

Fosun Pharma's licensed COVID-19 vaccine gets NMPA acceptance

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The clinical trial application of BNT162b1 Vaccine accepted by NMPA along with BioNTech collaboration



Shanghai Fosun Pharmaceutical (Group) Co., Ltd. has announced that its subsidiary Shanghai Fosun Pharmaceutical Industrial Development Co., Ltd. has received the acceptance notice of clinical trial application for the licensed COVID-19 vaccine product candidate BNT162b1 Vaccine. The clinical trial application of the Vaccine was accepted by the National Medical Products Administration (the "NMPA").

Dr. Aimin Hui, Senior Vice President, President of Global R&D, and Chief Medical Officer of Fosun Pharma said, "Fosun Pharma's Global R&D Center has been striving for a patient-centered and clinical-driven approach to the pandemic, and actively promoting the international collaboration with BioNTech to co-develop an mRNA vaccine against the COVID-19. We hope that the clinical trial will be initiated in China as soon as possible"

In March 2020, Fosun Pharma has obtained the license granted by German company BioNTech SE ("BioNTech") to exclusively develop and commercialize its vaccine products based on BioNTech's proprietary mRNA technology platform targeting COVID-19 in China. The Vaccine candidate is a prophylactic biological product, aiming at the precaution of COVID-19 for people who aged 18 or above. BioNTech has announced interim analysis data from an ongoing phase 1/2 study of mRNA-based vaccine candidate against SARS-CoV-2, and its two most advanced mRNA-based SARS-COV-2 vaccine candidates BNT162b1 and BNT162b2 have recently received the Fast Track Designation from the U.S. Food and Drug Administration (FDA). Subject to approval by regulatory authorities, BioNTech expects to begin a Phase2b/3 trial as early as in later this month and expects up to 30,000 subjects to be enrolled in the trial.