



news release

Pharma innovation delivers COVID-19 solutions beyond expectations, but calls for the dilution of intellectual property rights are counterproductive

8 December 2020, Geneva — The [biopharmaceutical industry has made the fight against the COVID-19 pandemic](#) its top priority, devoting its resources, expertise, know-how, and intellectual assets to developing potential treatments, diagnostics and vaccines at unprecedented pace, while committing to and engaging in new levels of international collaboration and coordination through initiatives such as [ACT-A](#), [ACTIV](#) and [CEPI](#) to ensure equitable access to products being developed. The industry stands by its commitment to fair and equitable access to COVID-19 treatments and vaccines. With three vaccines, and potentially as many as ten in the coming months being approved by regulators and produced in their billions by vaccine makers, there is hope of finding a lasting solution for the pandemic.

From the outset of the pandemic, biopharmaceutical companies have walked the talk. *“It has been a tremendously daunting challenge, and so far, things have gone better than could have expected, but going forwards, solidarity from richer countries to help others will be key”*, says Thomas Cueni, Director General of the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA). Cueni believes the timeline for achieving a new normal, *“will depend on working collaboratively to overcome the bumps along the road. Hopefully if governments are ready, we will start seeing herd immunity taking effect as early as summer 2021 in some countries. By summer 2022, we could hope to see much of the world achieving immunity.”*

In the light of such progress, and despite a lack of any evidence, there have been claims that intellectual property (IP) rights are hindering the response to the pandemic. A waiver [proposal](#) currently being discussed by the World Trade Organization (WTO) is looking to suspend Member States’ obligations to protect innovator’s intellectual property assets that are critical to tackle the COVID-19 pandemic. In view of the progress made so far in providing COVID-19 solutions and the partnerships in place to boost research and scale-up manufacturing of vaccines and treatments, diluting national and international IP frameworks during this pandemic is counterproductive. It will not lead to faster research and development or access, but it will undermine confidence in what has proven to be a well-functioning IP system, allowing industry to partner with confidence with academia, research institutes, foundations and other private companies, significantly expediting the research and development of medicines to address the worlds’ many unmet medical needs.

IP enables research and development and ensures that the next generation of inventors and investors will remain engaged. *“At a time, when the focus should be on science and innovation, undoing the very system that supports it, is dangerous and counterintuitive”* says Cueni.

In a matter of 10 months since the COVID-19 virus was shared with the world’s scientists, over 1138 treatments in investigation and 347 vaccines candidates (Airfinity) in preclinical and clinical trials are being researched or in clinical trials around the world. Some are for repurposed drugs proven to work against other diseases, others as novel as the virus itself. Such progress has been possible thanks to a thriving innovation ecosystem, underpinned by intellectual property rights. The contribution of millions of people who joined clinical trials, the rigorous scrutiny of regulators, and the tireless work of healthcare workers has meant that increasing numbers of people are surviving and the end of the pandemic through large-scale immunization is a concrete possibility.



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Country preparedness will be key to ensuring availability and access of the COVID-19 vaccines and therapeutics currently being developed. This includes timely regulatory approval, supply chain scrutiny and effective distribution of the treatments and vaccines under development. Finally, progress towards achieving immunity may be hindered by people having concerns about the safety of vaccines. In early 2021, IFPMA will launch an information campaign to answer concerns and explain how COVID-19 vaccines are going through a rigorous research and development processes; and that clinical trials of COVID-19 are of the same standard as other vaccines.

About IFPMA

IFPMA represents the 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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Note to the editor

Selected examples of collaborations with IFPMA companies for development and manufacturing of promising COVID-19 vaccines

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 an year, several vaccines candidates have concluded or are in advanced [Phase III](#) clinical trials with encouraging results. An impressive and unprecedented manufacturing scale-up is also taking place. Most collaboration 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.

Pfizer and BioNTech are [jointly developing](#) a promising mRNA vaccine. [Primary efficacy analysis](#) demonstrates the vaccine to be 95% effective against COVID-19 beginning 28 days after the first dose. Pfizer is confident in its vast experience, expertise and existing cold-chain infrastructure to distribute the vaccine around the world. The companies have developed specially designed, temperature-controlled thermal shippers utilizing dry ice to maintain temperature conditions of $-70^{\circ}\text{C}\pm 10^{\circ}\text{C}$. They can be used as temporary storage units for 15 days by refilling with dry ice. Based on current projections the companies expect to produce globally up to 50 million vaccine doses in 2020 and up to 1.3 billion doses in 2021. BioNTech is also collaborating with [Fosun Pharma](#) to supply the Chinese market.

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. [Positive high-level results](#) showed the vaccine had efficacy of up to 90% on a certain dosing regimen. To expand manufacturing capacity of the vaccine candidate, the company also entered into collaborations with [Catalent Biologics](#) (Italy), [Symbiosis Pharmaceutical Services](#) (UK), [Oxford Biomedica](#) (UK), [Emergent](#)

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[BioSolutions](#), [BioKangtai](#) (China), and [R-Pharm](#) (Russia). AstraZeneca also reached a [\\$750m agreement with CEPI and Gavi](#) to support the manufacturing, procurement and distribution of 300 million doses of the vaccine. In addition, AstraZeneca reached a [licensing](#) and technology transfer agreement with Serum Institute of India to supply one billion doses for low and middle-income countries

Johnson & Johnson began efforts to [develop a vaccine](#) in January 2020, as soon as the COVID-19 sequence became available. Research teams at Janssen, in collaboration with the Harvard Medical School, constructed and tested multiple vaccine candidates using the Janssen [AdVac® technology](#). The vaccine entered Phase III clinical trials on September 2020. The Company is committed to bringing an affordable vaccine to the public on a [not-for-profit basis](#) for emergency pandemic use and anticipates the first batches of a COVID-19 vaccine to be available for emergency use authorization in early 2021, if proven to be safe and effective. It also aims to manufacture more than one billion doses to be distributed globally through 2021. In July, [Emergent BioSolutions](#) and J&J announced a five-year manufacturing services agreement for large-scale drug substance manufacturing for its vaccines. 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 the 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.

GSK and Sanofi committed to join forces and jointly develop a vaccine using innovative adjuvanted recombinant protein-based technology. Together, they bring significant manufacturing capacity, and, if successful, will be able to make hundreds of millions of doses annually by the end of next year. 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. In this sense, they [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

MSD and IAVI [partnered](#) to advance the development and global clinical evaluation of a COVID-19 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 also acquired Vienna-based biotech company Themis to [accelerate the development](#) of its COVID-19 vaccine candidate.

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 manufacturing over 250 million doses of the COVID-19 vaccine per year.