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ASIA EDITION

BioNTech-Pfizer apply CMA for COVID-19 Vaccine to the EMA

02 December 2020 | News

Companies have also initiated additional rolling submissions across the globe including in Australia, Canada and Japan, and plan to submit applications to other regulatory agencies around the world along with the previous submission to EMA, FDA and U.K. MHRA

BioNTech SE and Pfizer Inc. on 30 Nov 2020 have submitted a formal Application for **Conditional Marketing Authorization (CMA)** to the European Medicines Agency (EMA) for their mRNA vaccine candidate, BNT162b2, against COVID-19. This submission completes the rolling review process initiated on October 6, 2020, with nonclinical data and partial Chemistry, Manufacturing, and Controls (CMC) data, followed by emerging clinical data submitted by Pfizer and BioNTech. If EMA concludes that the benefits of the vaccine candidate outweigh its risks in protecting against COVID?19, it will recommend granting a CMA that could potentially enable use of BNT162b2 in Europe before the end of 2020.

The submitted clinical data demonstrated a vaccine efficacy rate of 95% ($p<0.0001$) in the companies' Phase 3 clinical study 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. Efficacy was consistent across age, gender, race and ethnicity demographics, with an observed efficacy in adults age 65 and over of more than 94%. The first primary objective analysis was based on 170 confirmed cases of COVID-19. In the trial, BNT162b2 also showed an overall favorable tolerability with no safety concerns reported by the Data Monitoring Committee to date. Approximately 42% of global participants and 30% of U.S. participants in the Phase 3 study have racially and ethnically diverse backgrounds, and 41% of global and 45% of U.S. participants are 56-85 years of age.

Ugur Sahin, M.D., CEO and Co-founder of BioNTech said, "We will continue to work with regulatory agencies around the world to enable the rapid distribution, should the vaccine receives the approval"

The vaccine candidate will be assessed according to EMA's normal stringent standards for quality, safety and efficacy. The BNT162b2 vaccine candidate is currently not approved for distribution anywhere in the world.

In addition to submission to EMA, U.S. Food and Drug Administration (FDA) and U.K. MHRA (Medicines and Healthcare Products Regulatory Agency), the companies have also initiated additional rolling submissions across the globe including in Australia, Canada and Japan and plan to submit applications to other regulatory agencies around the world.