

Novartis provides manufacturing capabilities to support global COVID-19 vaccines, tocilizumab supply

Apr 16, 2021

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- *In January 2021 Novartis signed an initial agreement to support the production of the Pfizer-BioNTech COVID-19 Vaccine in the company's aseptic manufacturing facilities in Stein, Switzerland.*
- *In March 2021 Novartis signed an initial agreement to manufacture the mRNA and bulk drug product for the COVID-19 vaccine candidate CVnCoV from CureVac.*
- *On April 15, 2021 Novartis signed an initial agreement with Roche to reserve capacity and implement the technology transfer for the production of the active pharmaceutical ingredient (API) for Roche's innovator brand of tocilizumab.*

April 16, 2021 – Novartis is providing its manufacturing capacity and capabilities to support the global supply of COVID-19 vaccines and tocilizumab.

“Safe and effective vaccines and treatments are vital in helping contain the COVID-19 pandemic. This is why we are committed to provide our manufacturing capabilities to help support the supply of COVID-19 vaccines and tocilizumab around the world,” said Mr. Jugo Tsumura, President and Managing Director, Novartis Healthcare Philippines, Inc.

In May 2020, AveXis, a Novartis Company entered into a manufacturing agreement with Massachusetts Eye and Ear and Massachusetts General Hospital to produce the hospital's novel genetic COVID-19 vaccine. An industry leader in gene therapy, AveXis is leading the manufacturing efforts of the new vaccine, utilizing its cutting-edge AAV technology for treatment of rare and life-threatening neurological genetic diseases. AveXis is one of the first companies in the world to have successfully scaled up gene therapy manufacturing with over 1 million square feet of manufacturing capacity.¹

In January 2021 Novartis signed an initial agreement to support the production of the Pfizer-BioNTech COVID-19 Vaccine in the company's aseptic manufacturing facilities in Stein, Switzerland. Under the terms of the contract manufacturing agreement, Novartis plans to take bulk mRNA active ingredient from BioNTech and fill this into vials under aseptic conditions for shipment back to BioNTech for their distribution to healthcare system customers around the world. Subject to reaching a final agreement, Novartis plans to commence production in the second quarter of 2021 at its state-of-the art aseptic manufacturing plant in Stein. Initial shipment of finished product is expected in the third quarter.²

In March 2021 Novartis signed 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. Preparations for the start of production, technology transfer and test runs are already underway. Following final agreement, Novartis plans to start production in the second quarter of 2021. First deliveries of the bulk

drug product to CureVac are expected in the summer 2021.³

Production will take place in a new high-tech production facility that was already under construction at the Novartis Kundl, Austria site. This will be adapted to the needs of messenger RNA vaccine production for CureVac's CVnCoV, the manufacturing of which is highly complex. 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. The bulk drug product will then be delivered to CureVac for further processing and filling.³

On April 15, 2021 Novartis signed an initial agreement with Roche to reserve capacity and implement the technology transfer for the production of the active pharmaceutical ingredient (API) for Roche's innovator brand of tocilizumab. Tocilizumab is a treatment for rheumatoid arthritis which is also being tested in various clinical trials investigating the safety and efficacy in COVID-19 associated pneumonia.⁴ The COVID-19 Treatment Guidelines Panel of the U.S. National Institutes of Health (NIH) recommends the use of tocilizumab in combination with dexamethasone in certain hospitalized patients who are exhibiting rapid respiratory decompensation due to COVID-19.⁵

About Novartis

Novartis is reimagining medicine to improve and extend people's lives. As a leading global medicines company, we use innovative science and digital technologies to create transformative treatments in areas of great medical need. In our quest to find new medicines, we consistently rank among the world's top companies investing in research and development. Novartis products reach more than 750 million people globally and we are finding innovative ways to expand access to our latest treatments. About 105,000 people of more than 140 nationalities work at Novartis around the world. Find out more at www.novartis.com.

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