BioNTech and Fosun Pharma receive approval to commence COVID-19 Vaccine Candidate BNT162b2 trial in China

MAINZ, GERMANY, and SHANGHAI, CHINA, November 16, 2020 – BioNTech SE ("BioNTech"; Nasdaq: BNTX,) and Shanghai Fosun Pharmaceutical (Group) Co., Ltd ("Fosun Pharma"; Stock Code: 600196.SH, 02196.HK) today announced that the China National Medical Products Administration (hereinafter referred to as the "National Medical Products Administration") has approved the clinical trial in Mainland China for their mRNA vaccine candidate, BNT162b2.

Wu Yifang, Chairman and CEO of Fosun Pharma, said: "As the ultimate weapon against the COVID-19 pandemic, vaccines will play a vital role in the economic development and social stability of the entire world. I would like to thank the National Medical Products Administration for their great support and for their approval of the clinical trial and we will continue our close collaboration with BioNTech. We are working together and moving forward with the clinical trials and commercialization of mRNA vaccines, to be able to also supply China."

"This start of the b2 trial in China, in conjunction with the recent interim analysis of the global Phase 3 trial that indicates that our lead candidate may be effective in protecting against COVID-19, is another important step forward," said **Ugur Sahin, M.D., CEO and Co-founder of BioNTech**. "Time is of the essence in this effort and we greatly appreciate the support by Chinese regulators and the collaboration with our Chinese partner Fosun Pharma. We will continue to collaborate closely to advance clinical development in China toward market approval."

BioNTech through its partner Fosun Pharma will now commence a Phase 2 clinical trial in Mainland China. On March 13, 2020, BioNTech and Fosun Pharma announced their strategic collaboration to work jointly on the development and commercialization of potential COVID-19 vaccine products based on BioNTech's mRNA technology platform in Mainland China, Hong Kong and Macau Special Administration Region and the Taiwan Region.

BNT162b2 is currently in Phase 3 clinical trials in the United States, Germany, Argentina, Brazil, South Africa, Turkey and other countries, and received Fast Track designation from the U.S. FDA (the U.S. Food and Drug Administration). In addition, a rolling submission to the European Medicines Agency (EMA) for BNT162b2 has been initiated.

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 Phase 2/3 trial and/or in commercial use based on data observations to date; the expected timepoint for additional readouts on efficacy data of BNT162b2 in our Phase 2/3 trial; 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 authorization; the timing for submission of manufacturing data to the FDA; 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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