



BioNTech and Fosun Pharma Receive Authorization for Emergency Use in Hong Kong for COVID-19 Vaccine

January 25, 2021

- *COMIRNATY® (also known as BNT162b2, Chinese product name: 復必泰™) is the first COVID-19 vaccine to receive Authorization for Emergency Use in Hong Kong*

MAINZ, GERMANY, and SHANGHAI, CHINA, January 25, 2021 — [BioNTech SE](#) (Nasdaq: BNTX, “BioNTech” or “the Company”) and [Shanghai Fosun Pharmaceutical \(Group\) Co., Ltd.](#) (“Fosun Pharma” or “Group”; Stock Code: 600196.SH, 02196.HK) today announced that according to the Food and Health Bureau of the Hong Kong Special Administrative Region of the PRC (“Hong Kong”), the COVID-19 vaccine COMIRNATY® (also known as BNT162b2, Chinese product name: 復必泰™) based on BioNTech’s proprietary mRNA technology has received authorization for emergency use in Hong Kong. The vaccine will be produced in BioNTech’s manufacturing facilities in Germany and supplied to Hong Kong for administration under the Hong Kong SAR Government’s COVID-19 Vaccination Program.

“We are excited and encouraged that COMIRNATY® has been authorized to emergency use in Hong Kong. This is an important milestone in the joint efforts of BioNTech and Fosun Pharma to achieve vaccine accessibility globally. We will continue working closely with BioNTech to complete the ongoing clinical trial and marketing registration in Greater China,” **Wu Yifang, Chairman and CEO of Fosun Pharma** said. “We will also cooperate closely with HKSAR regarding vaccination deployment plan to ensure that Hong Kong citizens can receive a well-tolerated and effective mRNA COVID-19 vaccine as soon as possible in order to protect the health of millions of households.”

On 16 March 2020, BioNTech and Fosun Pharma announced a strategic collaboration to work jointly on the development and commercialization of a COVID-19 vaccine product in Greater China based on BioNTech’s proprietary mRNA technology platform.

Ugur Sahin, M.D., CEO and Co-founder of BioNTech commented: “The authorization for emergency use in Hong Kong is another step forward in bringing our vaccine to people worldwide. This Authorization is also a testament to the successful collaboration with our partner, Fosun Pharma, as we work together to help address the pandemic. Moving forward, we hope to rapidly rollout the vaccine across Asia and will continue to evaluate the vaccine for use against additional mutations that might occur.”

According to the data from the global Phase 3 Clinical trial, BioNTech’s mRNA-based COVID-19 vaccine met all primary efficacy endpoints, demonstrating effectiveness of 95% in preventing COVID-19 in adults and 94% in adults over 65 years of age. Efficacy in the trial was consistent across age, gender, race and ethnicity. This mRNA-based COVID-19 vaccine has been granted EUA in Hong Kong and has been authorized for use by the health regulatory authorities of over 50 countries and regions, including the United Kingdom, the United States, Canada, and the European Union.

COMIRNATY® is a COVID-19 vaccine which is based on messenger RNA, a natural molecule that acts like a blueprint providing instructions for human cells to make a target protein, or antigen, which activates the body’s immune response against the respective virus. mRNA vaccines utilize the genetic sequencing of the virus but not the virus itself. Therefore, mRNA vaccine has no viral component and no risk of infection. Also, mRNA vaccine has advantages such as short development cycle, enabling rapid development of novel vaccine candidates to meet viral mutations; the dual mechanism of humoral and T-cell immunity is immunogenic and does not require adjuvants; it is easy to mass-produce and supports the goal of global supply. The goal of all vaccines, mRNA and conventional vaccines is to stimulate the immune system to generate protective, long-lasting antibody and T cell responses against SARS-CoV-2 and prevent subsequent infection upon exposure to the virus.

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.

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 collaboration between BioNTech and 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 time point 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 marketing approval or Emergency Use Authorization; our contemplated shipping and storage plan, including our estimated product shelf-life at various temperatures; 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 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 predefined 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 production 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.

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 Fosun Pharma

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The information contained in this release is as of January 25, 2021. Fosun Pharma assumes no obligation to update forward-looking statements contained in this release as the result of new information or future events or developments.

A further description of risks and uncertainties can be found in Fosun Pharma's Annual Report for the fiscal year ended December 31, 2019 and Interim Report for the six months ended June 30, 2020, including in the section thereof captioned "Potential Risks", all of which are filed with The Stock Exchange of Hong Kong Limited and the Shanghai Stock Exchange and available at www.hkexnews.hk, www.sse.com.cn and www.fosunpharma.com.

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