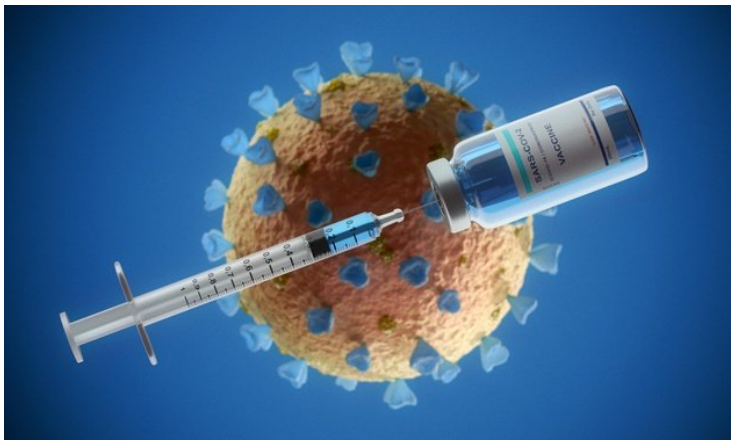
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ASIA EDITION

Pfizer and BioNTech achieve world first authorization for COVID-19 vaccine

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Companies are ready to deliver the first doses to the U.K. immediately



Pfizer Inc. and BioNTech SE have announced that the Medicines & Healthcare Products Regulatory Agency (MHRA) in the U.K. has granted a temporary authorization for emergency use for their COVID-19 mRNA vaccine (BNT162b2), against COVID-19. This constitutes the first Emergency Use Authorization following a worldwide Phase 3 trial of a vaccine to help fight the pandemic. Pfizer and BioNTech are anticipating further regulatory decisions across the globe in the coming days and weeks and are ready to deliver vaccine doses following potential regulatory authorizations or approvals. The distribution of the vaccine in the U.K. will be prioritized according to the populations identified in guidance from the Joint Committee on Vaccination and Immunisation (JCVI).

The MHRA's decision is based on a rolling submission, including data from the Phase 3 clinical study, which demonstrated a vaccine efficacy rate of 95% ($p<0.0001$) in participants without prior SARS-CoV-2 infection (first primary objective) and also in participants with and without prior SARS-CoV-2 infection (second primary objective), in each case measured from 7 days after the second dose. The first primary objective analysis is based on 170 cases of COVID-19, as specified in the study protocol. Efficacy was consistent across age, gender, race and ethnicity demographics, with an observed efficacy in adults age 65 and over of more than 94%. In the trial, BNT162b2 was generally well tolerated with no serious safety concerns reported by the Data Monitoring Committee to date. Today's decision also is based on a review of Pfizer's and BioNTech's Chemistry, Manufacturing and Control (CMC) data for BNT162b2.

In July 2020, Pfizer and BioNTech announced an agreement with the U.K. to supply 30 million doses of the BNT162b2 mRNA-based vaccine, once authorized for emergency use. That agreement was increased to 40 million doses in early October. The delivery of the 40 million doses will occur throughout 2020 and 2021, in stages, to ensure an equitable allocation of vaccines across the geographies with executed contracts. Now that the vaccine is authorized in the U.K., the companies will take immediate action to begin the delivery of vaccine doses. The first doses are expected to arrive in the U.K. in the coming days, with complete delivery fulfilment expected in 2021.

The companies have filed a request for Emergency Use Authorization with the U.S. Food and Drug Administration (FDA) and have submitted the final Conditional Marketing Authorization Application (CA) following rolling submissions with the European Medicines Agency (EMA) and several other regulatory agencies around the world.