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Pfizer, BioNTech initiate human trials with COVID-19 mRNA Vaccine

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The Phase 1/2 study of BNT162 vaccine program is designed to determine the safety, immunogenicity and optimal dose level of four mRNA vaccine candidates evaluated in a single, continuous study

Pfizer Inc. and BioNTech SE announced on 5 May 2020 that the first participants have been dosed in the U.S. in the Phase 1/2 clinical trial for the BNT162 vaccine program to prevent COVID-19. The trial is part of a global development program, and the dosing of the first cohort in Germany was completed last week.

The Phase 1/2 study is designed to determine the safety, immunogenicity and optimal dose level of four mRNA vaccine candidates evaluated in a single, continuous study. The dose level escalation portion (Stage 1) of the Phase 1/2 trial in the U.S. will enroll up to 360 healthy subjects into two age cohorts (18-55 and 65-85 years of age). The first subjects immunized in Stage 1 of the study will be healthy adults 18-55 years of age. Older adults will only be immunized with a given dose level of a vaccine candidate once testing of that candidate and dose level in younger adults has provided initial evidence of safety and immunogenicity. Sites currently dosing participants include NYU Grossman School of Medicine and the University of Maryland School of Medicine, with the

University of Rochester Medical Center/Rochester Regional Health and Cincinnati Children's Hospital Medical Center to begin enrollment shortly.

"With our unique and robust clinical study program underway, starting in Europe and now the U.S., we look forward to advancing quickly and collaboratively with our partners at BioNTech and regulatory authorities to bring a safe and efficacious vaccine to the patients who need it most. The short, less than four-month timeframe in which we've been able to move from pre-clinical studies to human testing is extraordinary and further demonstrates our commitment to dedicating our best-in-class resources, from the lab to manufacturing and beyond, in the battle against COVID-19," said Albert Bourla, Chairman and CEO, Pfizer.

Pfizer and BioNTech's development program includes four vaccine candidates, each representing a different combination of mRNA format and target antigen. The novel design of the trial allows for the evaluation of the various mRNA candidates

simultaneously in order to identify the safest and potentially most efficacious candidate in a greater number of volunteers, in a manner that will facilitate the sharing of data with regulatory authorities in real time.

“It is encouraging that we have been able to leverage more than a decade of experience in developing our mRNA platforms to initiate a global clinical trial in multiple regions for our vaccine program in such a short period. We are optimistic that advancing multiple vaccine candidates into human trials will allow us to identify the safest, most effective vaccination options against COVID-19,” said CEO and Co-founder of BioNTech, Ugur Sahin.

During the clinical development stage, BioNTech will provide clinical supply of the vaccine from its GMP-certified mRNA manufacturing facilities in Europe.

In anticipation of a successful clinical development program, Pfizer and BioNTech are working to scale up production for global supply. Pfizer plans to activate its extensive manufacturing network and invest at risk in an effort to produce an approved COVID-19 vaccine as quickly as possible for those most in need around the world. The breadth of this program should allow production of millions of vaccine doses in 2020, increasing to hundreds of millions in 2021. Pfizer-owned sites in three U.S. states (Massachusetts, Michigan and Missouri) and Puurs, Belgium have been identified as manufacturing centers for COVID-19 vaccine production, with more sites to be selected. Through its existing mRNA production sites in Mainz and Idar-Oberstein, Germany, BioNTech plans to ramp up its production capacity to provide further capacities for a global supply of the potential vaccine.

BioNTech and Pfizer will work jointly to commercialize the vaccine worldwide upon regulatory approval (excluding China, where BioNTech has a collaboration with Fosun Pharma for BNT162 for both clinical development and commercialization).