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Pfizer, BioNTech to supply 120M doses of COVID-19 vaccine to Japan

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Supply of 120 million doses to be provided in the first half of 2021, subject to regulatory approval



Pfizer Inc. and BioNTech SE have announced 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, beginning in 2021.

Financial details of the agreement were not disclosed, but the terms were based on the timing of delivery and the volume of doses. As requested by the Government of Japan, deliveries of the vaccine candidate are planned for the first half of 2021.

On July 27, Pfizer and BioNTech announced that following extensive review of preclinical and clinical data from Phase 1/2 clinical trials, and in consultation with the FDA's Center for Biologics Evaluation and Research (CBER) and other global regulators, the companies selected the BNT162b2 vaccine candidate to move forward into a Phase 2/3 study. BNT162b2 encodes an optimized SARS-CoV-2 full length spike glycoprotein (S), which is the target of virus neutralizing antibodies. In the late-stage trial, the companies will study a 30 µg dose level in a 2 dose regimen among up to 30,000 participants aged 18 – 85 years. It is expected to include approximately 120 sites globally including in regions with significant expected SARS-CoV-2 transmission.

Assuming clinical success, Pfizer and BioNTech are on track to seek regulatory review for BNT162b2 as early as October 2020 and, if regulatory authorization or approval is obtained, plan to supply up to 100 million doses worldwide by the end of 2020 and approximately 1.3 billion doses by the end of 2021.