



BioNTech and Fosun Pharma Announce the Start of a Phase 2 Clinical Trial of Lead mRNA COVID-19 Vaccine BNT162b2 in China

November 25, 2020

MAINZ, GERMANY, and SHANGHAI, CHINA, November 25, 2020 – [BioNTech SE](#) ("BioNTech"; Nasdaq: BNTX,) and [Shanghai Fosun Pharmaceutical](#) (Group) Co., Ltd ("Fosun Pharma"; Stock Code: 600196.SH, 02196.HK) jointly announced that their lead mRNA COVID-19 vaccine candidate BNT162b2 will be evaluated in a Phase 2 clinical trial in Taizhou and Lianshui, Jiangsu Province, China.

The Phase 2 clinical trial of BNT162b2 in China will be conducted by Jiangsu Provincial Center for Disease Control and Prevention (Public Health Research Institute of Jiangsu Province). The trial site is located in Taizhou China Medical City Vaccine Engineering Center and Lianshui County CDC, Jiangsu Taizhou People's Hospital, Lianshui County People's Hospital and other units. The online recruitment of volunteers will commence with the recruitment of 960 healthy participants, aged between 18 and 85, to assess the safety and immunogenicity of the vaccine candidate and to support future Biologic License Application (BLA) in China.

Ugur Sahin, M.D., CEO and Co-founder of BioNTech, said, "From the very beginning, our common goal has been to quickly design and develop a safe and effective vaccine for global supply. The clinical trial research carried out in China is an important part of the global research and development of BioNTech's COVID-19 vaccine and marks an important step in bringing this vaccine to the people of China."

Dr. Aimin Hui, President of Global Research and Development and Chief Medical Officer of Fosun Pharma, said, "The COVID-19 pandemic proves once again that global cooperation is needed to control infectious diseases. As an important part of global research and development, the Phase 2 clinical study with BNT162b2 in China will not only provide key data for the launch of the vaccine in China, but also may play a positive role in the widespread promotion and use of the vaccine throughout Asia and around the world."

In the ongoing Phase 3 clinical study of the vaccine, BNT162b2 met all primary efficacy endpoints, with an efficacy rate of 95% in preventing symptomatic COVID-19 infection. Sufficient safety data was collected to support the submission of an Emergency Use Authorization (EUA) to the US Food and Drug Administration (FDA) on November 20, 2020. In addition, BNT162b2 is currently under regulatory review by regulatory authorities in Europe, the United Kingdom and Canada.

On March 13, 2020, Fosun Pharma became the strategic partner of BioNTech in China, jointly developing and commercializing vaccine products for COVID-19 based on its proprietary mRNA technology platform in Mainland China, Hong Kong and Macau Special Administration Region and the Taiwan Region. Since the collaboration between the two sides, Fosun Pharma has been deeply involved in the research and development of mRNA vaccines. In addition to comprehensively and deeply discussing the research and development plans with partners and completing clinical trials in China, Fosun Pharma has also designed and completed animal challenge trials of selected mRNA vaccines, including BNT162b2, in collaboration with Chinese research institutes, and shared outcomes with partners in a timely manner.

About BioNTech

Biopharmaceutical New Technologies 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 Genmab, Sanofi, Bayer Animal Health, Genentech, a member of the Roche Group, Regeneron, Genevant, Fosun Pharma, and Pfizer.

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

About Fosun Pharma

Founded in 1994, Shanghai Fosun Pharmaceutical (Group) Co., Ltd. ("Fosun Pharma"; stock code: 600196.SH, 02196.HK) is a leading healthcare group in China. Fosun Pharma has built a strong root in China and developed a global operation strategy, with pharmaceutical manufacturing and R&D being the largest and core business segment, together with strong presences in medical devices and diagnostics, healthcare services, pharmaceutical distribution and retail.

With R&D innovation as core driving factor, Fosun Pharma continues to optimize its pharmaceutical operations across both innovative and generic drugs. The company has established international R&D centers for excellence in areas such as innovative small molecule drugs, high-value generic drugs, biologics, and cell-therapy.

Under guidance of our 4IN strategy (Innovation, Internationalization, Integration and Intelligentization), Fosun Pharma follows the brand concept of Innovation for Good Health and strives to be a leading enterprise in the global pharmaceutical and healthcare markets.

For more information, please visit: www.fosunpharma.com

Forward-looking Statements of BioNTech

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, statements concerning: BioNTech's efforts to combat COVID-19; the collaborations between BioNTech and Pfizer and BioNTech Fosun Pharma to develop a potential COVID-19 vaccine; our expectations regarding the potential characteristics of BNT162b2 in our clinical trials and/or in commercial use based on data observations to date; the expected timepoint for

additional readouts on efficacy data of BNT162b2 in our clinical trials; the nature of the clinical data, which is subject to ongoing peer review, regulatory review and market interpretation; the timing for submission of data for, or receipt of, any potential Emergency Use Authorization or marketing approval; the timing for submission of manufacturing and other data to the FDA or other regulatory authorities; and the ability of BioNTech to supply the quantities of BNT162 to support clinical development and, if approved, market demand, including our production estimates for 2020 and 2021. Any forward-looking statements in this press release are based on BioNTech 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: the ability to meet the pre-defined endpoints in clinical trials; competition to create a vaccine for COVID-19; the ability to produce comparable clinical or other results, including our stated rate of vaccine effectiveness and safety and tolerability profile observed to date, in the remainder of the trial or in larger, more diverse populations upon commercialization; the ability to effectively scale our productions capabilities; and other potential difficulties. For a discussion of these and other risks and uncertainties, see BioNTech's Quarterly Report for the Three and Nine Months Ended September 30, 2020, filed as Exhibit 99.2 to its Current Report on Form 6-K filed with the SEC on November 10, which is available on the SEC's website at www.sec.gov. 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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