BioNTech and Fosun Pharma Announce Start of Clinical Trial of mRNA-based COVID-19 Vaccine Candidate in China

August 5, 2020

- *Phase 1 study will evaluate safety and immunogenicity in Chinese participants to support potential regulatory approval pathway in China*
- *Total of 144 participants to be enrolled in two age groups (18-55 and >55 years)*
- *Trial participants to receive either 10µg or 30µg of BNT162 or a placebo*
- *Clinical supply from BioNTech's GMP-certified mRNA production facilities in Europe*

MAINZ, Germany, and SHANGHAI, China, Aug. 05, 2020 (GLOBE NEWSWIRE) -- BioNTech SE (Nasdaq: BNTX, "BioNTech" or "the Company") and Shanghai Fosun Pharmaceutical (Group) Co., Ltd ("Fosun Pharma" or "Group"; Stock Symbol: 600196.SH, 02196.HK), today announced that the first 72 participants have already been dosed with BNT162b1 following IND approval by the Chinese regulatory authority, National Medical Products Administration (NMPA). BioNTech and Fosun Pharma are jointly developing the COVID-19 vaccine candidate in China. The trial is part of BioNTech's global development program aimed at supporting a global supply upon regulatory approval.

The randomized, placebo-controlled, observer-blinded Phase 1 clinical trial in China will enroll 144 healthy subjects to evaluate the safety and immunogenicity of the vaccine as well as to confirm dose selection. The first group of subjects immunized in Stage 1 of the study will be healthy adults aged 18 to 55 years, followed by elderly healthy participants (>55 years). As part of the two-dose cohort design, subjects will receive two injections (prime-boost), 21 days apart, of 10µg or 30µg of the vaccine candidate or placebo. The dose range selection was determined based on early data from clinical trials conducted in Germany and the United States. The participants will be dosed in Taizhou Clinical Phase1 Center, Jiangsu province.

The study is designed to support the regulatory approval process for the Chinese market and intends to confirm that the safety and immunogenicity profile observed in participants from the German and US trials is comparable to that of Chinese participants. The ongoing clinical studies conducted in Germany and the United States will continue to support studies in China.

"We are proud to be among the first international biopharmaceutical companies to initiate a clinical trial of a COVID-19 vaccine candidate in China as part of our effort to make our vaccine available globally, if approved. This is an important step toward our goal to reach marketing authorization and ensure vaccine supply in China to help prevent new COVID-19 outbreaks in the most populous country in the world," said **CEO and Co-founder of BioNTech, Ugur Sahin.**

Ai-Min Hui, President of Global R&D, and Chief Medical Officer of Fosun Pharma said: "Dosing the first Chinese subject with BNT162b1 marks a milestone of the global co-development program in China. We are closely working with BioNTech and regulatory authorities to evaluate the safety and efficacy of BNT162b1 and other mRNA vaccine candidates, in order to synchronize the development process in China with other countries, and to bring the vaccine to public as soon as possible, if the vaccine succeeds."

Following on from the ongoing Phase 1/2 studies in Germany and the United States, the Chinese study will initially evaluate nucleoside-modified messenger RNA (modRNA) candidate BNT162b1, one of two vaccine candidates based on BioNTech's proprietary mRNA technology to have received FDA Fast Track designation in the United States. Meanwhile, BNT162b2, the other vaccine candidate is currently being evaluated in a global Phase 2b/3 trial conducted by BioNTech and Pfizer which commenced on July 27th. The companies also intend to explore the possibility of initiating clinical development of other vaccine candidates based on BioNTech's proprietary mRNA technology in China.

During the clinical development stage, BioNTech will provide the clinical supply of the vaccine from its GMP-certified mRNA manufacturing facilities in Europe. If the vaccine receives marketing authorization in China, Fosun Pharma will exclusively commercialize the vaccine in Mainland China, Hong Kong and Macau Special Administration Regions and in Taiwan.

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, 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

BioNTech's 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, BioNTech's efforts to combat COVID-19; the timing to initiate clinical trials of BNT162 and anticipated publication of data from these clinical trials; the collaboration between BioNTech and Fosun Pharma, to develop a potential COVID-19 vaccine; and the ability of BioNTech to supply the quantities of BNT162 to support clinical development and, if approved, market demand. Any forward-looking statements in this press release are based on BioNTech management'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. For a discussion of these and other risks and uncertainties, see BioNTech's Annual Report on Form 20-F filed with the SEC on March 31, 2020, 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.

BioNTech Contacts

Media Relations
Jasmina Alatovic
+49 (0)6131 9084 1513 or +49 (0)151 1978 1385
Media@biontech.de

Investor Relations
Sylke Maas, Ph.D.
+49 (0)6131 9084 1074
Investors@biontech.de

Fosun Pharma Media Contact
Barney Liu
+86 (21) 3396 7123
liumingyi@fosunpharma.com