customer-facing personnel are limiting in-person interactions in health care settings. The company is using remote technology to ensure continued support for health care professionals, patient care and access to its medicines. The company is also diligently monitoring manufacturing and supply facilities across the globe, including in areas which have seen a greater impact, and at this time BMS does not anticipate disruptions to the supply of our medicines for its patients due to COVID-19. The company has also made monetary and in-kind donations along with its The Bristol Myers Squibb Foundation to effected areas and supporting organizations.

## ELI LILLY AND COMPANY

Lilly is committed to doing everything possible to bring the full force of their scientific and medical expertise to attack the coronavirus pandemic. The company announced it has entered into an agreement with AbCellera to co-develop antibodies for the potential treatment and prevention of COVID-19, the disease caused by the SARS-CoV-2 novel coronavirus. The collaboration will leverage AbCellera's rapid pandemic response platform, developed under the DARPA Pandemic Prevention Platform (P3) Program, and Lilly's global capabilities for rapid development, manufacturing and distribution of therapeutic antibodies. The company also announced its scientists are partnering with the Indiana State Department of Health (ISDH), with support from the FDA, to accelerate testing in Indiana for SARS-CoV-2, the virus that causes COVID-19. Lilly will use its specialized research laboratories to analyze samples taken in Indiana health care facilities, including nursing homes and emergency rooms. Assuming the company can continuously access required diagnostic reagents, this should start to expand the state's ability to conduct testing and receive a timely diagnosis of individuals who suspect they may be carrying the virus. As Lilly's testing capacity expands, Lilly and ISDH will work together to maximize the impact of broader testing. Lilly is also closely monitoring their supply chain and does not currently anticipate shortages for any of their medicines, including all forms of insulin. Additionally, Lilly and the Lilly Foundation are actively engaged with community partners to address new and complex challenges arising from the coronavirus, including the economic impact on vulnerable people.

## 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.

## MERCK

The company has provided a half a million (500,000) personal protective masks to New York City for use as part of urgent efforts to address the outbreak in New York. In response to the COVID-19 pandemic, Merck remains focused on protecting the safety of its employees and their families, assuring that our supply of medicines and vaccines reach our patients, contributing its scientific expertise to the development of antiviral approaches, and supporting its healthcare providers and the communities in which they serve.

## NOVARTIS

Novartis has announced a broad range of initiatives to respond to the COVID-19 Pandemic. Efforts include the creation of a \$20 million global fund to support impacted communities and entering into new collaborative research efforts such as the COVID-19 Therapeutics Accelerator, coordinated by the Bill & Melinda Gates Foundation, Wellcome and Mastercard, as well as a COVID-19 directed partnership organized by the Innovative Medicines Initiative. The company has also made available a set of compounds from its libraries that it considers suitable for in vitro antiviral testing and is evaluating its existing products to see if any could be repurposed beyond their approved indications. The company will also donate up to 130 million doses of generic hydroxychloroquine to support the global COVID-19 pandemic response. Hydroxychloroquine and a related drug, chloroquine, are currently under evaluation in clinical trials for the treatment of COVID-19. Novartis is supporting ongoing clinical trial efforts, and will evaluate needs for additional clinical trials. When supported for use in COVID-19 infected patients by regulatory authorities, Novartis intends to donate up to 130 million 200 mg doses by the end of May, including its current stock of 50 million 200 mg doses. The company is also exploring further scaling of capacity to increase supply and is committed to working with manufacturers around the world to meet global demand.

## 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.

Additionally, Pfizer and BioNTech announced that the companies have agreed to a letter of intent regarding the co-development and distribution (excluding China) of a potential mRNA-based coronavirus vaccine aimed at preventing COVID-19 infection. The companies have executed a Material Transfer and Collaboration Agreement to enable the parties to immediately start working together. The collaboration aims 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 builds on the research and development collaboration into which Pfizer and BioNTech entered in 2018 to develop mRNA-based vaccines for prevention of influenza.

Furthermore, in the United States, the Pfizer Foundation has provided a \$500,000 grant to International Medical Corps. The funding will support the provision of urgently needed supplies to front-line health care workers, provide training, and deploy medical strike teams. Pfizer Inc has also donated select antibiotics to Direct Relief to manage complications related to COVID-19.

## 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.



## TEVA PHARMACEUTICAL

Teva is donating critical medicines, which are being studied in clinical trials to assess benefit against COVID-19 globally, including more than 10 million doses of hydroxychloroquine sulfate tablets through wholesalers to hospitals across the U.S. This includes tablets being used in critical research efforts. Teva's global manufacturing network continues to increase production of both active pharmaceutical ingredients (API) and finished product to ensure these medicines will get to patients globally, wherever and whenever they are needed.

**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.**