



COVID-19 R&D-based pharma industry's innovative partnership to meet urgent global supply needs

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*IFPMA member companies are at the forefront of the global effort to develop a safe and effective COVID-19 vaccine and scale up manufacturing to ensure equitable access to people around the world. In less than a year, several vaccines candidates have been approved or are in advanced [Phase III](#) clinical trials with encouraging results. An impressive and unprecedented manufacturing scale-up is also taking place. **Most collaborations - if not all - involved some sort of licensing and transfer of technology, which would not be possible in the absence of a robust global IP system.***

The examples below highlight a few selected collaborations with IFPMA companies. According to Airfinity data, as of March 2021 at least 263 manufacturing and production deals for COVID-19 vaccines around the globe were made public:

Pfizer and BioNTech have successfully developed a promising mRNA vaccine, the first to be authorized by a stringent regulatory agency. The collaboration between the companies was agreed in March 2020 and in less than a year, the two companies have developed the vaccine, undertaken vast clinical trials, filed for regulatory approval in multiple geographies, and scaled up manufacturing from zero to supply globally up to 2 billion doses by the end of 2021. Throughout the collaboration, BioNTech and Pfizer have partnered on all stages of the vaccine research, development and manufacturing—with BioNTech bringing the novel innovating technology and Pfizer bringing years of expertise in researching, developing, making and distributing vaccines at very large scale. On 31 December 2021, WHO granted COVAX emergency use authorization, paving the way for its use through COVAX, and in less than a month the companies announced they will [supply COVAX](#) with 40 million doses in 2021, with first deliveries in Q1.

AstraZeneca and the University of Oxford joined forces for the development, worldwide manufacturing and distribution of a vaccine, developed by the Jenner Institute and Oxford Vaccine Group. The company has committed to [sell on a not-for-profit](#) basis during the pandemic. In order to improve access to low- and middle-income countries. AstraZeneca reached a [licensing](#) and technology transfer agreement with the Serum Institute of India to supply one billion doses to low- and middle-income countries, and with [Daiichi Sankyo](#) to supply Japan. AstraZeneca also reached a [\\$750m agreement with CEPI and Gavi](#) to support the manufacturing, procurement and distribution of 300 million doses of the vaccine.

Johnson & Johnson's vaccine brings the promise of a one dose vaccine and in early 2021 the company [filed for FDA emergency approval](#). Johnson & Johnson has publicly committed to bringing an affordable vaccine to the public on a [not-for-profit basis](#) for emergency pandemic use. It aims to manufacture more than one billion doses to be distributed globally through 2021, and has entered in manufacturing agreement with multiple companies, including [Aspen](#) in South Africa and [Sanofi](#) in France. J&J also plans to allocate up to [500 million vaccine](#) doses to lower income countries with delivery beginning mid-2021.

GSK and Sanofi committed to join forces to develop a vaccine using innovative adjuvanted recombinant protein-based technology. Though the development has faced delays, the companies are working to improve the antigen formulation and conduct additional trials in 2021. These two leading vaccine manufacturers bring significant manufacturing capacity, and, if successful, will be able to make hundreds of millions of doses annually. They have [publicly committed](#) to making any vaccine that is developed through the collaboration affordable to the public and through mechanisms that offer fair access for people in all countries. The companies have [signed](#) a Statement of Intent with Gavi to make available 200 million doses of their COVID-19 vaccine, if approved by regulatory authorities, to the COVAX Facility. **GSK** also reached an [agreement in principle](#) with Novavax and the UK Government Vaccines Taskforce to support manufacturing of up to 60 million doses of Novavax' COVID-19 vaccine.



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Takeda, Novavax and the Japanese Ministry of Health, Labour and Welfare are [partnering to increase manufacturing capacity](#) of Novavax's COVID-19 vaccine candidate NVX CoV2373 in Japan. Takeda anticipates to manufacture over 250 million doses of the COVID-19 vaccine per year. Takeda is also partnering with [Moderna](#) to import and distribute 50 million doses in Japan.

Novartis has entered an initial agreement to manufacture the mRNA and bulk drug product for the COVID-19 vaccine candidate CVnCoV from CureVac to aid in the fight against the COVID-19 pandemic. Novartis plans to produce up to 50 million doses of the mRNA and bulk drug product for the CureVac vaccine in 2021 and up to a further 200 million doses in 2022. **Bayer** has also signed a collaboration and services agreement with CureVac, and [plans](#) to add an additional 160 million doses of CureVac's vaccine in 2022. **GSK** would support the manufacture of up to 100 million doses of CureVac's first generation COVID-19 vaccine candidate CVnCoV in 2021.

IFPMA member companies are committed to work with governments, insurers and international organizations to ensure equitable access to COVID-19 medicines. The examples below illustrate different initiatives IFPMA companies are taking to enhance access. In all of them, licensing, enabled by a well-functioning intellectual property system, is a key enabler. Sector-wide, according to Airfinity data, at least 60 manufacturing and production deals for COVID-19 therapeutics around the globe were made public (as of March 2021).

Eli Lilly and Company (Lilly) and the Bill & Melinda Gates Foundation, as part of the COVID-19 Therapeutics Accelerator, [have entered into an agreement to facilitate access](#) to future Lilly therapeutic antibodies under development for the prevention and treatment of COVID-19, to benefit low- and middle-income countries. Commercial manufacturing will commence in April 2021 at the FUJIFILM Diosynth Biotechnologies facility in Denmark, where the Therapeutics Accelerator reserved manufacturing capacity in an agreement announced in April. Lilly has already started the manufacturing technology transfer at risk, in anticipation of regulatory authorization for its antibody therapy. In the interest of making a supply of COVID-19 therapeutic innovations available globally as quickly as possible, Lilly will make certain volumes of its antibody therapeutic manufactured in other facilities available to lower-income countries prior to April 2021. Lilly's collaborators, AbCellera Biologics Inc., Shanghai Junshi Biosciences Co., Ltd. and Columbia University have agreed to waive their royalties on the Lilly therapeutic antibodies distributed in low- and middle-income countries as part of this initiative.

Gilead Sciences has entered into [voluntary licensing agreements](#) with 9 generics manufacturers to further expand supply of remdesivir to 127 countries, representing nearly all low-income and lower-middle income countries. Gilead has completed technology transfers with these companies. Moreover, Gilead has expanded its global network of both internal manufacturing sites and external organizations, including partnering with industry peers, to add manufacturing capacity around the world. The Veklury® manufacturing network now includes more than 40 companies in North America, Europe and Asia. **Pfizer** announced a multi-year agreement with Gilead to manufacture and supply Gilead's remdesivir.

Merck KGaA, IAVI, and Serum Institute of India (SII) are [collaborating to develop neutralizing monoclonal antibodies](#) (mAbs) co-invented by IAVI and Scripps Research as innovative interventions to address the COVID-19 pandemic. The global development plan is being led by the three organizations in partnership. If the highly potent and broadly cross-reactive SARS-CoV-2 neutralizing antibody candidates being advanced through this partnership are shown to be efficacious in clinical trials, either as a single antibody or a potential combination of both candidates, Merck will lead commercialization in developed countries and the SSI will lead global manufacturing as well as commercialization in low- and middle-low-income countries, including India.



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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.

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For more info, contact communications@ifpma.org

IFPMA represents research-based pharmaceutical companies and associations across the globe. The research-based pharmaceutical industry's 2 million employees discover, develop, and deliver medicines and vaccines that improve the life of patients worldwide. Based in Geneva, IFPMA has official relations with the United Nations and contributes industry expertise to help the global health community find solutions that improve global health.

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