

BioNTech and Pfizer announce completion of dosing for first cohort of Phase 1/2 trial of COVID-19 vaccine candidates in Germany

Wednesday, April 29, 2020 - 09:00am

MAINZ, Germany and NEW YORK, April 29, 2020 (GLOBE NEWSWIRE) -- BioNTech SE (Nasdaq: BNTX, “BioNTech” or “the Company”) and Pfizer Inc. (NYSE: PFE) have announced that the first cohort of BioNTech’s Phase 1/2 clinical trial has been dosed. Twelve study participants were dosed with vaccine candidate BNT162 in Germany since dosing began on April 23, 2020. The trial is the first clinical trial of a COVID-19 vaccine candidate in Germany. Pfizer and BioNTech plan to initiate trials for BNT162 in the United States upon regulatory approval, which is expected shortly.

The dose escalation portion of the Phase 1/2 trial will include approximately 200 healthy subjects between the ages of 18 to 55 and will target a dose range of 1 µg to 100 µg, aiming to determine the optimal dose for further studies as well as to evaluate the safety and immunogenicity of the vaccine. The study will also assess the effects of repeated vaccination following a prime injection for the three vaccine candidates that contain uridine containing mRNA (uRNA) or nucleoside modified mRNA (modRNA). A fourth vaccine candidate, which contains self-amplifying mRNA (saRNA) will be evaluated after a single dose of vaccine. Subjects with a higher risk of severe COVID-19 disease will be included in the second part of the study.

BioNTech and Pfizer are jointly developing BNT162. During the clinical development stage, BioNTech will provide its partner’s clinical supply of the vaccine from its GMP-certified mRNA manufacturing facilities in Europe. BioNTech is collaborating with Fosun Pharma to develop BNT162 in China, where the companies expect to conduct trials.

About BioNTech

Biopharmaceutical New Technologies (BioNTech) is a next generation immunotherapy company pioneering novel therapies for cancer and other serious diseases. The Company exploits a wide array of computational discovery and therapeutic drug platforms for the rapid development of novel biopharmaceuticals. Its broad portfolio of oncology product candidates includes individualized and off-the-shelf mRNA-based therapies, innovative chimeric antigen receptor T cells, bi-specific checkpoint immuno-modulators, targeted cancer antibodies and small molecules. Based on its deep expertise in mRNA vaccine development and in-house manufacturing capabilities, BioNTech and its collaborators are developing multiple mRNA vaccine candidates for a range of infectious diseases alongside its diverse oncology pipeline. BioNTech has established a broad set of relationships with multiple global pharmaceutical collaborators, including Eli Lilly and Company, Genmab, Sanofi, Bayer Animal Health, Genentech, a member of the Roche Group, Genevant, Fosun Pharma, and Pfizer.

For more information, please visit www.BioNTech.de.

will be commercially successful; decisions by regulatory authorities impacting labeling, manufacturing processes, safety and/or other matters that could affect the availability or commercial potential of any such vaccine candidates, including development of products or therapies by other companies; manufacturing capabilities or capacity; uncertainties regarding the ability to obtain recommendations from vaccine technical committees and other public health authorities regarding any such vaccine candidates and uncertainties regarding the commercial impact of any such recommendations; and competitive developments.

A further description of risks and uncertainties can be found in Pfizer's Annual Report on Form 10-K for the fiscal year ended December 31, 2019 and in its subsequent reports on Form 10-Q, including in the sections thereof captioned "Risk Factors" and "Forward-Looking Information and Factors That May Affect Future Results", as well as in its subsequent reports on Form 8-K, all of which are filed with the U.S. Securities and Exchange Commission and available at www.sec.gov and www.Pfizer.com.

BioNTech Media Relations Jasmina Alatovic

Senior Manager Global External Communications Tel: +49 (0)6131 9084 7640 or +49 (0)151 1978 1385

E-mail: media@biontech.de

BioNTech Investor Relations Sylke Maas, Ph.D.

VP Investor Relations & Business Strategy Tel: +49 (0)6131 9084 1074

E-mail: Investors@biontech.de

Pfizer Media Relations

Amy Rose (U.S.)

+1 (212) 733-7410

amy.rose@pfizer.com

Lisa O'Neill (UK)

+44 7929339560

lisa.o'neill@pfizer.com

Pfizer Investor Relations

Ryan Crowe

+1 (212) 733-8160

ryan.crowe@pfizer.com