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BioNTech, Pfizer to initiate Ph 1/2 trial of COVID-19 mRNA vaccine candidate in Japan

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Pfizer Inc. and BioNTech SE on 21 Oct 2020 announced the start of a Phase 1/2 study in Japan for their BNT162 mRNA-based vaccine candidate against SARS-CoV-2. The clinical trial protocol notification for this study has been reviewed and confirmed by the regulatory authority in Japan.

The Phase 1/2 trial is designed as a 3:1 vaccine candidate to placebo, randomized, observer-blinded study to evaluate safety, tolerability, and immunogenicity of the BNT162b2 vaccine candidate. The study will be conducted across multiple sites in Japan with up to 160 participants between 20 and 85 years of age. BNT162b2 will be administered at a 30µg dose level in a two-dose regimen 21 days apart, and participants will be followed for 12 months after the final dose. BNT162b2 encodes an optimized SARS-CoV-2 full-length spike glycoprotein (S).

For further information about this trial, visit ClinicalTrials.gov using the number NCT04588480.

The vaccine candidate is currently being evaluated in a global Phase 2/3 study of 44,000 subjects ongoing at up to 120 clinical sites worldwide including in Germany, the United States, Brazil and Argentina. Data from the pivotal global study and as well as from Japan’s study will be utilized to seek marketing authorization for BNT162b2 in Japan.

On July 31, the companies announced an agreement with the Government of Japan to supply 120 million doses of the COVID-19 vaccine to Japan, subject to clinical success and regulatory approval, in the first half of 2021.