



## BioNTech and Fosun Pharma Receive Special Import Authorization in Macau for COVID-19 Vaccine

February 25, 2021

- COMIRNATY® (also known as BNT162b2, Chinese product name: 復必泰™) COVID-19 vaccine received the special import authorization for the use of the local COVID-19 vaccination program of Macau by Health Bureau of Macau, of which the limit amount is 105,000 doses
- Macau proposed to purchase a total of 400,000 doses of COMIRNATY® (including the 105,000 doses granted the Special Import Authorization) for the local COVID-19 vaccination program

**MAINZ, GERMANY, and SHANGHAI, CHINA, 25 February 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 the COVID-19 vaccine COMIRNATY® (also known as BNT162b2, Chinese product name: 復必泰™) has received Special Import Authorization granted by the Health Bureau of Macau Special Administrative Region of the PRC (“Macau”) for the use of the local COVID-19 vaccination program, of which the limit amount is 105,000 doses.

Macau plans to purchase a total of 400,000 doses (including the 105,000 doses granted the Special Import Authorization) COVID-19 vaccine BNT162b2 for the local COVID-19 vaccination program. The rest of the procurement in addition to the Special Import Authorization, will be in accordance with the needs of the Macau government’s COVID-19 vaccination program on re-application and approval.

“With the support from the Macau SAR government, we reached another important milestone in Greater China for the COVID-19 vaccine co-developed by BioNTech and Fosun Pharma.” **Wu Yifang, Chairman and CEO of Fosun Pharma** said. “We are working to deliver our vaccines to Macau as soon as possible, in order to help Macau to consolidate the gains of success pandemic control and to protect the health of millions of households in the region.”

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.

“The Special Import Authorization granted in Macau marks another step forward on our path to delivering a safe and efficacious vaccine to the global population,” said **Ugur Sahin, M.D., CEO and Co-founder of BioNTech**. “This joint development effort with our partner, Fosun Pharma, is a testament to the importance of global cooperation to help address the pandemic.”

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 Macau and has been authorized for use by the Food and Health Bureau in Hong Kong and currently in a Phase 2 Clinical trial in China.

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](http://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](http://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](http://www.fosunpharma.com)

#### **Forward-looking Statements of Fosun Pharma**

This press release contains "forward-looking statements" of Fosun Pharma. These forward-looking statements may include, but may not be limited to, statements concerning: Fosun Pharma's efforts to combat COVID-19; the collaboration between Fosun Pharma and BioNTech to develop a potential COVID-19 vaccine; our expectations regarding the potential characteristics of BNT162b2 in our clinical trial and/or in commercial use based on data observations to date; 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; and if approved, the ability of BioNTech and Fosun Pharma to supply the quantities of BNT162 to meet market demands, including our production estimates for 2021. Any forward-looking statements in this press release are based on Fosun Pharma'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: the uncertainties inherent in research and development, including the ability to meet the predefined endpoints in clinical trials, commencement and/or completion dates for clinical trials, regulatory submission dates, regulatory approval dates and/or launch dates, as well as risks associated with clinical data, including the possibility of unfavorable new clinical trial data and further analyses of existing clinical trial data; 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 risk that more widespread use of the vaccine will lead to new information about efficacy, safety, or other developments, including the risk of additional adverse reactions, some of which may be serious; whether and when any other biologics license and/or emergency use authorization applications may be filed in particular jurisdictions for BNT162b2 or any other potential vaccine candidates; whether and when any applications that may be pending or filed for BNT162b2 may be approved by particular regulatory authorities, which will depend on myriad factors, including making a determination as to whether the vaccine's benefits outweigh its known risks and determination of the vaccine's efficacy; whether the conditions set forth by particular regulatory authorities for conditional approvals could be satisfied on a timely basis; whether and when the production facility may be certified or verified by particular regulatory authorities; disruptions in the relationships between us and our collaboration partners or third-party suppliers; risks related to the availability of raw materials to manufacture a vaccine; whether BioNTech's manufacturing capacity is commensurate with the demand for our vaccine; disruptions in the manufacturing stability; challenges related to our vaccine's ultra-low temperature shipping and storage; whether and when additional supply agreements will be reached and other potential difficulties.

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 Macau Limited and the Shanghai Stock Exchange and available at [www.hkexnews.hk](http://www.hkexnews.hk), [www.sse.com.cn](http://www.sse.com.cn) and [www.fosunpharma.com](http://www.fosunpharma.com).

#### **BioNTech's Media Relations**

Jasmina Alatovic  
Director Global External Communications  
+49 89 62 81 75 46  
E-mail: [Media@biontech.de](mailto:Media@biontech.de)

#### **Fosun Pharma's Media Relations**

Barney Liu  
Deputy Director of Media and Public Relations  
Tel: +86 21-3398 7123  
E-mail: [liumingyi@fosunpharma.com](mailto:liumingyi@fosunpharma.com)