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 gained profound scientific insights from decades of experience in developing solutions for infectious diseases such as MERS, SARS, Ebola and influenza as well as in working with health authorities and regulators to swiftly bring safe and effective medicines, vaccines and diagnostics to patients.

The rapid worldwide spread of SARS-CoV-2 is a public health emergency. More than ever, we need effective international cooperation to ensure that no-one is left behind in the race to tackle this crisis. This requires coordinated, multi-stakeholder action embracing the private sector as a critical partner. IFPMA members are fully committed to bringing their unique expertise in R&D and manufacturing of therapeutics, vaccines and diagnostics to the table.

IFPMA members are also committed to collaborate closely with national regulatory agencies, academia and global health stakeholders to retain access to existing medicines and vaccines for treatment and prevention of other conditions. Clinical research into new options and treatments for serious, life-threatening diseases also remains a priority (read our Regulatory Guiding Principles here).
IFPMA has joined the global public-private partnership, ACT Accelerator, as founding partner, offering its knowledge and expertise in finding/developing novel medicines and vaccines and in building manufacturing capacity and distribution networks. IFPMA has published the Vaccines policy principles that will guide its work with the ACT Accelerator Vaccines Partnership (CoVax).

**REPURPOSE EXISTING & TEST NEW TREATMENTS**

Rapidly screen the industry’s vast libraries of medicines to identify potential treatments and undertake numerous clinical trials to test new and existing therapies.

The WHO Solidarity Trial has brought together over 100 countries working together to find effective therapeutics for COVID-19 as swiftly as possible. IFPMA members have also been reviewing their drug portfolios for potentially safe and effective assets that could help with the development of new or repurposed treatments. Gilead’s remdesivir was approved as the first COVID-19 treatment by the US FDA in May, and the EMA in June. On 24 July the EMA began reviewing the results from the RECOVERY clinical trial of dexamethasone for treating adult cases requiring respiratory support.

**Large-scale COVID-19 partnerships with broad industry involvement to speed up COVID-19 Therapeutics R&D**

The following IFPMA member companies have partnered with the COVID-19 Therapeutics Accelerator initiative, initiated by the Gates Foundation, Wellcome and Mastercard, to accelerate the development, manufacture, and delivery of vaccines, diagnostics, and treatments for COVID-19: Bayer, Boehringer Ingelheim, Bristol-Myers Squibb, Eisai, Eli Lilly, Gilead, GSK, Johnson & Johnson, Merck (known as MSD outside the U.S. and Canada), Merck KGaA, Novartis, Pfizer, and Sanofi.

The NIH set up the Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) public-private partnership to develop a coordinated research strategy for prioritizing and speeding development of the most promising treatments and vaccines. The following IFPMA member companies have partnered with the ACTIV initiative: AbbVie, Amgen, AstraZeneca, Bristol Myers Squibb, Eisai, Eli Lilly and Company, Gilead, GSK, Johnson & Johnson, Merck & Co., Inc., Novartis, Pfizer, Roche-Genentech, Sanofi, and Takeda.

The Corona Accelerated R&D in Europe (CARE) consortium, a coalition of 37 globally renowned academic institutions, pharmaceutical companies and non-profit research organizations, committed to the development of therapeutics (i) to provide an emergency response towards the current COVID-19 pandemic by drug repositioning and (ii) to address the current and/or future coronavirus outbreaks by broad-spectrum small-molecule drug discovery and/or virus-neutralizing antibody discovery. The following IFPMA members have joined the consortium: AbbVie, Astellas, Boehringer Ingelheim, Johnson & Johnson, Merck, Novartis, Pfizer, and Takeda.

AbbVie partnered with global authorities to determine the effectiveness of HIV drugs lopinavir/ritonavir in treating...
COVID-19. WHO interim trial results showed that lopinavir/ritonavir produced little or no reduction in mortality of hospitalized COVID-19 patients, hence trials were interrupted with immediate effect. AbbVie also entered into a collaboration with Harbour BioM, Utrecht University, and Erasmus Medical Center to develop a novel antibody therapeutic. AbbVie, and partners of the COVID R&D Alliance, Amgen, and Takeda, announced the start of the I-SPY COVID trial evaluating the efficacy of cenicriviroc, apremilast, and icatibant in hospitalized COVID-19 patients.

Amgen and Adaptive Biotechnologies are partnering to combine expertise to discover and develop fully human neutralizing antibodies targeting SARS-CoV-2. Amgen, and partners of the COVID R&D Alliance, AbbVie, and Takeda, announced the start of the I-SPY COVID trial evaluating the efficacy of cenicriviroc, apremilast, and icatibant in hospitalized COVID-19 patients.

Astellas In Japan, Astellas is providing compounds in response to a request from the government to cooperate in the "Basic Screening Plan for Drugs for Coronavirus Disease". Astellas is also responding to requests from EFPIA and IMI to cooperate in "Activities Aimed at Developing Drugs for the Novel Virus" and providing consultation on countermeasures.

AstraZeneca AstraZeneca signed an interagency agreement with DARPA, part of the US Department of Defense, and BARDA to support the company's efforts to develop a mAb treatment against SARS-CoV-2. The company has announced the advancement of its LAAB combination, AZD7442, into two Phase III clinical trials in more than 6,000 participants at sites in and outside the US. In ongoing trials supported by AstraZeneca, results published in Science Immunology showed that acalabrutinib, a Bruton's tyrosine kinase inhibitor, reduced markers of inflammation and improved clinical outcomes of patients with severe COVID-19 disease.

Boehringer IngelHeim is a member of the CARE consortium, leading the work stream focusing on the development of virus neutralizing antibodies. The company will also provide antiviral molecules from its legacy HIV and HCV portfolio and small molecule candidates from a complete screen of its molecule library.

Chugai Pharmabody Research Pte. Ltd. and the Agency for Science, Technology and Research in Singapore are jointly researching a therapeutic antibody to fight COVID-19. Chugai entered into a license agreement for worldwide non-exclusive rights of several Chugai's antibody engineering technologies with Eli Lilly.

CSL Group is collaborating with Takeda, Biotest AG, Bio Products Laboratory, LFB and Octapharma to accelerate development of a potential COVID-19 Hyperimmune therapy.

Daiichi Sankyo reached a basic agreement with the University of Tokyo, RIKEN and Nichi-Iko Pharmaceutical Co., Ltd. on collaborative R&D on a Nafamostat inhalation formulation for treating COVID-19.

EFPIA through the IMI, IMI associated partners and other organisations provided up to 45 million EUR to fund 8 COVID-19 R&D projects with 3 focusing on treatments.

In June, Eli Lilly dosed first patients in a Phase 1 study of LY-CoV555, the lead antibody from Lilly's collaboration with AbCellera. Eli Lilly also announced the start of a Phase 1 study for its second potential COVID-19 antibody treatment in collaboration with Junshi Biosciences. Eli Lilly entered into an agreement with NIAID to study baricitinib as an arm in NIAID's Adaptive COVID-19 Treatment Trial. Complementing this data, Eli Lilly separately started a Phase 3 study to evaluate the efficacy and safety of...
baricitinib in hospitalized adults with COVID-19. Eli Lilly is also advancing its investigational selective monoclonal antibody LY3127804 against Angiopoietin 2 to Phase 2 testing in pneumonia patients hospitalized with COVID-19. Eli Lilly received the rights to use Chugai's antibody engineering technologies for their research activities to develop next-generation COVID-19 treatments and the rights for the development and marketing of therapeutic antibodies applying the technologies.

Eisai, in collaboration with the Global Coalition for Adaptive Research and the University of Pittsburgh Medical Center, joined REMAP-COVID, a study that tests multiple interventions for the treatment of patients hospitalized with COVID-19. Eritoran, an investigational TLR4 antagonist discovered and developed by Eisai, was selected as the first investigational immune modulation therapy to be evaluated. Eisai announced that it has entered into a joint research agreement with four research organizations in Japan concerning the "Development of Therapeutics to Prevent the Aggravation of the Novel Coronavirus Infectious Disease (COVID-19)" (Grant Number: 20fk0108255).

Gilead identified remdesivir as a potential COVID-19 treatment. In April 2020, positive data emerged from the NIAID study of remdesivir. Additional data from a Phase 3 SIMPLE-severe study, and new analyses of the company's compassionate use program revealed remdesivir to improve recovery time and reduce mortality in COVID-19 patients. Gilead received an authorization from the US FDA for remdesivir in October 2020, regulatory approval by Japan in May, and conditional approval from the EMA in July. Gilead initiated a Phase 1a clinical study to evaluate the safety, tolerability and pharmacokinetics of an investigational, inhaled solution of remdesivir in healthy volunteers, for potential outpatient treatment of COVID-19. Gilead and the US FDA launched an open-label, single-arm phase 2/3 clinical trial to evaluate safety, tolerability, pharmacokinetics and efficacy of remdesivir in treating paediatric patients with moderate-to-severe COVID-19, across 30 sites in the US and Europe.

GSK and Vir Biotechnology Inc entered into a collaboration using Vir's proprietary monoclonal antibody platform technology to accelerate existing and identify new anti-viral antibodies. Vir Biotechnology and GSK announced that the first patient was dosed in a phase 2/3 study with VIR-7831 (also known as GSK4182136), a fully human anti-SARS-CoV-2 monoclonal antibody, for the early treatment of COVID-19 in patients who are at high risk of hospitalisation. GSK initiated clinical trials of otilimab, an experimental rheumatoid arthritis drug, on patients suffering from severe pulmonary COVID-19 related disease, running from May to December 2020.

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.

Johnson & Johnson expand its partnership with BARDA to accelerate the discovery of potential COVID-19 treatments. Johnson & Johnson, in partnership with the Rega Institute for Medical Research, and the University of Leuven (Belgium), are working to identify existing or new compounds with antiviral activity against COVID-19.

LEO Pharma is participating in a pharma industry initiative supported by the EU Commission to identify active compounds and compile a sample library for testing with the potential of reducing lead time for treatment development for COVID-19.

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. Merck donated 290,000 units of its interferon beta-1a (Rebif®) to the WHO for use in their global SOLIDARITY trial.
which investigates several potential therapeutics for the treatment of COVID-19.

**MSD** MSD and Ridgeback Biotherapeutics LP entered into a collaboration agreement to develop EIDD-2801, an orally available antiviral candidate currently in early clinical development for the treatment of patients with COVID-19. The candidate antiviral, renamed to MK-4882, is currently in phase 2 clinical trials.

**Novartis** Novartis initiated a 450-person study in the US to determine if the malaria drug hydroxychloroquine can effectively treat COVID-19. Novartis discontinued the study due to feasibility of recruitment. Novartis initiated a Phase III clinical trial to study canakinumab, an interleukin (IL)-1β blocker, to treat a type of severe immune overreaction called cytokine release syndrome (CRS) in people with COVID-19 pneumonia. Novartis initiated a Phase III clinical trial in collaboration with Incyte to evaluate the use of ruxolitinib for the treatment of CRS that can lead to life-threatening respiratory complications in patients with COVID-19. Novartis and Molecular Partners announced a collaboration in the form of an option and license agreement to develop, manufacture and commercialize Molecular Partners’ anti-COVID-19 DARPin® program, consisting of two therapeutic candidates, MP0420 and MP0423.

**Pfizer** Pfizer confirmed a lead compound and analogues as potent inhibitors of the SARS-CoV-2 3C-like protease. In addition, preliminary data suggest the lead protease inhibitor shows antiviral activity against SARS-CoV-2. Pfizer will perform pre-clinical confirmatory studies. Pfizer shared in vitro and clinical data regarding azithromycin which may facilitate the use of azithromycin in future research on COVID-19. Pfizer is supporting an independent Phase 2 investigator-initiated study for the use of tofacitinib in patients with SARS-CoV-2 with a grant. Pfizer and the Liverpool School of Tropical Medicine's Respiratory Infection Clinical Research Group launched two new studies to provide insights on the interaction between S. pneumoniae and SARS-CoV-2.

**Roche** Roche's tocilizumab was approved by China on March 5 to treat COVID-19 patients with lung complications and subsequently entered phase III clinical trials in the REMDACTA and COVACTA clinical trials. On 29 July, Roche announced that tocilizumab did not meet its primary and secondary endpoints of improved clinical status and mortality in COVID-19 associated pneumonia. Roche initiated a phase 3 clinical trial of tocilizumab plus remdesivir in hospitalised patients with severe COVID-19 pneumonia. Roche and Atea Pharmaceuticals announced that they are joining forces in the fight against COVID-19 to develop, manufacture and distribute AT-527, Atea's investigational oral direct-acting antiviral, to people around the globe.

**Sanofi** Sanofi entered into a partnership with Regeneron Pharmaceuticals to start a clinical program evaluating sarilumab, a drug originally to treat arthritis, in patients hospitalized with severe COVID-19. A US phase 3 clinical trial in COVID-19 patients requiring mechanical ventilation did not meet its primary and key secondary endpoints, and was subsequently halted. Detailed results will be submitted to a peer-reviewed publication later this year.

**Shionogi** Shionogi identified various number of promising lead compounds against SARS-CoV-2 through a collaborative research effort with the Hokkaido University Research Center for Zoonosis Control. The company aims to start clinical trials in FY2020.

**Sumitomo Dainippon Pharma** Sumitomo Dainippon Pharma donated 10 million yen to the Kitasato Institute's Project for COVID-19 to identify clinical candidates for the treatment of COVID-19 through a large-scale screening of approved pharmaceuticals.
Takeda and CSL Group formed the CoVig-19 Plasma Alliance with other leading global plasma companies to develop a potential plasma-derived therapy for treating COVID-19. The CoVig-19 Plasma Alliance expanded to comprise 10 companies and attracted the support of major companies and organizations. In parallel, the Alliance confirmed it will work with NIAID to test the safety, tolerability and efficacy of the hyperimmune therapy in adult patients with COVID-19. Takeda, and partners of the COVID R&D Alliance AbbVie and Amgen, announced the start of the I-SPY COVID trial evaluating the efficacy of cenicriviroc, apremilast, and icatibant in hospitalized COVID-19 patients who require high-flow oxygen.

Teva is actively looking through its range of products to determine if any products may be relevant for COVID-19.

UCB In the US, UCB is working with the Seattle Structural Genomics Center for Infectious Disease to identify crystal structures of SARS-CoV-2 proteins. In the UK, the company partnered with Diamond Light Source and the University of Oxford to design inhibitors of SARS-CoV-2's main protease for treatment of COVID-19 patients.

SHARE REAL-TIME CLINICAL TRIAL DATA WITH GOVERNMENTS, COMPANIES & THE PUBLIC
Share real-time clinical trial data with governments and other companies around the world to advance the development of additional therapies.

"Open Access" data-sharing channels are key to securing a response capacity as we have seen with influenza networks. The speed with which researchers have understood this novel strain of virus and got therapeutics and vaccines into clinical trials is unprecedented. The Global Initiative on Sharing All Influenza Data (GISAID), an open access platform part-funded by the private sector, played a critical role in sharing the first genome sequences of the novel coronavirus – a vital element in speeding up information sharing among scientists and public health authorities.

IFPMA & EFPIA support EMA’s initiative to implement exceptional transparency measures that are targeting regulatory activities for the assessment and approval of medicines and vaccines for COVID-19. The biopharmaceutical industry represented by IFPMA and EFPIA encourage other national regulatory authorities to follow EMA’s example.

AbbVie worked closely with European health authorities, US FDA, US CDC, NIH, and BARDA to research the effectiveness of lopinavir/ritonavir in clinical studies. Trials were interrupted immediately after no reduction in mortality of hospitalized COVID-19 patients was noticed.

Amgen’s subsidiary deCODE genetics, Iceland’s Directorate of Health and the National University Hospital published a population-based study of the early spread of SARS-Cov-2 in Iceland’s population in the NEJM. Amgen, together with AstraZeneca, Eli Lilly, Roche’s Genentech subsidiary, GSK and AbCellera, has been allowed to share manufacturing information that could help speed up coronavirus antibody production by the US Department of Justice, since 23 July.

Astellas In Japan, Astellas is providing compounds in response to a request from the government to cooperate in the "Basic
AstraZeneca and partner Oxford University are undertaking clinical trials in the US, UK, Brazil, and South Africa for their co-developed candidate COVID-19 vaccine AZD1222. Interim results, published in *The Lancet*, showed that AZD1222 was tolerated and generated robust immune responses against the SARS-CoV-2 virus in all evaluated participants. On 6 September 2020, as part of the randomised, controlled clinical trials of the AstraZeneca Oxford coronavirus vaccine, AZD1222, standard review process triggered a voluntary pause to vaccination across all global trials to allow review of safety data by independent committees, and international regulators. Clinical trials for the AstraZeneca Oxford coronavirus vaccine, AZD1222, resumed across the world with regulators in the US, UK, Brazil, South Africa and Japan confirming that it was safe to do so.

AstraZeneca announced the advancement of its LAAB combination, AZD7442, into two Phase III clinical trials in more than 6,000 participants at sites in and outside the US. Published in *Science Immunology*, results showed that acalabrutinib, calquence showed promising clinical improvement in majority of 19 hospitalised COVID-19 patients. The CALAVI Phase II trials for Calquence (acalabrutinib) in patients hospitalised with respiratory symptoms of COVID-19 did not meet the primary efficacy endpoint.

AstraZeneca is sharing manufacturing information concerning COVID-19 antibody production with other companies. Please see previous entries on Amgen for more info.

AstraZeneca published the full protocol for its COVID-19 vaccine study.
bamlanivimab (LY-CoV555) 700 mg. Bamlanivimab is authorized for the treatment of mild to moderate COVID-19 in adults and pediatric patients 12 years and older with a positive COVID-19 test, who are at high risk for progressing to severe COVID-19 and/or hospitalization.

**Gilead** identified remdesivir as a potential COVID-19 treatment. In April 2020, positive data emerged from the NIAID study of remdesivir. Additional data from a Phase 3 SIMPLE-severe study, and new analyses of the company’s compassionate use program revealed remdesivir to improve recovery time and reduce mortality in COVID-19 patients. Further results demonstrate that treatment with remdesivir result in a faster time to recovery than previously reported. Gilead announced that the US FDA has approved the antiviral drug Veklury® (remdesivir) for the treatment of patients with COVID-19 requiring hospitalization.

**GSK** is sharing manufacturing information concerning COVID-19 antibody production with other companies. Please see previous entries on Amgen for more info. GSK and Vir Biotechnology announced the global expansion to Phase 3 of the COMET-ICE study evaluating VIR-7831, a fully human antiSARS-CoV-2 monoclonal antibody for the early treatment of COVID-19 in patients who are at high risk of hospitalisation.

**Johnson & Johnson** and BARDA partnered for the phase 1/2a first-in-human clinical trials of the candidate vaccine Ad26.COV2.S. Johnson & Johnson announced that they selected a lead COVID-19 vaccine candidate, Ad26.COV2-S, in March 2020. Results from pre-clinical studies showed a robust immune response in non-human primates against SARS-CoV-2. Following positive interim results from Phase 1/2a clinical study, a Phase 3 clinical trial of the vaccine commenced in September, and would enroll up to 60,000 volunteers across three continents and in order to study the safety and efficacy of a single vaccine dose versus placebo in preventing COVID-19. The company temporarily paused further dosing in all its COVID-19 vaccine candidate clinical trials, including the Phase 3 ENSEMBLE trial, due to an unexplained illness in a study participant. Following its guidelines, the participant’s illness would be reviewed and evaluated by the ENSEMBLE independent Data Safety Monitoring Board (DSMB) as well as its internal clinical and safety physicians. After the temporary pause, Johnson & Johnson announced the preparation to resume recruitment in the pivotal Phase 3 ENSEMBLE trial of its investigational Janssen COVID-19 vaccine in the United States.

**MSD**, BARDA and the US-based ISB are collaborating to investigate and define the molecular mechanisms of SARS-CoV-2, COVID-19 and identifying targets for medicines and vaccines. Findings will be made available to the worldwide scientific and biomedical community.

**Novartis** announced new data from an interim analysis for the trial evaluating the efficacy and safety of canakinumab in hospitalized patients with COVID-19 pneumonia and cytokine release syndrome. The ongoing trial failed to meet its primary and secondary endpoint.

**Pfizer** in its Five-Point-Plan published in March, Pfizer commits to making tools that they develop available on an open source platform and to share data and learnings gained with other companies in real time to advance therapy and vaccine development. The company also commits to sharing clinical development and regulatory expertise to support promising drug candidates of smaller biotech companies. Following up on its commitments, Pfizer confirmed a lead compound and analogues as potent inhibitors of the SARS-CoV-2 3C-like protease. In addition, preliminary data suggest the lead protease inhibitor shows antiviral activity against SARS-CoV-2. Pfizer will perform pre-clinical confirmatory studies. Pfizer also shared in vitro and clinical data regarding azithromycin which may facilitate the use of azithromycin in future research on COVID-19. Early positive data from Pfizer & BioNTech’s vaccine development partnership was published in early July 2020. Initial data from their ongoing German Phase 1/2 trial, released in late July, demonstrated the ability of one of their vaccine candidates, BNT162b1, to elicit high SARS-CoV-2 neutralizing titers. In August 2020, the companies shared additional
Phase 1 safety and immunogenicity data from their ongoing U.S. study. Pfizer and BioNTech announced preliminary preclinical data in mouse and non-human primate models from their BNT162b2 mRNA-based vaccine program against SARS-CoV-2. Pfizer published the full protocol for its COVID-19 vaccine study to reinforce Pfizer’s commitment to scientific and regulatory rigor.

As part of a two-day virtual Investor Day, Pfizer and BioNTech continued to share several updates from their BNT162 mRNA-based vaccine program against SARS-CoV-2. Pfizer and BioNTech announced their mRNA-based vaccine candidate, BNT162b2, against SARS-CoV-2 demonstrated evidence of efficacy against COVID-19 in participants without prior evidence of SARS-CoV-2 infection. Based on the first interim efficacy analysis conducted on November 8, 2020 by an external, independent Data Monitoring Committee from the Phase 3 clinical study, the vaccine candidate was found to be more than 90% effective in preventing COVID-19 in participants without evidence of prior SARS-CoV-2 infection in the first interim efficacy analysis.

Roche

In late July, Roche announced that tocilizumab did not meet its primary and secondary endpoints of improved clinical status and mortality in COVID-19 associated pneumonia in their global clinical trial. Roche announced that the phase III EMPACTA study met its primary endpoint, showing that patients with COVID-19 associated pneumonia who received tocilizumab plus standard of care were less likely to progress to mechanical ventilation or death.

Roche’s subsidiary Genentech is sharing manufacturing information concerning COVID-19 antibody production with other companies. Please see previous entries on Amgen for more info.

Sanofi

Sanofi is collaborating with CEPI and sharing its vaccine R&D experience and expertise to advance vaccine solutions. In July, Sanofi announced that a US phase 3 clinical trial of sarilumab 400mg in COVID-19 patients requiring mechanical ventilation did not meet its primary and key secondary endpoints, and was subsequently halted. Detailed results will be submitted to a peer-reviewed publication later this year. In September, the company also announced that sarilumab at a dose of 200 mg or 400 mg in severely or critically ill patients hospitalized with COVID-19 did not meet its primary endpoint and key secondary endpoint when comparing it to placebo added to usual hospital care. Sanofi and GSK started the Phase 1/2 clinical trial for their adjuvanted COVID-19 vaccine.

Sanofi and Translate Bio announced the preclinical results for MRT5500, a mRNA-based vaccine candidate against SARS-CoV-2, which demonstrated a favorable immune response profile against SARS-CoV-2. These data support the selection of MRT5500 for clinical development. Full results are available here.

Sumitomo Dainippon Pharma

Sumitomo Dainippon Pharma collaborates in the “COVID-19 Research Database” consortium to provide researchers with free access to the medical information database.

Takeda

Takeda partnered with IMI to leverage collective expertise to develop inhibitors to help prevent future outbreaks. The CoVlg-19 Plasma Alliance, an unprecedented collaboration of leading plasma companies supported by global organizations outside the plasma industry, confirmed that patients are being enrolled in the ITAC Phase 3 clinical trial sponsored by the NIAID, part of the NIH. The investigational H-Ig materials for the trial would be provided by CSL Behring and Takeda on behalf of the CoVlg-19 Plasma Alliance, as well as by two other companies.
As of 12 November 2020, the WHO reports 48 candidate vaccines in clinical evaluation and 164 candidate vaccines in preclinical evaluation. Several biopharmaceutical companies are researching vaccine candidates and sharing existing technologies in a way that can be leveraged to allow a rapid upscale of production once a vaccine candidate is identified.

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

**AstraZeneca** and the University of Oxford joined forces for the development and distribution of the University’s potential recombinant adenovirus vaccine. A Phase I/II vaccine clinical trial to assess safety, immunogenicity and efficacy of the vaccine candidate, AZD1222, was initiated in April 2020. Interim results, published in *The Lancet*, showed that AZD1222 was tolerated and generated robust immune responses against the SARS-CoV-2 virus in all evaluated participants. AstraZeneca received support of more than $1bn from BARDA for the development, production and delivery of the vaccine. The development programme would include a Phase III clinical trial with 30,000 participants and a paediatric trial.

**CSL Group/Seqirus** partnered with the University of Queensland’s COVID-19 vaccine development program to provide technical expertise as well as a donation of Seqirus’ proprietary adjuvant technology, MF59®, to the University’s preclinical development program.

**Daiichi Sankyo** is developing an mRNA vaccine for COVID-19. The company is also participating in "Fundamental Research on the Control of a Novel Coronavirus", an initiative supported by the AMED.

**GSK** and Sanofi joined forces to develop an adjuvanted vaccine for COVID-19, using innovative technologies from both companies. The vaccine candidate started the Phase 1/2 clinical trial. GSK is also collaborating with the University of Queensland, Clover Biopharmaceuticals and Xiamen Innovax Biotech Co. GSK’s scientific collaboration with Clover Pharmaceuticals to develop an adjuvanted COVID-19 vaccine entered into a Phase 1 human clinical study in June 2020. Another collaboration between GSK and Medicago aims to develop and evaluate a COVID-19 candidate vaccine combining Medicago’s recombinant Coronavirus Virus-Like Particles with GSK’s pandemic adjuvant system. The two companies announced the start of Phase 2/3 clinical trials of its plant-derived vaccine candidate for COVID-19 to evaluate its efficacy, safety, and immunogenicity.

**Johnson & Johnson** expedited its investigational coronavirus vaccine program through an expanded collaboration with BARDA. Both have committed more than $1 billion of investment to co-fund vaccine research, development, and clinical testing. Johnson & Johnson selected a lead COVID-19 vaccine candidate, Ad26.COV2-S, in March 2020. Results from pre-clinical studies showed a robust immune response in non-human primates against SARS-CoV-2. Following
positive interim results from Phase 1/2a clinical study, A Phase 3 clinical trial of the vaccine commenced in September, and would enroll up to 60,000 volunteers across three continents and in order to study the safety and efficacy of a single vaccine dose versus placebo in preventing COVID-19.

Johnson & Johnson also established a collaboration with Beth Israel Deaconess Medical Center to support the development of a preventive vaccine candidate for COVID-19. MSD and IAVI, a nonprofit scientific research organization dedicated to addressing urgent, unmet global health challenges, partnered to advance the development and global clinical evaluation of a SARS-CoV-2 vaccine candidate. This vaccine candidate would use the recombinant vesicular stomatitis virus (rVSV) technology that is the basis for MSD's Ebola Zaire virus vaccine, ERVEBO®. MSD acquired Vienna-based biotech company Themis. The acquisition is expected to accelerate the development of Themis' COVID-19 vaccine candidate in the near term and in the longer-term MSD is planning to establish a pandemic preparedness capability.

MSD

Novartis

Novartis' AveXis division partnered with Massachusetts Eye and Ear and Massachusetts General Hospital, members of Mass General Brigham, entering into a manufacturing agreement to contribute to the development and production of their novel genetic vaccine.

Novartis

Pfizer

Pfizer and BioNTech entered into a partnership to jointly develop BioNTech’s an mRNA-based vaccine candidate to prevent a COVID-19 infection. Early positive data from the most advanced of four investigational vaccine candidates from their BNT162 mRNA-based vaccine program, Project Lightspeed, emerged in early July 2020. Initial data from their ongoing German Phase 1/2 trial, released in late July, further demonstrated the ability of BNT162b1 to elicit high SARS-CoV-2 neutralizing titers. In August 2020, the companies shared additional Phase 1 safety and immunogenicity data from their ongoing U.S. study. A global (except for China) Phase 2/3 safety and efficacy clinical study to evaluate their chosen lead COVID-19 vaccine, BNT162b2, commenced on 28 July 2020. Pfizer and BioNTech announced that, after conducting the final efficacy analysis in their ongoing Phase 3 study, their mRNA-based COVID-19 vaccine candidate, BNT162b2, met all of the study's primary efficacy endpoints. Analysis of the data indicates a vaccine efficacy rate of 95%. Pfizer and BioNTech also received a Fast Track designation from the US FDA for two of the companies’ four investigational vaccine candidates from their BNT162 mRNA-based vaccine program. The two companies submitted an amended protocol to the US FDA to expand the enrollment of their Phase 3 pivotal COVID-19 vaccine trial to up to approximately 44,000 participants which also allows for the enrollment of new populations. Pfizer and BioNTech announced the initiation of a rolling submission to the EMA for BNT162b2.

Pfizer

Sanofi

Sanofi and GSK joined forces to develop an adjuvanted vaccine for COVID-19, using innovative technologies from both companies. The vaccine candidate started Phase 1/2 clinical trial. Sanofi announced a collaboration with 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 partnered 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, which was expanded in 2020.

Sanofi

Shionogi

Shionogi's subsidiary UMN Pharma Inc. is pursuing the discovery and development of a recombinant protein vaccine, supported by the AMED. Shionogi reports that, in parallel and in collaboration with the NIID, an immunogenicity testing of protein antigens and adjuvant candidates added to vaccine formulations have been initiated.

Shionogi

UCB

UCB is collaborating with the University of Oxford on developing a vaccine.
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 ramping 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.

**EFPIA** through the IMI, with IMI Associated Partners and other organisations has provided up to 45 million EUR to fund 8 COVID-19 R&D projects with 5 focusing on diagnostics.

**GSK** is partnering with AstraZeneca and Cambridge University to create a state-of-the-art, high-throughput testing laboratory in Cambridge, which is introducing state-of-the-art robotics, automation and other diagnostic innovations to optimise COVID-19 testing. GSK is also conducting large-scale testing at its facility in Rixensart, Belgium.

**GSK Consumer Healthcare** is teaming up with Mammoth Biosciences to develop an accurate, easy-to-use, fully disposable, rapid and handheld test that consumers and healthcare providers in clinics can use to detect active SARS-CoV-2. The companies are aiming to have a device submitted for FDA EUA review before the end of 2020.

**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 entered into an exclusive distribution agreement for the VitaPCR™ SARS-CoV-2 assay kit.

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

**Otsuka** and Denka Company announced to co-market the rapid-diagnostic test kit QuickNavi™ to medical
Roche received an EUA 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 has also received an EUA from the US FDA for its diagnostic kit the cobas® SARS-CoV-2 & Influenza A/B Test for use on the cobas® 6800/8800 Systems. This test is intended for the simultaneous qualitative detection and differentiation of SARS-CoV-2, Influenza A and Influenza B.

Roche announced the launch of its Elecsys® Anti-SARS-CoV-2 S antibody test for markets accepting the CE Mark. Roche also received an EUA 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.

Shionogi marketed the IgG/IgM Antibody-test Kit for COVID-19 as a research reagent in Japan since June 3, 2020 to be useful for epidemiological surveillance and studies of SARS-CoV-2/COVID-19 aiming to determine the number of individuals previously infected with SARS-CoV-2. Shionogi had entered into an agreement with Micro Blood Science Inc., the licensor of the kit.

Shionogi signed a license agreement with Nihon University, Gunma University, and Tokyo Medical University to develop new rapid diagnostic methods for COVID-19, using an innovative nucleic acid amplification technique.

Takeda is partnering with public entities and other pharmaceutical companies through the 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.

SECURE ESSENTIAL SUPPLIES FOR OTHER MEDICINES & VACCINES

Work to secure continuity of supply for all essential medicines, and vaccines for patients with other life-threatening diseases, urging governments to implement policies and decisions that facilitate access for all those in need.

IFPMA member companies are committed to ensure the continued supply of essential medicines and vaccines for patients suffering from chronic illnesses and other health conditions. So far, they have found no obvious near-term impacts on medicine and vaccine availability. Companies are working to prevent and mitigate any potential shortages through close coordination with national regulatory authorities and other global stakeholders, including the WHO.
The threat of falsified medicines is rising and targeting existing products but also new potential treatments against COVID-19. IFPMA and its members continue to tackle the global public health threat posed by falsified medical products, and to support the Fight the Fakes campaign (Statement).

**AbbVie** does not anticipate disruption to the supply of HIV medicines as a result of investigating their effectiveness against COVID-19.

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

**Astellas** maintains an adequate inventory level of raw materials and finished products, cooperating with outsourcing manufacturers and suppliers of raw materials.

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

**Biogen** does not anticipate any interruptions to its supply chain, and is diminishing any impact the COVID-19 pandemic has on future manufacturing capabilities.

**Boehringer Ingelheim** ensured further discovery, development, production and supply of its products that are needed by patients around the globe.

**Bristol-Myers Squibb** has made sure raw materials and products reach their markets and clinical sites and does not foresee any disruption due to the pandemic.

**Chiesi** continued production of all medicines without interruption at sites in Italy, Brazil, France and other countries.

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

**Daiichi-Sankyo** was monitoring the evolving situation very carefully to maintain supply and delivery of these medicines, and does not foresee any shortages.

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

**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.

**Gilead** has no manufacturing issues or supply shortages with any Gilead products, including HIV and hepatitis portfolios.

**Grünenthal** is not experiencing any significant supply shortages and is continuously monitoring the current situation.

**GSK** increased production of high demand products (e.g. multi-vitamins, respiratory medicines and antibiotics).

**Ipsen** is monitoring supply chains with national and international suppliers and does not anticipate any supply shortages.

**LEO Pharma** is taking additional measures to avoid any shortages of medicines or raw materials and to mitigate any
Lundbeck announced that its supply chain remains intact and it has not experienced any supply disruptions. Novartis subsidiary Sandoz was maintaining prices on a basket of essential medicines that may help in the treatment of COVID-19. Novartis and the AU through the AMSP announced a new collaboration to facilitate the supply of medicines from the Novartis Pandemic Response Portfolio to the AU member states and Caricom countries.

Novo Nordisk is ensuring the supply of lifesaving medicines for people with serious chronic diseases across the globe, using their experience with Chinese lockdown measures to assure continuity of service.

Roche is ensuring an adequate supply of medicines, calling upon governments to work with the industry to keep global manufacturing and supplies running.

Servier is ensuring the continuity of its products and is providing its expertise to the multi-stakeholder partnership “Health Innovation Coalition – Health Crisis” in France.

Sumitomo Dainippon Pharma strives to ensure a stable supply of products and business continuity.

Takeda is monitoring the situation as it evolves and will take all necessary actions in an effort to ensure supply continuity for patients.

Teva has inventory and redundancy plans in place to address potential shortfalls, with their supply chain remaining largely uninterrupted.

INCREASE AND SHARE MANUFACTURING CAPACITY & SECURE ESSENTIAL SUPPLIES FOR COVID-19 MEDICINES AND VACCINES
Increase our manufacturing capabilities and share available capacity to ramp up production once a successful vaccine or treatment is developed.

Collaboration in fast-tracking the development of therapeutics and new vaccines creates networks of centres of excellence that can deliver a real impact and a preparedness infrastructure that in turn can be mobilized for future outbreaks. Companies are partnering with manufacturers and other biopharmaceutical companies to extensively scale-up at-risk production capacity, particularly for COVID-19 vaccines. Building up manufacturing capacity now – before clinical trials have concluded – will make it possible to more quickly secure and dispense a working vaccine.

COVID-19 vaccines

AstraZeneca In April 2020, AstraZeneca (AZ) and the University of Oxford joined forces for the development, worldwide
manufacturing and distribution of the vaccine, developed by the Jenner Institute and Oxford Vaccine Group, at the University of Oxford.

By May, AZ concluded the first agreements for at least 400 million doses and secured total manufacturing capacity for one billion doses.

By summer 2020, AZ reached manufacturing and supply deals with various countries and organisations:

- In early June, AZ reached a $750m agreement with CEPI and Gavi to support the manufacturing, procurement and distribution of 300 million doses of the vaccine, with delivery starting by the end of the year. In addition, AstraZeneca reached a licensing agreement with Serum Institute India to supply one billion doses for low and middle-income countries, with a commitment to provide 400 million before the end of 2020.
- In mid-August, AZ concluded an agreement with the European Commission to supply up to 400 million doses of the AZD1222 COVID-19 vaccine. Building on the existing agreement with Europe’s Inclusive Vaccines Alliance spearheaded by Germany, France, Italy and the Netherlands, this new agreement will give all EU member states the option to access the vaccine in an equitable manner at no profit during the pandemic.
- In mid-November, AZ concluded an agreement with the Swiss federal government for the delivery of up to 5.3 million doses of vaccine, provided it successfully passes the clinical trial phase and is approved by Swissmedic.

To expand manufacturing capacity of AZ’s vaccine candidate AZD1222, the company also entered into collaborations with Catalent Biologics (Italy), Symbiosis Pharmaceutical Services (UK), Oxford Biomedica (UK), Emergent BioSolutions, BioKangtai (China), and R-Pharm (Russia).

Daiichi Sankyo was selected by the Ministry of Health, Labour and Welfare of Japan to be a provider for the Japanese Government’s “Emergent Initiative to Build Production Capacity for COVID-19 Vaccines” with respect to Daiichi Sankyo’s mRNA vaccine for COVID-19. Daiichi-Sankyo announced its agreement to proceed with discussions with AstraZeneca for the stable supply in Japan of a potential novel corona virus vaccine being developed by AstraZeneca and Oxford University.

GSK Under GSK and Sanofi vaccine development collaboration, both companies commit to create and supply sufficient quantities of their vaccine candidate. Both companies bring significant manufacturing capacity, and, if successful, they will be able to make hundreds of millions of doses annually by the end of next year.

In late May, GSK confirmed its intention to manufacture 1 billion doses of its pandemic vaccine adjuvant system, in 2021, to support the development of multiple adjuvanted COVID-19 vaccine candidates.

In summer 2020, GSK and Sanofi reached manufacturing and supply deals with various countries and organizations:

- They reached an agreement with the UK Government for the supply of up to 60 million doses of a COVID-19 vaccine.
- Their vaccine candidate was selected for “Operation Warp Speed” to supply the US with 100 million doses of their COVID-19 vaccine. Under the agreement, the US will provide funding of up to $2.1 billion – parts of it to be used for manufacturing scale up.
- They signed an advanced purchase agreement with the European Commission for the supply of up to 300 million doses of their COVID-19 vaccine.
- They reached an agreement with the Government of Canada to supply up to 72 million doses of their COVID-19 vaccine.
- They signed a Statement of Intent with Gavi, the legal administrator of the COVAX Facility, to make available 200 million doses of their COVID-19 vaccine.
In April 2020, Johnson & Johnson (J&J) announced a collaboration with Emergent BioSolutions to expand the manufacturing capacity of its lead investigational COVID-19 vaccine candidate, Ad26.COV2-S. In July, Emergent BioSolutions and Janssen Pharmaceutical Companies of J&J announced a five-year manufacturing services agreement for large-scale drug substance manufacturing for Ad26.COV2-S. J&J also signed a deal with Catalent to accelerate rapid scale-up of manufacturing capacity over the coming months to support the production of J&J’s vaccine candidate. Aspen announced that it entered into a preliminary agreement with Janssen Pharmaceuticals, for the technical transfer and proposed commercial manufacture of their COVID-19 vaccine candidate, Ad26.COV2-S.

In summer 2020, J&J signed manufacturing and supply deals with various countries:

- J&J entered into an agreement with the US for the large scale domestic manufacturing and delivery of 100 million doses of J&J’s vaccine candidate for use in the US following approval or EUA by the US FDA.
- J&J also agreed to an Advance Purchase Agreement with the European Commission to provide 200 million doses of its COVID-19 vaccine candidate to EU Member States. The EU Member States also have the option to secure up to 200 million additional doses.
- J&J has also agreed in principle to supply the UK Government with initially 30 million doses of its vaccine candidate, Ad26.COV2.S. The UK Government has the option to purchase an additional 22 million doses.
- J&J also agreed in principle with the Government of Canada to supply the country with 38 million doses of its vaccine candidate.

Merck partnered with the Jenner Institute for the large-scale production of its Covid-19 vaccine candidate, ChAdOx1 nCoV-19. Merck expanded its capacity to keep up with a surge in demand of materials to mass-produce COVID-19 vaccines.

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. The companies plan to supply up to 100 million doses worldwide by the end of 2020 of their lead vaccine candidate BNT162b2 against SARS-CoV-2 and approximately 1.3 billion doses by the end of 2021.

In summer 2020, Pfizer and BioNTech reached manufacturing and supply deals with various countries:

- They announced the execution of an agreement with the HHS and the US Department of Defense, which will provide the US with 100 million doses of the vaccine candidate, after approval or EUA from the US FDA. The US government will pay the companies $1.95 billion upon the receipt of the first 100 million doses, with the option of acquiring up to an additional 500 million doses.
- They signed an agreement with the UK for the supply of 30 million doses of their BNT162 mRNA-based vaccine candidate, as well as an agreement with the Government of Canada, and with the Ministry of Health, Labour and Welfare in Japan for the supply of 120 million doses.
- They received the authorization from the European Commission to conclude a contract for the supply of up to 300 million doses of their investigational BNT162 mRNA-based vaccine candidate against SARS-CoV-2 to European Union (EU) Member States.
- They signed an agreement with the Ministry of Health, Labour and Welfare (MHLW) in Japan to supply 120 million doses of BNT162 mRNA-based vaccine candidate against SARS-CoV2, subject to clinical success and regulatory approval.
- They announced an agreement with the Government of Canada to supply their BNT162 mRNA-based
vaccine candidate against SARS-CoV2, subject to clinical success and Health Canada approval.

- They reached an agreement with the Government of Australia to provide 10 million doses of BNT162 mRNA-based vaccine candidate against SARS-CoV2, should the vaccines be proven safe and effective.

**Sanofi**
Under 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 regarding their joint COVID-19 vaccine development.
Sanofi will invest €610 million to create a new production site and research center in France, both dedicated to increase its vaccines research and production capacities. This way it will also contribute in responding to future pandemic risks.

**CSL/ Seqirus**
CSL partners with CEPI and the University of Queensland to accelerate the development, manufacture and distribution of the University's COVID-19 vaccine candidate. If trials are successful, initial large-scale production of the vaccine will happen at CSL's biotech manufacturing headquarters in Melbourne. The company estimates that the scale-up can help generate millions of doses by the end of next year.
CSL announced it has signed a Heads of Agreement (HoA) with the Australian Government for the supply of 51 million doses of the University of Queensland's (UQ) COVID-19 vaccine candidate (V451), and a separate HoA with AstraZeneca to manufacture the Oxford University candidate (AZD1222), should clinical trials of both prove successful.

**Shionogi**
Shionogi is making preparations to offer its vaccine to 10 million people as early as possible by collaboration with Api Co., Ltd. and its group company UNIGEN Inc. It also applied for the "Grant to Promote the Domestic Investment Project to Combat the Supply Chain" publicly established by the Japanese Ministry of Economy, Trade and Industry and three companies. It has begun preparing commercial production in advance of the Ministry’s review of the application.

**Takeda**

**COVID-19 therapeutics**

**Eli Lilly** and AbCellera collaborate on AbCellera’s rapid pandemic response platform for the rapid development, manufacturing and distribution of therapeutic antibodies.
Eli Lilly and Amgen announced a global antibody manufacturing collaboration to significantly increase the supply capacity available for Lilly's potential COVID-19 therapies.
Eli Lilly announced an initial agreement with the U.S. government to supply 300,000 vials of bamlanivimab (LY-CoV555) 700 mg, an investigational neutralizing antibody, for $375 million. The U.S. government will accept the vials of bamlanivimab if it is granted an EUA by the U.S. FDA.

**Gilead** has proactively scaled up manufacturing of remdesivir to increase available supply as rapidly as possible in anticipation of potential future supply needs. In August 2020, Gilead announced that it had increased supply more than 50-fold since January, and was likely able to meet real-time global demand starting in October. The company is planning to produce more than two million treatment courses by the end of 2020, and several million more in 2021, if needed.
To further expand global supply, Gilead is in discussions with leading chemical and pharmaceutical manufacturing companies about their ability, under voluntary licenses, to produce remdesivir for Europe, Asia and the developing world at
least through 2022. Gilead also negotiated long-term voluntary licenses with several generic drugmakers in India and Pakistan and is in active discussions with the Medicines Patent Pool to license remdesivir, and with UNICEF to deliver the drug using its established distribution networks.

As of August 2020, Gilead’s manufacturing network for remdesivir includes more than 40 companies in North America, Europe and Asia. Gilead also reached an agreement with the EU Commission to secure sufficient doses of remdesivir for 30,000 patients presenting severe COVID-19 symptoms. In addition, the company also signed a JPA with the EU Commission that will enable rapid and equitable access to remdesivir.

Pfizer announced a multi-year agreement with Gilead to manufacture and supply Gilead’s remdesivir.

Roche and Regeneron joined forces to significantly increase global supply of REGN-COV2, Regeneron’s investigational antiviral antibody combination, to at least three and a half times the current capacity, with the potential for even further expansion.

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

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.

---

**SUPPORT GLOBAL HEALTHCARE SYSTEMS IN THE FIGHT AGAINST COVID-19**

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 helping to boost healthcare system capacities and protect healthcare workers, particularly in the hardest-hit and vulnerable countries that 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 gain access to necessary health care services. This experience has since repeated around the world as the virus spreads with increased efforts with member companies donating PPE and money to ease burdens on hard-pressed health services.

**Support to affected countries worldwide (on-going)**

AbbVie donated $35 million to COVID-19 relief efforts. In the US, it supported healthcare capacity for hospitals and secured access to food and essential supplies for vulnerable populations. In Europe, it provided critical equipment and supplies to patients and front-line healthcare workers in hard-hit countries.

AbbVie made donations to 26 community non-profit organizations to support COVID-19 relief efforts, totaling $5 million. The AbbVie COVID-19 Community Resilience Fund helped these organizations to support front-line
healthcare workers and vulnerable populations in hard-hit communities.

AFIDRO donated medical equipment to the Central Military Hospital of Bogota (Colombia) to strengthen the COVID-19 pandemic response.

Almirall donated topical cream to healthcare professionals in Spain and the UK, repurposed production facilities in Germany to manufacture antibacterial gels, and donated PPE to healthcare workers in Spain.

Amgen and the Amgen Foundation donated $12.5 million to support US and global relief efforts for communities with critical needs impacted by COVID-19.

Amgen donated $1 million to support AHA’s COVID-19 rapid response efforts in the cardiovascular health community.

APCRG donated 35,000 Georgian lari to the STOPCOV fund (State Treasury Fund) created by the Government of Georgia to fight COVID-19.

APIFARMA donated medical equipment to healthcare professionals in Spain and the UK, repurposed production facilities in Germany to manufacture antibacterial gels, and donated PPE to healthcare workers in Spain.

Astellas and the Astellas Global Health Foundation donated up to $2 million of financial assistance to meet the urgent demand for resources to help US patients, healthcare workers, and first responders in the fight against COVID-19.

Astellas also donated €150,000 euros worth of necessary supplies to public medical institutions and civil society organizations in Italy, and €200,000 to Spain's health ministry to secure the supply of goods to medical institutions.

Astellas authorized paid leave (in accordance with each country's provision) to employees who are medically qualified and wish to volunteer within their community.

Astrazeneca donated 9 million face masks to healthcare workers around the world and partnered with WEF’s COVID Action Platform to identify countries in greatest need.

Bayer made financial donations to Lombardy, Brazil (€1 million), and France (€1 million) to support COVID-19 relief efforts. The company also donated 1 million chloroquine tablets to Italy; and another 3 million tablets to the US.

Bayer produced hand sanitizers in Indonesia based on their expertise from their plants in Germany.

Bayer supplied German hospitals with ventilators, provided health care workers with masks, provided the German Army with 600,000 chloroquine tablets, and supported employees wishing to volunteer in the local health system by offering 4 weeks paid leave.

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

Boehringer Ingelheim contributed €5.8 million from their Global Support Program donations fund, provided paid leave for its 51,000 employees to volunteer for COVID-19 relief, donated over $1 million to protect healthcare professionals, and established a €580,000 relief fund for social entrepreneurs and their communities in Kenya and India via its Making More Health program.

Bristol-Myers Squibb and the BMS Foundation have contributed more than $31 million in financial support and needed products (e.g. PPE and medical equipment) to relief efforts in 43 countries. The BMS Foundation has supported nearly 50 organizations in the U.S. and more than 150 organizations globally that care for patients and that support those on the frontlines of the COVID-19 response. In addition, it has contributed funding to support the work
of more than 40 patient advocacy groups and professional societies. Also, to support research, education, and a wide range of efforts to benefit patients in need, BMS is engaging with more than 250 patient and professional organizations.

**BMS**
BMS partnered with GRYT Health to develop the COVID Advocacy Exchange, a virtual platform to unite patient advocacy organizations, patients, policy makers, healthcare practitioners and industry in the exchange of information. It supported research, education, and a wide range of efforts to benefit patients in need, BMS is engaging with more than 250 patient and professional organizations.

**Chiesi**
Chiesi donated €3 million to COVID-19 relief efforts in Italy, donated 50,000 units of sanitizing hand gel to public transport operators and PPE to hospitals, partnered with associations of general practitioners providing advice and guidance, and supported the purchase of respiratory equipment in hospitals.

**Chugai**
Chugai donated JPY 50 million to support healthcare professionals fighting COVID-19 in Japan.

**Daiichi-Sankyo**
Daiichi-Sankyo donated $1 million to the WHO COVID-19 Solidarity Response Fund through the Japan Center for International Exchange, supporting COVID-19 relief efforts.

**Eisai**
Eisai provided $250,000 in funding to US civil society organisations, and provided PPE to local healthcare providers in the US. Eisai provided €945,000 to professional organizations such as the WHO, as well as healthcare providers and vulnerable communities in the UK, Italy, Germany, Spain, Belgium, France, Portugal, and Slovakia. Eisai donated 11.8 million rupees to federal emergency funding in India, and donated funding and supplies in Indonesia, Thailand, the Philippines, Malaysia, and Vietnam. Eisai announced that it has committed the equivalent of 1 million USD in aid towards various activities in response to the spread of the novel coronavirus infection in Africa.

**Eli Lilly**
Eli Lilly deployed medical professionals to staff a free drive-through COVID-19 testing facility at its corporate headquarters in Indianapolis. Eli Lilly and Company Foundation contributed $500,000 to the Central Indiana COVID-19 Community Economic Relief Fund.

**Farmindustria**
Farmindustria and member companies donated over €9.4 million worth of medicines to Italian hospitals, €21.8 million of financial and medical equipment donations, and 4 members modified their production lines to meet health needs during the pandemic.

**Gilead**
Gilead provided remdesivir to physicians for compassionate use to treat hundreds of severely ill COVID-19 patients. Gilead committed another 1.5 million individual doses of remdesivir for donation, representing 140,000 treatment courses based on a 10-day treatment duration. Gilead announced the $20 million Gilead CARES (COVID-19 Acute Relief and Emergency Support) Grantee Fund to support civil society organisations impacted by the COVID-19 pandemic. Gilead partnered with Satcher Health Leadership Institute at Morehouse School of Medicine to study racial health inequities associated with COVID-19.

**GSK**
GSK donated $10 million to the WHO COVID-19 Solidarity Response Fund to enable distribution of essential supplies to frontline health workers. GSK donated lab equipment, instruments, and scientific kits to support government testing and donated over 700,000 PPE units to frontline health workers in 29 countries. GSK donated more than 660,000 GSK products to more than 24 countries in Asia, Americas and EU.

**HKAPI**
HKAPI delivered 17,000 surgical face masks to patient organizations together with the continued support of their member companies in sourcing PPE.
Johnson & Johnson committed $50 million to support frontline health workers during the COVID-19 pandemic. Johnson & Johnson encouraged medically trained employees worldwide to take paid leave and volunteer within their community. Financial donations made by employees or retirees to the Covid-19 Solidarity Response Fund or the CDC Foundation's All of Us Campaign were matched, dollar for dollar, up to a total of $1 million for each organization.

LEO Pharma made donations supporting local hospitals and communities in Northern Italy, Spain and New Jersey (US) in fighting COVID-19.

Lundbeck supported fundraising activities in Italy, donated PPE to France and the US, committed $1 million to COVID-19 relief efforts in North America, and donated to the COVID Response Funds in regions where the company is present.

Medicines Australia joined forces with 15 healthcare organisations in the Continuity of Care Collaboration to stress the importance for people to continue monitoring their health and maintaining regular medical care.

Menarini converted a topical pharmaceutical producing plant in Florence into an antibacterial gels producing plant, donated products across Italy and increased production from 20 to 100 tons per month.

MSD committed more than $30 million to COVID-19 relief efforts, including donations of medicines, PPE and funding to relief organizations, and pledged another $10 million to support disparately impacted patients and communities in the US and globally. Through MSD for Mothers, MSD committed $3 million to address critical maternal health needs during COVID-19. MSD encouraged medically trained employees to volunteer in local communities, providing paid leave. MSD announced it was taking a number of new steps to support patients in the US who may have lost their jobs and health insurance coverage.

Merck donated 150,000 liters of disinfectant to the German state of Hesse.

Novartis donated up to 130 million doses of hydroxychloroquine. Novartis’ COVID-19 Response Fund provided $20 million in support to the most impacted communities around the world. Novartis and the Novartis US Foundation established a $5 million US COVID-19 Community Response Fund. Novartis Canada and Sandoz Canada donated $500,000 to community and patient groups via the Community Strong COVID-19 response program. Novartis contributed $1 million to the International Rescue Committee to support the COVID-19 response in East Africa. Novartis and its subsidiary Sandoz launched a not-for-profit portfolio of medicines for symptomatic treatment of COVID-19, which were made available to governments, NGOs and other institutional customers in up to 79 eligible countries.

Novo Nordisk donated PPE, provided 20 tons of hand sanitizer to hospitals, and through its Novo Nordisk Foundation donated more than $7 million to fight COVID-19 in Denmark.

Pfizer created a Global COVID-19 Medical Service Program to empower medical colleagues to provide diagnostic, treatment, and public health support. Pfizer and the Pfizer Foundation provided $40 million in medical and charitable cash grants to combat the COVID-19 pandemic.

Roche's subsidiary, Genentech and the Genentech Foundation, provided $42 million to address the devastating impact
of the COVID-19 pandemic.

Sanofi made 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. Sanofi also donated 100 million doses of hydroxychloroquine across 50 countries globally.

Servier provided PPE to hospitals in affected countries, donated to foundations and NGOs, and encouraged medically-trained staff to volunteer in the French healthcare system to combat COVID-19.

Sumitomo Dainippon Pharma (SDP) manufactured 20,000 face shields and procured PPE through its Chinese subsidiary for use in the worst affected Japanese prefectures. SDP subsidiary Sunovion Pharmaceuticals provided a monetary donation to the US CDP COVID-19 Response Fund, donated PPE, delivered food donations to a food bank and sent out volunteers to support the activities of the NHS in the UK, and provided further financial support to several organizations. SDP also joined forces with Innovative Medicines Canada to set up a Canadian COVID-19 fund.

Takeda donated $6.25 million to the American Red Cross, the city of Cambridge, and the town of Lexington to fight COVID-19.

Teva donated more than 10 million hydroxychloroquine doses to hospitals in the US, and another 2 million hydroxychloroquine units to the Israeli Ministry of Health. The company also donated hydroxychloroquine as well as PPE to Spain and allowed UK employees to volunteer with the NHS, providing paid leave. Teva provided PPE, kits and food to populations in need in India.

UCB donated hydro-alcoholic solutions to the Belgian and Swiss authorities which it started producing at its own manufacturing sites. UCB encouraged healthcare professionals to volunteer in line with local government needs and guidance. UCB donated PPE 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.

Astellas Pharma China donated 1 million yuan to the Red Cross Society of China for purchasing PPE and procuring medical treatment equipment and donated 300,000 yuan worth of PPE to hospitals in Wuhan, China.

Bayer made financial contributions and donations of several medicines to the Chinese Red Cross.

Boehringer Ingelheim made financial donations to the Chinese Red Cross to purchase PPE and made donations of medicines.

Bristol-Myers Squibb (BMS) and the BMS Foundation provided more than $5 million in financial support and essential products to COVID-19 relief efforts.

CSL Group/Seqirus donated 1 million RMB to the China Red Cross in support of COVID-19 relief efforts.
Eisai donated 1 million yuan to the Wuhan Charity Federation and provided local healthcare providers with medicines and medical relief supplies.

Johnson & Johnson donated 300 boxes of HIV medication to the Shanghai Public Health Clinical Centre and Zhongnan Hospital of Wuhan University. The company also provided drug-screening for antiviral properties against SARS-CoV-2 to assist laboratory-based investigations of the Chinese CDC.

Eli Lilly donated 1 million yuan to the Chinese Red Cross. The Lilly Foundation donated $100,000 to Direct Relief, and $150,000 to Project HOPE to support their COVID-19 relief efforts.

Lundbeck supported local communities and societies with monetary and medicine donations to Wuhan, China.

MSD donated 1 million RMB to the Chinese Red Cross Foundation and supported the construction of a second specialty hospital (Leishenshan Hospital) to treat COVID-19 patients in Wuhan. MSD 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 donated 1 million RMB to the Red Cross located in Jinnan Community Hangzhou Lin’an Area for medical supplies and PPE, 500,000 RMB to the Sichuan Red Cross, medical supplies to the Hubei Charity Federation, and provided supportive nutritional products to medical staff, the Tianjin Red Cross and designated hospitals in Beijing.

Pfizer made cash contributions to its global NGO partners who shipped supplies to hospitals in China. The Pfizer Foundation provided $500,000 in grants for direct COVID-19 relief efforts of Direct Relief and Project HOPE.

Roche donated diagnostics tests, medical supplies and financial support, including a donation of $2 million worth of tocilizumab to China to help manage the COVID-19 outbreak. Roche subsidiary Genentech also worked with Chinese government and health authorities to provide screening and health care.

Sumitomo Dainippon Pharma subsidiary Sumitomo Pharmaceuticals donated 1 million RMB to the Chinese Red Cross Foundation for prevention and containment efforts.

Teva donated 9,600 packs of azithromycin to 15 hospitals in Hubei.

---

### Abbreviations

<table>
<thead>
<tr>
<th>Abbreviated Term</th>
<th>Full name</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACT Accelerator</td>
<td>The Access to COVID-19 Tools Accelerator</td>
</tr>
<tr>
<td>ACTIV</td>
<td>Accelerating COVID-19 Therapeutic Interventions and Vaccines</td>
</tr>
<tr>
<td>AHA</td>
<td>American Hospital Association</td>
</tr>
<tr>
<td>AMED</td>
<td>Agency for Medical Research and Development (Japan)</td>
</tr>
<tr>
<td>Acronym</td>
<td>Description</td>
</tr>
<tr>
<td>---------</td>
<td>-------------</td>
</tr>
<tr>
<td>AMSP</td>
<td>Africa Medical Supplies Platform</td>
</tr>
<tr>
<td>AU</td>
<td>African Union</td>
</tr>
<tr>
<td>BARDA</td>
<td>Biomedical Advanced Research and Development Authority</td>
</tr>
<tr>
<td>CEPI</td>
<td>Coalition for Epidemic Preparedness Innovations</td>
</tr>
<tr>
<td>COMET-ICE</td>
<td>COVID-19 Monoclonal antibody Efficacy Trial - Intent to Care Early</td>
</tr>
<tr>
<td>CRS</td>
<td>Cytokine Release Syndrome &quot;cytokine storm&quot;</td>
</tr>
<tr>
<td>CoVax</td>
<td>Vaccines pillar of the Access to COVID-19 Tools (ACT) Accelerator</td>
</tr>
<tr>
<td>DARPA</td>
<td>The Defense Advanced Research Projects Agency (US)</td>
</tr>
<tr>
<td>EFPIA</td>
<td>European Federation of Pharmaceutical Industries Associations</td>
</tr>
<tr>
<td>EMA</td>
<td>European Medicines Agency</td>
</tr>
<tr>
<td>EUA</td>
<td>Emergency Use Authorization</td>
</tr>
<tr>
<td>GISAID</td>
<td>The Global Initiative on Sharing All Influenza Data</td>
</tr>
<tr>
<td>HHS</td>
<td>U.S. Department of Health and Human Services</td>
</tr>
<tr>
<td>H-IG</td>
<td>Hyperimmune globulin</td>
</tr>
<tr>
<td>IAVI</td>
<td>International AIDS Vaccine Initiative</td>
</tr>
<tr>
<td>IMI</td>
<td>Innovative Medicines Initiative</td>
</tr>
<tr>
<td>INSERM</td>
<td>Institut National de la Santé et de la Recherche Médicale (France)</td>
</tr>
<tr>
<td>ISB</td>
<td>Institute for Systems Biology (US)</td>
</tr>
<tr>
<td>ITAC</td>
<td>Inpatient Treatment with Anti-Coronavirus Immunoglobulin</td>
</tr>
<tr>
<td>JPA</td>
<td>Joint Procurement Agreement</td>
</tr>
<tr>
<td>LAAB</td>
<td>long-acting antibody</td>
</tr>
</tbody>
</table>
LSTM  Liverpool School of Tropical Medicine
mAbs  Monoclonal antibodies
MIT   Massachusetts Institute of Technology
mRNA  Messenger ribonucleic acid
NEJM  New England Journal of Medicine
NHS   National Health Service (UK)
NIAID National Institute of Allergy and Infectious Diseases (US)
NIH   National Institutes of Health (US)
NIID  National Institute of Infectious Diseases (Japan)
PHRI  Population Health Research Institute
PPE   Personal Protection Equipment
US CDC United States Centre for Disease Control and Prevention
US DOJ United States Department of Justice
US FDA United States Food and Drug Administration
WHO   World Health Organisation

Videos
Global Biopharma CEO/Top Executives COVID-19 Media Briefing – COVID-19 therapeutics - 3 September 2020 (Video)
September 3, 2020

Global Biopharma CEO/Top Executives COVID-19 Media Briefing - 28 May 2020 (Video)
May 28, 2020

IFPMA President David Ricks on Global Pledge Committing to Work Together to Beat COVID-19 (Video)
May 5, 2020

Global Biopharma CEO/Top Executives Virtual Press Briefing - 30 April 2020 (Video)
April 30, 2020

The value of the Ethos in the context of COVID-19
April 17, 2020

The biopharmaceutical industry commitments to tackle the coronavirus pandemic (Video playlist)
March 24, 2020

Pharma CEO/Top Executives Global Response to COVID-19 - Virtual Press Briefing - 19 March 2020 (Video)
March 19, 2020

News Releases
Biopharma industry updates on COVID-19 treatments progress and warns about upholding regulatory standards of quality

September 3, 2020

Pharma partners in efforts to give coronavirus vaccine for everyone

May 28, 2020

Pharma industry updates advice on engaging with healthcare professionals as countries emerge from COVID-19 lockdown

May 28, 2020

Pharma and other innovative health groups tell World Health Assembly it stands united with governments and global health stakeholders worldwide to combat COVID-19

May 19, 2020

Pharma Joins Global Pledge Committing to Work Together to Beat COVID-19

May 4, 2020

Global Pharma update on unprecedented efforts to collaborate in speeding up the search for safe and effective COVID-19 therapies

April 30, 2020

Pharma industry body joins as founding partner a new global collaboration to accelerate the development, production and equitable access to new COVID-19 tools

April 24, 2020

Global Biopharmaceutical Industry pulling out all the stops to address Coronavirus public health crisis

March 19, 2020
IFPMA statement on “Intellectual Property and COVID-19”
October 16, 2020

Safety of vaccinated individuals is the top priority in development of COVID-19 vaccines
September 15, 2020

COVID-19 Vaccine Maker Pledge
September 8, 2020

Innovative vaccine industry strongly committed to rigorous regulatory standards for approval of COVID-19 vaccines
August 27, 2020

IFPMA Statement on the “Solidarity Call to Action to realize equitable global access to COVID-19 health technologies through pooling of knowledge, intellectual property and data”
May 28, 2020

Joint Statement – Innovative Health Industries @ WHA73
May 18, 2020

Pharma Statement for The Coronavirus Global Response Pledging Marathon
May 4, 2020

IFPMA Statement on the launch of a new global collaboration to accelerate the development, production and equitable access to new COVID-19 tools
April 24, 2020

Innovative health industries united in welcoming United Nations General Assembly Resolution on “International Cooperation to ensure global access to medicines, vaccines and medical equipment to face COVID-19”
April 21, 2020

IFPMA remarks on intellectual property management and the global response to COVID-19
April 6, 2020

Global Biopharmaceutical Industry Commitment to Address Coronavirus Public Health Crisis
March 19, 2020

IFPMA and WHO Global Research and Innovation Forum
February 12, 2020
IFPMA Members’ support in countering the novel coronavirus (2019-nCoV)

February 10, 2020
Joint Guidance on Virtual International Medical Congresses Impacted by COVID-19

July 2, 2020

WHO Links

IFPMA Policy Principles on COVID-19
Vaccines Initiative
September 15, 2020

WHO - COVID-19 situation dashboard
WHO - WHO R&D Blueprint
WHO - Coronavirus Diseases (COVID-19) Outbreak
WHO - Coronavirus Diseases (COVID-19) Situation Reports
WHO - Q&A on the Coronavirus
WHO - Global Research on Coronavirus Disease (COVID-19)
WHO - Speeches of WHO DG Dr Tedros at daily media briefings
WHO - Updated Country Preparedness and Response Status for COVID-19 as of 6 March 2020
WHO COVID-19: WHO’s Global Research Roadmap
WHO - A Coordinated Global Research Roadmap: 2019 Novel Coronavirus
WHO - Draft landscape of COVID 19 candidate vaccines
Access to COVID-19 Tools (act) Accelerator
Ethical Considerations for Resuming In-Person Interactions with Healthcare Professionals Post COVID-19: A Guidance Document

May 28, 2020

COVID-19 Biopharmaceutical Industry – Regulatory Guiding Principles

May 14, 2020