COVID-19: The biopharmaceutical industry is leading the way in developing vaccines, treatments & diagnostics

As a science-driven industry that aims to address some of the world’s biggest healthcare challenges, the biopharmaceutical industry is uniquely positioned to respond rapidly to COVID-19. It has deep scientific knowledge gained from decades of experience working on developing solutions for combatting a range of infectious diseases such as MERS, SARS, Ebola and influenza, as well as experience working with health authorities and regulators to find a fast-tracked approach to bringing safe and effective medicines, vaccines and diagnostics to the market for patients.

The rapid spread of SARS-CoV-2 across the globe is a major public health threat for all, with profound health, social and economic impacts around the world. More than ever, we need effective international cooperation to ensure that no-one is left behind in the race to tackle the spread of COVID-19. This cooperation requires coordinated, multi-stakeholder action that includes the private sector as a critical partner. IFPMA members are fully committed to bringing their unique expertise in research, development and manufacturing of diagnostics, medicines and vaccines to the table.

RELATED RESOURCES

Videos
IFPMA President David Ricks on Global Pledge Committing to Work Together to Beat COVID-19 (Video)
As of 14 April 2020, the WHO’s landscape analysis of potential treatments for COVID-19 contains 133 therapeutics. Further, the WHO Solidarity Trial has brought together over 100 countries working together to find effective therapeutics for COVID-19 as fast as possible. IFPMA members have also been reviewing their drug portfolios, which involves scientists searching for potentially useful assets that could help with the development of new or repurposed treatments to fight against the novel coronavirus.

**AbbVie** is partnering with global authorities to determine the effectiveness of HIV drugs lopinavir/ritonavir in treating COVID-19.

**Amgen** and Adaptive Biotechnologies (Seattle, USA) are partnering to combine expertise to discover and develop fully human neutralizing antibodies targeting SARS-CoV-2 to potentially prevent or treat COVID-19.

**Astellas** is providing compounds in response to a request from the Ministry of Health, Labour and Welfare and National Institute of Infectious Diseases to cooperate in the “Basic Screening Plan for Drugs for Coronavirus Disease”.

**AstraZeneca** has mobilized its R&D expertise in infectious disease and antibody discovery technology to discover novel coronavirus-neutralising antibodies as a potential preventative treatment.

**Boehringer Ingelheim** is searching for novel virus-neutralizing antibodies. It is also screening its entire molecule library for compounds that could target the virus.

**Bristol-Myers Squibb** is joining the COVID-19 Therapeutics Accelerator initiative, initiated by the Gates Foundation, Wellcome and Mastercard, to speed up the development of therapeutics, but also vaccines and diagnostics for COVID-19.

**CSL Group/ Seqirus** is collaborating with Takeda, Biotest AG, Bio Products Laboratory, LFB and Octapharma to accelerate development of an unbranded anti-SARS-CoV-2 polyclonal hyperimmune immunoglobulin medicine to treat COVID-19 patients with serious
complications. **CSL Group** is evaluating potential treatment candidates with SAB Therapeutics as part of its previously announced collaboration to investigate new therapies to treat infectious diseases as well as immunological and neurological conditions.

**Eli Lilly** and AbCellera (Canadian biotech firm) have agreed to co-develop antibody products for the treatment and prevention of COVID-19. **Eli Lilly** and Junshi Biosciences have partnered to co-develop antibody therapies for the prevention and treatment of COVID-19. Lilly will receive an exclusive license to conduct clinical development, manufacturing and distribution of products outside of Greater China. Junshi Biosciences will maintain all rights in Greater China. **Eli Lilly** is joining the COVID-19 Therapeutics Accelerator initiative, initiated by the Gates Foundation, Wellcome and Mastercard, to speed up the development of therapeutics, but also vaccines and diagnostics for COVID-19.

**Eisai** is joining the COVID-19 Therapeutics Accelerator initiative, initiated by the Gates Foundation, Wellcome and Mastercard, to speed up the development of therapeutics, but also vaccines and diagnostics for COVID-19.

**Gilead** is investigating the use of remdesivir (previously developed to treat Ebola, SARS and MERS). **Gilead** announced that positive data is emerging from the National Institute of Allergy and Infectious Diseases’ (NIAID) study of the investigational antiviral remdesivir for the treatment of COVID-19. **Gilead** is joining the COVID-19 Therapeutics Accelerator initiative, initiated by the Gates Foundation, Wellcome and Mastercard, to speed up the development of therapeutics, but also vaccines and diagnostics for COVID-19. **Gilead** has received FDA Emergency Use Authorization for its potential COVID-19 treatment remdesivir.

**GSK** and Vir Biotechnology Inc are in a collaboration using Vir’s proprietary monoclonal antibody platform technology to accelerate existing and identify new anti-viral antibodies for use in therapeutics or preventative treatments. **GSK** is also evaluating its marketed pharmaceutical products and medicines in development to determine if any could be used beyond their current indications in response to the pandemic. **GSK** is also evaluating options to make available specialised laboratory space to help in research and testing of COVID-19. **GSK** is joining the COVID-19 Therapeutics Accelerator initiative, initiated by the Gates Foundation, Wellcome and Mastercard, to speed up the development of therapeutics, but also vaccines and diagnostics for COVID-19.

**Johnson & Johnson**, in partnership with the Rega Institute for Medical Research, University of Leuven (Belgium), are working to identify existing or new compounds with antiviral activity against COVID-19. **Johnson & Johnson** is joining the COVID-19 Therapeutics Accelerator initiative, initiated by the Gates Foundation, Wellcome and Mastercard, to speed up the
MSD is joining the COVID-19 Therapeutics Accelerator initiative, initiated by the Gates Foundation, Wellcome and Mastercard, to speed up the development of therapeutics, but also vaccines and diagnostics for COVID-19.

Merck is joining the COVID-19 Therapeutics Accelerator initiative, initiated by the Gates Foundation, Wellcome and Mastercard, to speed up the development of therapeutics, but also vaccines and diagnostics for COVID-19.

Novartis is rapidly evaluating existing products to see if any could be utilized beyond their approved indications in response to the pandemic. Novartis announced it would conduct a 450-person study in the US to determine if its malaria drug hydroxychloroquine can effectively treat Covid-19. Novartis announced plans to initiate a Phase III clinical trial to study canakinumab in patients with COVID-19 pneumonia. The company aims to rapidly enroll 450 patients at multiple medical centers across France, Germany, Italy, Spain, UK and the US. Novartis is co-chairing the COVID-19 Therapeutics Accelerator initiative, initiated by the Gates Foundation, Wellcome and Mastercard, to speed up the development of therapeutics, but also vaccines and diagnostics for COVID-19.

Pfizer finalised a preliminary assessment of certain antiviral compounds that were previously in development and that inhibited the replication of coronaviruses. Pfizer is working to revive a compound identified as potential treatment for the 2003 SARS-CoV-1 which inhibits a specific enzyme (a protease) produced by coronaviruses. Pfizer is joining the COVID-19 Therapeutics Accelerator initiative, initiated by the Gates Foundation, Wellcome and Mastercard, to speed up the development of therapeutics, but also vaccines and diagnostics for COVID-19.

Roche’s Actemra® was approved by China on March 5 to treat COVID-19 patients with lung complications. Actemra has been on the European market since 2010 for treatment of several kinds of arthritis.

Sanofi SA has entered into a partnership with Regeneron Pharmaceuticals to start a clinical program evaluating Kevzara in patients hospitalized with severe COVID-19. Kevzara, a drug originally used to treat arthritis, is a interleukin-6 (IL-6) pathway inhibitor which might help in slowing the overactive inflammatory response in the lungs of COVID-19 patients. Sanofi is joining the COVID-19 Therapeutics Accelerator initiative, initiated by the Gates Foundation, Wellcome and Mastercard, to speed up the development of therapeutics, but also vaccines and diagnostics for COVID-19.

Shionogi and the Hokkaido University Research Center for Zoonosis Control are in early stages of identifying several promising lead compounds from internal in vitro studies. They are accelerating drug discovery efforts with the aim of starting clinical trials in FY2020.

Takeda is initiating the development of an experimental drug derived from the blood
of COVID-19 patients that recovered. In parallel, Takeda is exploring if products currently marketed or in pipeline may be effective to treat COVID-19. Takeda and CSL Group formed an alliance with 4 other companies to develop a potential plasma-derived therapy for treating COVID-19. See CSL Group/Seqirus for more info.

Teva is actively looking through its range of products to determine if it can help provide any products that may be relevant in addressing acute and substantial need during the COVID-19 crisis.

The rapid virus sequencing by the scientific community enabled researchers to characterize and begin to understand the new threat posed by COVID-19. "Open Access” data-sharing channels are the backbone to securing a response capacity and have proven their worth with influenza networks. The rapid pace with which researchers have been able to understand this novel strain of virus and get medicines into human clinical trials is a testament to the lessons learned from past public health emergencies. The Global Initiative on Sharing All Influenza Data or GISAID Initiative, an open access platform partly funded by the private sector, played a critical role in sharing the first genome sequences of the novel coronavirus and centralizing their collection. This has proven vital in speeding up the sharing of information among scientists as well as public health authorities. But there is still a lot to learn about the virus, both in terms of how it spreads as well as what existing treatments may be effective in helping patients who contract the disease.

Abbvie is supporting clinical studies and basic research with lopinavir/ritonavir, working closely with European health authorities and the US FDA, Centres for Disease Control and Prevention, National Institutes of Health and the Biomedical Advanced Research and Development Authority to coordinate efforts.

Amgen’s subsidiary deCODE genetics and colleagues from Iceland’s Directorate of Health and the National University Hospital published in the New England Journal of Medicine a population-based study of the early spread of SARS-Cov-2 (causing COVID-19 disease) in Iceland’s population.

AstraZeneca will initiate a randomised, global clinical trial to assess the potential of Calquence (acalabrutinib) in the treatment of the exaggerated immune response (cytokine storm) associated with COVID-19 infection in severely ill patients. Calquence is approved for the treatment of adult patients with chronic lymphocytic leukaemia (CLL) in the US and a few other countries with an active global filing programme.

Boehringer supports scientists worldwide with its open innovation portal opnMe.com, which offers 6
**Ingelheim** anti-viral compounds out of 43 high quality pharmacological tool compounds at no cost for testing of research hypotheses.

**Bristol-Myers Squibb** (BMS) identified 1,000 compounds in its discovery library that they are making available to collaborators for screening for potential treatments for COVID-19. BMS is actively evaluating certain medicines in its portfolio that could be included in near-term clinical trials with a focus on agents impacting the inflammatory immune response associated with COVID-19.

**Eli Lilly** has entered into an agreement with the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH), to study baricitinib as a potential treatment for hospitalized patients diagnosed with COVID-19. Baricitinib is approved in more than 65 countries as a treatment for adults with moderately to severely active rheumatoid arthritis.

**Gilead** initiated two Phase 3 clinical trials of remdesivir in countries with high prevalence of COVID-19. The company is also supporting two Phase 3 trials in China and a global Phase 2 trial led by the US National Institute of Allergy and Infectious Diseases. Gilead reports on the New England Journal of Medicine (NEJM) publishing an analysis of the effects of their investigational medicine remdesivir on a small group of patients with severe COVID-19 symptoms.

**Ipsen** donated financial resources to the Institut Pasteur that has devoted a portion of its research, since January, to understanding SARS-CoV-2 in terms of epidemiology, biological characteristics and pathogenicity.

**Merck** donated a supply of interferon beta-1a (Rebif®) to the French Institut National de la Santé et de la Recherche Médicale (INSERM) following a request for use in a clinical trial to investigate it as a potential therapeutic for COVID-19.

**Novartis** is contributing by making several compounds from its libraries available that are considered suitable for in vitro antiviral testing. Novartis plans to initiate a Phase III clinical trial in collaboration with Incyte to evaluate the use of Jakavi® (ruxolitinib) for treatment of a type of severe immune overreaction called a cytokine storm that can lead to life-threatening respiratory complications in COVID-19 patients. Novartis and Incyte will take Jakafi into a second phase 3 trial for COVID-19 patients with acute respiratory distress syndrome (ARDS).

**Pfizer** is committed to making the vital tools they develop available on an open source platform to the broader scientific community and to share data and learnings gained with other companies in real time to rapidly advance therapies and vaccines to patients. Pfizer is committed to share their clinical development and regulatory expertise to support the most promising candidates smaller biotech companies bring forward. Pfizer is reaching out to US federal agencies including NIH, NIAID and CDC to build a cross-industry rapid response team of scientists, clinicians and technicians able to move into action immediately when future epidemics surface. Pfizer followed up on its commitments by sharing safety data on the Azithromycin-Hydroxychloroquine Combination.

Pfizer shared preliminary data confirming the anti-SARS-CoV-1 compound shows antiviral activity against SARS-CoV-2. Pfizer will perform pre-clinical confirmatory studies, including further anti-viral profiling and assessment of the suitability of the lead molecule for IV administration clinically.
Pfizer and the Liverpool School of Tropical Medicine's Respiratory Infection Clinical Research Group are launching two new studies to provide insights on the interaction between S. pneumoniae and SARS-CoV-2.

Roche is working with the US FDA to initiate a Phase III clinical trial to evaluate the safety and efficacy of Actemra in hospitalised adult patients with severe COVID-19 pneumonia. This is the first global study of Actemra in this setting and is expected to begin enrolling in early April hoping to attract 330 patients globally, including the US. Roche (through its daughter company Chugai) announced it will initiate a randomized, double-blind, placebo-controlled Phase III clinical trial (COVACTA study) globally to evaluate the safety and efficacy of Actemra plus standard of care in hospitalized patients with severe COVID-19.

Sanofi is coordinating with the Coalition for Epidemic Preparedness Innovations (CEPI) and sharing its vaccine R&D experience and expertise to advance vaccine solutions. Sanofi commits to donating hydroxychloroquine (Plaquenil®) to governments worldwide if ongoing clinical trials demonstrate its safety and efficacy in COVID-19 patients. Sanofi and Regeneron shared preliminary results from the Phase 2 portion of an ongoing Phase 2/3 trial evaluating Kevzara® (sarilumab) for treating hospitalized patients with "severe" or "critical" respiratory illness caused by COVID-19. In the preliminary Phase 2 analysis, Kevzara had no notable benefit on clinical outcomes when combining the "severe" and "critical" groups, versus placebo. The trial will now be amended so that only "critical" patients continue to be enrolled to receive Kevzara 400 mg or placebo.

Takeda partnered with IMI in Europe to leverage collective expertise in the hope to develop inhibitors to help prevent future outbreaks.

UCB is working with the US-based Seattle Structural Genomics Center for Infectious Disease to identify crystal structures of SARS-CoV-2 proteins. It is also partnering with UK-based Diamond Light Source and The University of Oxford to design inhibitors of SARS-CoV-2's main protease for treatment of COVID-19 patients. It is also working with government agencies and the healthcare community to determine if any of their therapies could be used effectively against COVID-19.

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**SPEED UP R&D OF SAFE & EFFECTIVE VACCINES**

Use our expertise and know-how to speed up the development of safe and effective vaccines to prevent COVID-19 in partnership with others.

As of 5 May 2020, the WHO reports there are currently 8 candidate vaccines in clinical evaluation and 100 candidate vaccines in preclinical evaluation. Several biopharmaceutical companies are researching vaccine candidates for the prevention of COVID-19 and collaborating in the sharing of existing technologies that can be leveraged to allow a rapid upscale of production once a vaccine candidate is identified. IFPMA members are also sharing technologies that act as an adjuvant which can boost the
effectiveness of a potential vaccine.

Experts are hoping it will take as little as 12 to 18 months before there is a vaccine available. This is a best-case estimate that assumes one or two of the first few vaccines that enter development and complete three phases of clinical trials will be successful. Typically, only approximately one in ten experimental vaccines make it all the way through to regulatory approval. Therefore, the more companies taking different approaches to find a vaccine, the greater the chance of success.

IFPMA is a founding partner of Access to COVID-19 Tools (act) Accelerator, a global collaboration to accelerate the development, production and equitable access to new COVID-19 diagnostics, therapeutics and vaccines.

**AstraZeneca** and the University of Oxford are joining forces for the global development and distribution of the University's potential recombinant adenovirus vaccine aimed at preventing COVID-19 infection from SARS-CoV-2.

**CSL Group/Seqirus** provides scientific and technical expertise together with its established MF59\(^*$\) adjuvant technology to the University of Queensland in Australia to fast-track R&D of their CEPI-funded COVID-19 vaccine candidate, which uses novel molecular-clamp technology.

**GSK** is partnering with Chinese biotech company Clover Biopharmaceuticals, providing it with its proprietary adjuvants which enhance the effectiveness of vaccines. GSK is also collaborating with CEPI to help the global effort to develop a vaccine for the novel coronavirus. GSK is making its adjuvant technology available to support rapid development of candidate vaccines and is working with The University of Queensland, Australia. GSK is collaborating with Innovax and Xiamen University, developing and testing a recombinant protein-based coronavirus vaccine candidate.

By mid-March, GSK further expanded collaborations to five partner companies and research groups across the world, including in the USA and China. GSK entered into a collaboration with Sanofi to develop an adjuvanted vaccine for COVID-19, using innovative technologies from both companies. The vaccine would be ready to begin testing in humans in the second half of 2020.

**Johnson & Johnson** expanded its collaboration with the Biomedical Advanced Research and Development Authority (BARDA) and established a new collaboration with Beth Israel Deaconess Medical Center (BIDMC). Johnson & Johnson and partners announced the selection of a lead COVID-19 vaccine candidate from constructs it has been working on since January 2020. The Company has already begun preparations for clinical vaccine production at its facility in Leiden, the Netherlands, with the aim of initiating Phase 1 human clinical studies of its vaccine candidate in September 2020.

**Pfizer** and BioNTech have entered into a partnership to jointly develop BioNTech's mRNA-based vaccine candidate BNT162 to prevent COVID-19 infection. The two companies plan to jointly conduct clinical trials initially in the United States and Europe across multiple sites by the end of April 2020. On April 22, the German regulatory authority, the Paul-Ehrlich-Institut, has approved the Phase 1/2 clinical trial for BioNTech's BNT162 vaccine program to prevent COVID-19 infection.

Pfizer and BioNTech announced that the first cohort of BioNTech's Phase 1/2 clinical trial has been dosed. Twelve
study participants were dosed with vaccine candidate BNT162 in Germany since dosing began on April 23, 2020. Pfizer and BioNTech announced that the first participants have been dosed in the U.S. in the Phase 1/2 clinical trial for the BNT162 vaccine program to prevent COVID-19. The Phase 1/2 trial in the U.S. will enroll up to 360 healthy subjects into two age cohorts (18-55 and 65-85 years of age).

Sanofi announced a collaboration with the Biomedical Advanced Research and Development Authority (BARDA) to advance a novel COVID-19 vaccine candidate. Work is underway to leverage previous development efforts of a SARS vaccine candidate using Sanofi’s recombinant DNA technology. Sanofi, and Translate Bio, a clinical-stage messenger RNA (mRNA) therapeutics company, will collaborate to develop a novel mRNA vaccine for COVID-19. This collaboration leverages an existing agreement from 2018 between the two companies to develop mRNA vaccines for infectious diseases. Sanofi joined forces with GSK, sharing innovative technologies from both companies. For more details see GSK.

Shionogi’s subsidiary UMN Pharma Inc. is pursuing the discovery and development of a recombinant protein vaccine in a project supported by the Japan Agency for Medical Research and Development (AMED). Shionogi made the decision to develop a prophylactic vaccine for COVID-19. The company is looking to offer the vaccine for 10 million people.

UCB is collaborating with The University of Oxford on a vaccine development.

**DEVELOP DIAGNOSTIC TESTING & SECURE CONTINUOUS SUPPLY**

Develop and scale up the capacity of diagnostics testing for COVID-19 patients as much as possible and secure the continuous supply of diagnostic test kits to countries around the world.

Rolling out diagnostics to detect whether patients are genuinely infected with the new coronavirus is a key step in preventing or slowing its spread. However, the rapid spread of COVID-19 has drastically increased the demand for testing kits around the world and governments are trying to ramp up their testing capacities. The biopharmaceutical industry is therefore pushing the boundaries, uniting and collaborating to increase and secure the production and development of diagnostics for COVID-19.

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 programmes to supplement testing. AstraZeneca is collaborating with GSK and Cambridge University by setting up a new testing laboratory at the University’s facilities for high throughput screening for COVID-19 testing. It will also explore the use of alternative chemical reagents for test kits to help overcome current supply shortages.

Bayer is making more than 40 virus diagnostics devices available from its research operations to scale up Germany’s COVID-19 analysis by several thousand tests daily. It is also freeing up specially trained personnel for this purpose.
GSK is joining forces with AstraZeneca and Cambridge University. For more details see AstraZeneca.

Johnson & Johnson entered into a research collaboration with Alveo Technologies to advance Alveo’s be.well™ platform of analyzers, nasal swabs and cartridges for the detection of viral infectious diseases, including potentially SARS-CoV-2. J&J will provide Alveo with financial support as well as technical and regulatory counsel.

Menarini Diagnostics and Credo Diagnostics Biomedical have entered into an exclusive distribution agreement for the VitaPCR™ SARS-CoV-2 assay kit.

Johnson & Johnson entered into a research collaboration with Alveo Technologies to advance Alveo’s be.well™ platform of analyzers, nasal swabs and cartridges for the detection of viral infectious diseases, including potentially SARS-CoV-2. J&J will provide Alveo with financial support as well as technical and regulatory counsel.

Novo Nordisk scientists are working in R&D laboratories to boost Denmark's COVID-19 testing capacity.

Roche received Emergency Use Authorization from the US FDA for its diagnostic kit cobas® SARS-CoV-2 Test. Roche is committed to delivering as many tests as possible and is going to the limits of production capacity. Roche announced the development and upcoming launch of its Elecsys® Anti-SARS-CoV-2 serology test to detect antibodies in people who have been exposed to SARS-CoV-2.

Roche received Emergency Use Authorization from the US FDA for its COVID-19 antibody test. Roche has already started shipping the new antibody test to leading laboratories globally and will ramp up production capacity to high double-digit millions per month to serve healthcare systems in countries accepting the CE mark as well as the U.S.

Roche is doing everything possible to ensure an adequate supply of their tests. It calls upon governments to work with the industry to keep global manufacturing and supplies running.

Sanofi joined forces with Luminostics to develop a COVID-19 smartphone-based self-testing solution. Luminostics would contribute its proprietary technology for consumer-diagnostics for COVID-19 testing while Sanofi would bring its clinical research testing experience and capabilities.

Shionogi and Micro Blood Science (MBS) entered into a partnership to develop COVID-19 antibody-test kits using MBS’ original technology, including unique trace-blood collection devices. Shionogi is currently undertaking performance testing to demonstrate its suitability for practical use in Japan and are collecting clinical data for regulatory approval.

Shionogi entered a partnership with MBS and Vazyme Biotech to support delivery of their COVID-19 antibody-test kits to medical institutions, testing facilities, research laboratories, etc.

Takeda is partnering with public entities and other pharmaceutical companies through the Innovative Medicines Initiative (IMI) in Europe to leverage collective expertise in the hope of developing diagnostics for COVID-19.

UCB is working closely with the Belgian government to scale up COVID-19 testing capabilities. It is looking at similar possibilities in the UK.
IFPMA and its member companies are monitoring the impact the SARS-CoV2 outbreak and measures put in place by governments to prevent the spread of the virus (e.g. restrictions on travel, movement, border closures or measures on supply chains). Member companies are committed to ensure the continued supply of essential supplies for medicines and vaccines, for patients that suffer from chronic illnesses or other health conditions. Member companies are not aware of any near-term impacts on the availability of medicines and vaccines. They are continuously monitoring and proactively handling the situation as it develops and do currently not expect any long-term impact on the availability of medicines and vaccines, unless any disruption caused by the pandemic is sustained over the next several months.

Biopharmaceutical companies are working to prevent and mitigate any shortages through close coordination with national regulatory authorities and other global stakeholders, including the World Health Organization.

There is an increase in the threat of falsified medicines, targeting existing products but also new potential treatment against COVID. On April 9, the WHO issued an alert warning that between 31 March and 2 April 2020, the WHO global surveillance and monitoring system on substandard and falsified (SF) medical products received nine reports of confirmed falsified chloroquine products from three countries. IFPMA and its members continue their commitment to tackling the global public health threat that are falsified medical products. IFPMA, as a member of the Fight the Fakes campaign, supports the campaign’s activities (Statement).

**AbbVie**
AbbVie is not anticipating disruption to the medicine supply for HIV patients as a result of the investigation of the effectiveness of HIV medicines against COVID-19.

**Almirall**
Almirall will continue production of all its essential products and has increased production of specific medicines, such as paracetamol.

**Astellas**
At Astellas there are currently no problems with the supply of products as we have been able to maintain an adequate inventory level of raw materials and finished products, by closely cooperating with outsourcing manufacturers and suppliers of raw materials taking into account the continuation of business and the stable supply of products.

**Bayer**
Bayer is continuing the production of medicines and health care products at their plant in Garbagnate, Italy for both the Italian and global market.

**Biogen**
Biogen take the vital role they play in ensuring an uninterrupted supply of their medicines to patients very seriously. It does not anticipate any interruptions but cannot exclude the possibility that COVID-19 might have an impact on manufacturing capabilities in the future.

**Boehringer Ingelheim**
Boehringer Ingelheim ensures further discovery, development, production and supply of highly innovative medicines that are needed by patients around the globe.

**Bristol-Myers Squibb**
Clinical and commercial supply chain teams at Bristol Myers Squibb have proactively made sure raw materials and products reach their markets and clinical sites. It has not seen any disruption in its clinical or commercial supply...
Chain due to the pandemic.

**Chiesi** Chiesi Group will continue the production of all medicines without interruption at sites in Italy and abroad at the same high-quality standards. Currently, it is able to deliver medicines under normal production and distribution channels from all production plants in Italy, Brazil and France.

**CSL Group/Seqirus** Seqirus has enacted its business continuity plans across the globe to minimise disruption to the manufacture and on-time supply of its influenza vaccines.

**Daiichi-Sankyo** Daiichi-Sankyo announced it has not any shortage of its medicines. Its Supply Chain team is monitoring the evolving situation very carefully to maintain supply and delivery of these medicines.

**Eisai** Eisai maintains necessary stocks for the stable supply of medicines in addition to the stable production of medicines.

**Eli Lilly** Eli Lilly launched the Lilly Insulin Value Program in the US allowing anyone with commercial insurance and those without insurance to fill their monthly prescription of Lilly insulin for $35.

**Grünenthal** Grünenthal is not experiencing any significant supply shortages. If their team detects any severe supply shortages that might potentially disrupt the supply of their products, affected partners will be informed as soon as possible.

**Ipsen** Ipsen is closely working with national and international supplies to monitor the provision of goods and services, with the goal of continuing operations as seamlessly as possible. It does not anticipate any supply shortages.

**Leo Pharma** LEO Pharma has activated business continuity plans to uninterruptedly supply patients with the medicines they need. LEO Pharma is taking additional measures to avoid any shortages of medicines or raw materials and to mitigate any interruptions.

**Lundbeck** Lundbeck has been extremely busy with taking precautions to provide treatments to the millions of people relying on them. Its supply chain remains intact and it has not experienced any supply disruptions.

**Merck** Merck and The Jenner Institute announced they have laid the foundation for large-scale production of The Jenner Institute’s COVID-19 vaccine candidate, ChAdOx1 nCoV-19. Their joint team reduced process development time to two months from a year.

**MSD** Recognizing the changing needs of patients during the COVID-19 pandemic, MSD announced it is taking a number of new steps to support patients in the United States who may have lost their jobs and insurance coverage.

**Novartis** Sandoz, the Novartis generics and biosimilars division, is maintaining prices on a basket of essential medicines that may help in the treatment of COVID-19. Novartis encourages industry, governments and international institutions to work together to ensure adequate global access of medications to treat COVID-19 patients.

**Novo Nordisk** Novo Nordisk is ensuring the supply of their lifesaving medicines to people with serious chronic diseases across the globe. Novo Nordisk is applying its experience with Chinese lockdown measures around the globe to assure continuity of their supply chain.

**Roche** Roche is doing everything possible to ensure an adequate supply of their medicines. It calls upon governments to work with the industry to keep global manufacturing and supplies running by ensuring the free flow of vital goods across national borders, consider pragmatic temporary adjustments to regulations on packaging, reviews, customs
etc. and to work together across governments internationally.

**Sanofi** Sanofi to provide hydroxychloroquine (Plaquenil®) wherever possible and will secure appropriate supply levels of current approved indications.

**Servier** Servier puts its best efforts forward to ensure the continuity of its production in order for its medicines to remain available to patients who rely on them. It therefore brings its expertise to the multi-stakeholder partnership “Health Innovation Coalition – Health Crisis” in France.

**Takeda** Takeda is currently not experiencing any potential supply disruption due to the Coronavirus outbreak. The company is tracking the situation as it evolves and will take all necessary actions in an effort to ensure supply continuity for patients.

**Teva** Teva is prepared for various scenarios and has inventory and redundancy plans in place to address potential shortfalls, if necessary. The supply chain for their key products, brand, generics and APIs remains largely uninterrupted with adequate inventory of products.

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**INCREASE & SHARE MANUFACTURING CAPACITY FOR MEDICINES & VACCINES**

Increase our manufacturing capabilities and share available capacity to ramp up production once a successful vaccine or treatment is developed.

Biopharmaceutical companies are part of a wider research community which is collaborating to fast-track the development of therapeutics and new vaccines. Collaborating in this way could speed up development of resources to tackle this outbreak. It creates networks of centres of excellence that can deliver a real impact and a preparedness infrastructure which can be mobilized for future outbreaks. While there are still many unknowns about the virus, companies are entering in partnerships to scale-up production capacity.

IFPMA is a founding part of **Access to COVID-19 Tools (act) Accelerator**, a global collaboration to accelerate the development, production and equitable access to new COVID-19 diagnostics, therapeutics and vaccines.

**AstraZeneca** AstraZeneca and the University of Oxford joined forces to be responsible for the development, worldwide manufacturing and distribution of the vaccine, developed by the Jenner Institute and Oxford Vaccine Group, at the University of Oxford, if clinical trials prove successful.

**Eli Lilly** Eli Lilly and AbCellera collaborate on AbCellera’s rapid pandemic response platform, developed under the DARPA Pandemic Prevention Platform Program, and Lilly’s global capabilities for rapid development, manufacturing and distribution of therapeutic antibodies.

**GSK** Under **GSK** and Sanofi vaccine development collaboration, both companies commit to create and supply sufficient quantities of vaccines that will help stop this virus. Both companies bring significant manufacturing capacity, and,
if successful, we will be able to make hundreds of millions of doses annually by the end of next year.

Gilead has accelerated manufacturing of remdesivir at risk, in anticipation of potential future supply needs.

Johnson & Johnson announced a collaboration Emergent BioSolutions, Inc. to support the manufacturing of its lead investigational COVID-19 vaccine candidate. Johnson & Johnson has committed to rapidly produce and supply more than one billion doses of a safe and effective vaccine globally on a not-for-profit basis for emergency pandemic use.

Johnson & Johnson signed a deal with Catalent to accelerate rapid scale-up of segregated manufacturing capacity over the coming months to support dedicated production of Johnson & Johnson’s investigational vaccine candidate. Catalent plans to hire approximately 300 additional employees at the site for this program starting in July 2020 to meet operational readiness and 24×7 manufacturing schedules by January 2021.

Pfizer and BioNTech are jointly developing a COVID-19 vaccine, to be produced initially in the US and Europe. Manufacturing capacity will be scaled-up to support global supply. Pfizer will contribute its leading global vaccine clinical R&D, regulatory, manufacturing and distribution infrastructure and capabilities.

Pfizer is committed to use any excess manufacturing capacity and to potentially shift production to support others in rapidly getting life-saving breakthroughs into the hands of patients as quickly as possible.

Sanofi increased production capacity of hydroxychloroquine (Plaquenil®) by 50% and is on track to further increase production over the coming months.

Sanofi and GSK vaccine development collaboration, both companies commit to create and supply sufficient quantities of vaccines that will help stop this virus. See GSK for more details.

Teva is assessing additional production of hydroxychloroquine sulfate tablets with materials that are being sent to Teva from its ingredient supplier.

Teva’s global manufacturing network has been working tirelessly on securing and scaling production of both API and finished doses for potential treatments that my prove essential in treating COVID-19 everywhere Teva does business.

UCB is assuring a reliable supply of medicines in every market it has a commercial presence in. It has not experienced shortages for any of our products due to this epidemic.

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**SUPPORT GLOBAL HEALTHCARE SYSTEMS**

Use our medical expertise to support global healthcare systems to manage the unprecedented increase in the pressure they are experiencing.

IFPMA member companies are committed to support health care system capacities and protect health care workers, particularly in the most hard-hit countries and vulnerable countries which are ill prepared to cope with an accelerating outbreak of COVID-19. When the novel coronavirus first emerged in Wuhan, China, IFPMA and its member companies started working with their teams on
the ground, and with the Chinese authorities to ensure people can get access to necessary health care services.

Given the spread of the virus to other regions across the world, IFPMA member companies have stepped up these efforts and are donating personal protective equipment and financial resources to ease the burden on health care systems. Company employees are also volunteering in community efforts to relieve the burden on healthcare systems.

Support to the most affected countries (on-going)

**AbbVie** announced a donation of $35 million to support COVID-19 relief efforts. In the US, AbbVie's funds will be used to support healthcare capacity for hospitals as well as protect vulnerable populations by enabling access to food and essential supplies. In Europe, the donation will provide critical equipment and supplies to patients and front-line healthcare workers in the hardest-hit countries. AbbVie set up the AbbVie COVID-19 Community Resilience Fund and is committing $5 million to support healthcare systems and underserved communities in response to the impact of COVID-19.

**Almirall** has donated topical cream to healthcare professionals in Spain and the UK. It has also repurposed production facilities in Germany to manufacture antibacterial gels. It also donated protective equipment to healthcare workers in Spain.

**Amgen** and the Amgen Foundation announced an initial commitment of up to $12.5 million to support US and global relief efforts to address critical needs in communities impacted by COVID-19. The funds will be used to support emergency response efforts in Amgen’s US and international communities, patient-focused organizations that are mounting their own response efforts, and international relief efforts by Direct Relief and International Medical Corps.

**Astellas** announced Astellas Pharma US, Inc. and the Astellas Global Health Foundation are each expanding support for global and local communities fighting COVID-19 by providing up to $2 million of new financial assistance, in aggregate, to meet the urgent demand for resources to help patients, health care workers, and first responders.

In Italy, Astellas Pharma S.p.A., has decided on a donation worth 150,000 euros for the necessary supply of goods to public medical institutions and NPOs.

In Spain, Astellas Pharma S.A., has decided on a donation worth 200,000 euros to its country's health ministry for the necessary supply of goods to medical institutions.

Furthermore, to assist health care systems coping with increasing demands by government or non-profit organization presented by the escalation of COVID-19 around the world, Astellas will authorize a maximum of 4 weeks of paid leave (in accordance with each country’s provision) to employees who are medically qualified and wishes to contribute in volunteer activities within their community.

**AstraZeneca** is donating 9 million face masks to support healthcare workers around the world. It has partnered with the World Economic Forum’s COVID Action Platform, created with the support of the WHO, to identify countries in greatest need. Italy will receive the first shipments with other countries to follow.

AstraZeneca and GSK are collaborating to provide process optimisation support to various UK national testing centres for COVID-19 to expand testing capacity.

**Bayer** made financial donations to an aid fund of the regional authorities in Lombardy, Italy to help procure
urgent needed equipment for intensive care units in hospitals with the greatest needs. Bayer started producing hand sanitizers in Cimanggis, Indonesia based on their expertise from their plants in Wuppertal and Bergkamen, Germany. Bayer is also supplying German hospitals with ventilators from their pharmacology labs and health care workers with masks. It also supports employees from the Pharmaceutical Division with a medical background to support the local health care system by offering them paid leave for 4 weeks. It is also providing the German Army with 600,000 chloroquine tablets. Bayer made a donation of one million products to support the health of underserved US communities, including 3 million chloroquine tablets.

Biogen The Biogen Foundation has committed $10 million to support global response efforts and communities around the world.

Boehringer Ingelheim Boehringer Ingelheim contributes €5.8 million from their Global Support Program donations fund, provides paid leave for its 51,000 employees to volunteer for COVID-19 relief and established a €580,000 relief fund for social entrepreneurs and their communities in Kenya and India via its Making More Health program. Boehringer Ingelheim as also made a number of financial contributions totaling over $1 million to protect health care professionals in the critical services they are providing to patients.

Bristol-Myers Squibb Bristol Myers Squibb (BMS) Company and the Bristol Myers Squibb Foundation donated more than $6 million in financial support and necessary products (i.e., personal protection equipment) to affected areas around the world, including the US, Italy, Greece, Israel, Romania, Canada, Korea and China. Licensed healthcare professionals employed by BMS are supported to volunteer in local hospitals and will continue to receive pay.

Chiesi Chiesi Group commits €3 million for donations to support the ongoing emergency in Italy. It donated 50,000 units of sanitizing hand gel to public transport operators and personal protective equipment to hospitals. It collaborates with associations of general practitioners on advice and guidance, providing support for the purchase of respiratory equipment in hospitals that support COVID-19 patients.

Daiichi-Sankyo Daiichi-Sankyo will make a donation of $1 million to the WHO’s COVID-19 Solidarity Response Fund through the Japan Center for International Exchange in support of relief efforts for countermeasures against COVID-19.

Eisai In the US, Eisai has provided $250,000 in funding to non-profit patient organizations, in addition to providing Personal Protection Equipment to local healthcare providers. In Europe, Eisai has provided €945,000 in funding to professional organizations such as the WHO, as well as to support healthcare providers and vulnerable communities in the UK, Italy, Germany, Spain, Belgium, France, Portugal, and Slovakia. In Asian countries outside of China, Eisai has donated 11.8 million rupees to federal emergency funding in India, and is planning donations of funding and supplies in Indonesia, Thailand, the Philippines, Malaysia, and Vietnam.

Eli Lilly Eli Lilly is deploying its medical professionals to staff a free drive-through COVID-19 testing facility at its corporate headquarters in Indianapolis. The testing facility serves active frontline health care workers and first responders, as a service to the community and in an effort to protect people working on the front lines of this pandemic.

Farmindustria Farmindustria and its member companies have donated over €9.4 million worth of medicines to Italian hospitals; €21.8 million of financial and material donations, such as respiratory personal protective equipment, and disinfectant gels, and four companies have modified their production lines in order to meet health needs during
Gilead has provided remdesivir to physicians for compassionate use to treat several hundred severely ill patients with confirmed COVID-19. Gilead announced that their existing supply, including finished product ready for distribution as well as materials in the final stages of production, amounts to 1.5 million individual doses of remdesivir. This presents 140,000 treatment courses based on a 10-day treatment duration, all of which Gilead has committed for donation.

Gilead announced a $20 Million Philanthropic Fund called Gilead CARES (COVID-19 Acute Relief and Emergency Support) Grantee Fund to support nonprofit organizations impacted by the COVID-19 Crisis. Organizations may be eligible to receive up to $100,000 in emergency assistance. Gilead will also make two significant community donations: $1 million to the San Mateo County Strong Fund and $1 million to the Mayor’s Fund for Los Angeles.

GSK is donating $10 million to the COVID-19 Solidarity Response Fund, created by the UN Foundation and WHO, to enable distribution of essential supplies such as personal protective equipment (PPE) to frontline health workers. GSK is donating surplus reagents to support diagnostic testing to several countries and is preparing to do the same for surplus PPE. GSK joined forces with AstraZeneca to help expand UK testing capabilities. For more info see AstraZeneca.

Johnson & Johnson announced a $50 million commitment to support frontline health workers, especially doctors, nurses, midwives and community health workers who are working tirelessly to treat COVID-19 patients around the world. Johnson & Johnson is encouraging medically trained employees to donate their time and expertise by joining the local health workforce in combating COVID-19. Medically trained employees worldwide can take a paid leave for up to 14 weeks through March 31, 2021. Any Johnson & Johnson employee or retiree who donates to the Covid-19 Solidarity Response Fund or the CDC Foundation’s All of Us Campaign will be matched by the company, dollar for dollar, up to a total match of $1 million for each organization.

Lundbeck is supporting local communities and societies with for example monetary and medicine donations to Wuhan, fundraising activities in Italy, donations of protective equipment in France and in the US, together with support for local patient organizations. Lundbeck North America has committed $1 million in support of COVID-19 relief efforts and is donating to COVID Response Funds in regions where the company is present.

Menarini converted a topical pharmaceutical producing plant in Florence into a plant producing antibacterial gels, fully used for donations across Italy. Menarini is invested to scale up production from 5 tons to 30 tons of antibacterial gel per week.

MSD has provided 500,000 personal protective masks to New York City for use as part of urgent efforts to address the outbreak. MSD will support its employees around the world who are uniquely qualified to provide medical services and wish to aid communities affected by the COVID-19 pandemic. In the US, MSD intends to collaborate with the Health Management Academy to identify facilities with the greatest need and triage potential qualifying volunteers to serve. MSD will make an additional commitment of $10 million in support of COVID-19 relief efforts to help address health disparities and inequality among patients and communities. With this commitment, MSD has contributed or committed more than $30 million in support of global, national and local COVID-19 relief efforts.
**Merck** donated 150,000 liters of disinfectant to the German state of Hesse.

**Novartis** commits to donate up to 130 million doses of hydroxychloroquine to support the global COVID-19 pandemic response. The Novartis COVID-19 Response Fund will provide $20 million to support communities around the world most impacted by the coronavirus pandemic. Novartis Canada and Sandoz Canada announced a donation of $500,000 to community and patient groups as part of the companies’ newly created Community Strong COVID-19 response program.

**Novo Nordisk** is donating essential equipment including masks and gloves and provided 20 tonnes of alcohol to replenish stocks of hand sanitiser in hospitals. Novo Nordisk Foundation also made a donation of more than $7 million to fight COVID-19 in Denmark.

**Pfizer** created a new Global COVID-19 Medical Service Program that empowers medical colleagues to provide diagnostic, treatment, and public health support. Pfizer and the Pfizer Foundation announced a $40 million commitment in medical and charitable cash grants to help combat the COVID-19 pandemic. The donation addresses the urgent needs of partners who are working to slow the spread of the virus and strengthen vulnerable healthcare systems against future public health threats.

**Sanofi** announced it will make a charitable gift of 100 million euros to help tackle the coronavirus crisis in France, with the money going to hospitals, care homes and other initiatives.

**Servier** actively contributes by providing personal protection equipment to hospitals in affected countries, as well as making donations to foundations and NGOs (e.g.: Chinese Red Cross and APHP Foundation). In addition, tens of healthcare professionals employed by Servier have volunteered and have been made available to French health authorities to join medical staff on the front line against SARS-CoV-2.

**Sumitomo Dainippon Pharma** donated 10 million yen to the Kitasato Institute's Project for COVID-19. The project aims to identify clinical candidates for the treatment of COVID-19 through a large-scale screening of approved pharmaceuticals.

**Takeda** is in total donating $6.25 million to the American Red Cross, the city of Cambridge, and the town of Lexington to fight COVID-19. The Red Cross will receive $4 million to make sure the organization can maintain a sufficient blood supply during the health crisis. Takeda is donating $2 million to the Cambridge Mayor's Relief Fund and $250,000 to the Lexington Emergency Assistance Fund to help families affected by the epidemic.

**Teva** is donating more than 6 million doses of hydroxychloroquine sulfate tablets through wholesalers to hospitals across the US by March 31, and more than 10 million within a month.

**UCB** is donating hydro-alcoholic solutions to the Belgian and Swiss authorities which it started producing at its own major manufacturing sites. It is further supporting healthcare professionals in its company that wish to volunteer in line with local government needs and guidance. It also donated masks and goggles to Belgian healthcare authorities and local hospitals.

**Support to China during the start of the outbreak (Jan/ Feb 2020)**

**AbbVie** donated older antiviral drugs upon request from the Chinese government as an experimental option to support the growing public health crisis.
Bayer made substantial financial contributions as well as donations of several medicines to the Chinese Red Cross.

Boehringer Ingelheim (BI) made financial donations to the Chinese Red Cross to purchase medical protective equipment and also made donations of medicines.

Bristol-Myers Squibb Company and the Bristol Myers Squibb Foundation are committed to supporting communities deeply affected by COVID-19. More than $5 million in financial support and needed products (i.e., personal protection equipment) has been provided to relief efforts in affected areas around the world, including Wuhan city and Hubei province (China).

CSL Limited donation of 1 million RMB to the China Red Cross in support of efforts to combat the pandemic.

Eisai has donated 1 million yuan to the Wuhan Charity Federation NPO and provided local healthcare providers with medicines and medical relief supplies.

Johnson & Johnson provided drug-screening for antiviral properties against the novel coronavirus to assist with laboratory-based investigations to the Chinese Centre for Disease and Prevention and donated 300 boxes of HIV medication to the Shanghai Public Health Clinical Centre and Zhongnan Hospital of Wuhan University.

Lilly China made a cash donation of one million yuan (approximately $150,000) to the Red Cross, and the Lilly Foundation donated an additional $100,000 to Direct Relief, a US non-profit organization. In addition, the Lilly Foundation made a $150,000 donation to Project HOPE to help with their efforts in response to the Coronavirus.

Eisai has donated 1 million yuan to the Wuhan Charity Federation NPO and provided local healthcare providers with medicines and medical relief supplies.

MSD compiled a 1 million RMB donation for the Chinese Red Cross Foundation and supported the construction of a second specialty hospital (Leishenshan Hospital) to treat COVID-19 patients in Wuhan. Their team in China also launched online campaigns to educate the public about respiratory disease and helped provide up-to-date articles on treatment guidelines for health care professionals.

Otsuka China donated medical supplies to the Hubei Charity Federation. Supportive nutritional products were sent to support medical staff, the Tianjin Red Cross and designated hospitals in Beijing. ZOP donated 1 million RMB to Red Cross located in Jinnan Community Hangzhou Lin’an Area to buy medical supplies and personal protective equipment. LOP donated 500,000 RMB to the Sichuan Red Cross to support the local epidemic response.

Pfizer has made cash contributions to its global NGO partners who have shipped supplies to hospitals in China. Pfizer Foundation has provided $500,000 in grants to support the provision of urgently needed aid and supplies to front-line healthcare workers. This grant funding supports urgent assistance by Direct Relief and Project HOPE, who are working with local partners on the ground to provide supplies and other support to healthcare workers and health systems in affected areas of China.

Roche donated diagnostics tests, medical supplies and financial support. Genentech, a member of the Roche Group, 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.

Roche donated nearly $2m-worth of Actemra to China to help manage the COVID-19 outbreak.
KEY FACTS & FIGURES

>20
COMPANIES INVOLVED IN R&D
for therapeutics, vaccines and diagnostics

25
CLINICAL TRIALS
evaluating the effectiveness of therapeutics

350
PEOPLE ON AVERAGE IN CLINICAL TRIALS
(except large-scale Gilead + Teva trials which have >1000 participants)

$700M
IN MONETARY DONATIONS

$40M
NON-MONETARY DONATIONS

25M
DONATED UNITS OF MEDICINES AND PERSONAL PROTECTIVE EQUIPMENT

WHO LINKS
OTHER LINKS

International Clinical Trials Registry Platform
Policy Cures Research - COVID-19 R&D Tracker
COVID-19 NMA - a living mapping of ongoing research.
Global Coronavirus COVID-19 Clinical Trial Tracker