

# BioNTech reports rapid progress on COVID-19 vaccine program to address global public health threat

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- Announces BNT162 vaccine program for the prevention of COVID-19 infection
- Anticipates start of clinical testing for vaccine in late April 2020
- Plans to assemble a global consortium of partners to address the pandemic

MAINZ, Germany, March 16, 2020 (GLOBE NEWSWIRE) -- BioNTech\_SE (Nasdaq: BNTX, "BioNTech" or "the Company") provides further details today on the Company's R&D effort, "Project Lightspeed", to develop a potential vaccine to induce immunity and prevent COVID-19 infection in response to the growing global health threat posed by the disease. BioNTech's product candidate, BNT162, is a potential first-in-class mRNA vaccine in the worldwide effort against COVID-19.

BioNTech intends to initiate clinical testing for BNT162 in late April 2020, subject to regulatory approval, as part of a global clinical development program in Europe (commencing in Germany), the United States and China. The Company has been in close contact with regulatory and scientific authorities around the world and is in ongoing discussions with research organizations to make a vaccine available to the public as quickly as possible worldwide.

As part of its global development program, BioNTech announced today a strategic alliance with Fosun Pharma to jointly develop its COVID-19 vaccine in China. In addition, BioNTech is in advanced discussions with its existing collaborator Pfizer regarding the development of the vaccine outside China. BioNTech plans to manufacture the vaccine for clinical trials along with its partner Polymun at BioNTech's state-of-the-art GMP certified mRNA manufacturing facilities in Europe, and is preparing to ramp up production for global supply in collaboration with its partners.

"We feel a duty to exploit our full technology and immunotherapy expertise to help address the COVID-19 pandemic emergency. We are working closely together with regulatory agencies and our existing collaborators in the infectious disease field, including Pfizer, to rapidly initiate trials in order to make a vaccine available to the public as quickly as possible worldwide. In addition, we are working on a novel therapeutics approach for those patients who have already been infected – we plan to disclose more on that effort in the coming weeks," says **Founder and CEO of BioNTech, Ugur Sahin, M.D.** 

## About BNT162

BNT162 is BioNTech's mRNA vaccine program aimed at preventing COVID-19 infection and is the first product candidate from Project Lightspeed. Lightspeed is BioNTech's accelerated development program encompassing the prevention and treatment of COVID-19 infection, which leverages BioNTech's proprietary mRNA platforms for infectious diseases, its fully-owned GMP manufacturing infrastructure for mRNA vaccine production and its global clinical development capabilities, drawing on BioNTech's broad network of global collaborators.

#### About BioNTech's mRNA vaccine capabilities for Infectious Diseases

BioNTech's mRNA platform for infectious disease spans three types of mRNA: uridine-containing mRNA (uRNA), nucleoside modified mRNA (modRNA) and self-amplifying mRNA (saRNA). Each type can be used to encode immunogens specific to a target pathogen and delivered in various LNP formulations in order to activate and direct T cells and B cells to attack the pathogen. mRNA vaccines have been shown to be highly immunogenic and may offer several advantages over traditional vaccine approaches, particularly where rapid development and scale-up is essential. BioNTech has established four partnerships to develop mRNA vaccines for infectious diseases, including Pfizer, The University of Pennsylvania, The Bill and Melinda Gates Foundation and Fosun Pharma.

#### **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 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.

#### Forward-looking statements

This press release contains "forward-looking statements" of BioNTech within the meaning of the Private Securities Litigation Reform Act of 1995. These forward-looking statements may include, but may not be limited to, the ability of BioNTech to develop and commercialize a vaccine for COVID-19. Any forward-looking statements in this press release are based on BioNTech's current expectations and beliefs of future events, and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those set forth in or implied by such forward-looking statements. These risks and uncertainties include, but are not limited to: competition to create a vaccine for COVID-19 and potential difficulties. For a discussion of these and other risks and uncertainties, see the section entitled "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" in BioNTech's Registration Statement on Form F-1 filed with the SEC on September 9, 2019, as amended, which has been filed with the SEC and is available on the SEC's website at <a href="https://www.sec.gov">www.sec.gov</a>. All information in this press release is as of the date of the release, and BioNTech undertakes no duty to update this information unless required by law.

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