



BioNTech and Fosun Pharma Receive Emergency Use Authorization for Omicron-BA.4/BA.5 Adapted Bivalent Vaccine in Hong Kong and Special Import Authorization for Macau

November 11, 2022

- *Omicron BA.4/BA.5-adapted bivalent vaccine will become available in Hong Kong SAR and Macau SAR as a booster dose for individuals 12 years of age and older*
- *BA.4/BA.5-adapted bivalent vaccine combines 15-µg of mRNA encoding the wild-type spike protein found in the original COVID-19 mRNA vaccine and 15-µg of mRNA encoding the spike protein of the Omicron BA.4/BA.5 subvariants*

MAINZ, GERMANY, and SHANGHAI, CHINA, November 11, 2022 — [BioNTech SE](#) (Nasdaq: BNTX, “BioNTech”) and [Shanghai Fosun Pharmaceutical](#) (Group) Co., Ltd. (“Fosun Pharma” or “Group”; Stock Code: 600196.SH, 02196.HK) today announced that the Health Bureau of the Hong Kong Special Administrative Region of the People’s Republic of China (“Hong Kong”) granted Emergency Use Authorization (EUA) of a booster dose of an Omicron BA.4/BA.5-adapted bivalent COVID-19 vaccine (COMIRNATY® Original/Omicron BA.1 15/15 µg) for individuals 12 years of age and older on November 10, 2022. In addition, the Pharmaceutical Administration Bureau (ISAF) of Macau Special Administrative Region of the People’s Republic of China (“Macau”) granted a Special Import Authorization for the Omicron BA.4/BA.5-adapted bivalent COVID-19 vaccine on November 11, 2022.

The bivalent vaccine contains 15-µg of mRNA encoding for the spike-protein of the wild-type of SARS-CoV-2, which is present in the original mRNA COVID-19 vaccine, and 15-µg of mRNA encoding for the spike protein of the Omicron BA.4/BA.5 sublineage of SARS-CoV-2. Because the Omicron BA.4 and BA.5 sublineages contain identical spike protein amino acid sequences, both can be targeted at once with a single mRNA strand. Pre-clinical data showed a booster dose of the company’s Omicron BA.4/BA.5-adapted bivalent vaccine generated a strong neutralizing antibody response against Omicron BA.1, BA.2 and BA.4/BA.5 variants, as well as the original wild-type strain.

For consideration of the EUA, the Health Bureau of Hong Kong reviewed the data package based on clinical data from an Omicron BA.1-adapted bivalent vaccine as well as pre-clinical and manufacturing data from the Omicron BA.4/BA.5-adapted bivalent vaccine. Clinical data from a Phase 2/3 trial showed a booster dose of an Omicron BA.1-adapted bivalent vaccine elicited a superior immune response against the Omicron BA.1 subvariant compared to the companies’ current COVID-19 vaccine, with a favorable safety profile. Additionally, pre-clinical data showed a booster dose of the BA.4/BA.5-adapted bivalent vaccine generated a strong neutralizing antibody response against the Omicron sublineages including BA.1, BA.2, BA.4 and BA.5 subvariants, as well as the original virus. A Phase 2/3 clinical trial ([NCT05472038](#)) evaluating the safety, tolerability, and immunogenicity of the Omicron BA.4/BA.5-adapted bivalent COVID-19 vaccine in adults as well as a Phase 1/2/3 pediatric study ([NCT05543616](#), C4591048) are currently underway.

On 16 March 2020, BioNTech and Fosun Pharma announced a strategic collaboration to develop and commercialize COVID-19 vaccines based on BioNTech’s mRNA technology platform for Greater China Market including the Chinese Mainland, Hong Kong SAR, Macau SAR and Taiwan region. Thus far, the mRNA COVID-19 vaccine has been granted Emergency Use Application in Hong Kong SAR (January 2021) and Special Import Authorizations in Macau SAR (February 2021) and Taiwan region (July 2021).

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, bispecific immune checkpoint 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, Genentech, a member of the Roche Group, Regeneron, Genevant, Fosun Pharma, and Pfizer. For more information, please visit www.BioNTech.com.

BioNTech 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, statements concerning: BioNTech’s efforts to combat COVID-19; the collaboration between BioNTech and Fosun Pharma to develop a COVID-19 vaccine (including emergency use authorization in the Greater China Region for persons 12 years of age and older of an Omicron-adapted COVID-19 bivalent vaccine based on the BA.4/BA.5 subvariant and planned regulatory submissions, qualitative assessments of available data, potential benefits, expectations for clinical trials, the anticipated timing of regulatory submissions, regulatory approvals or authorizations and anticipated manufacturing, distribution and supply); our expectations regarding the potential characteristics of BNT162b2, any monovalent or bivalent vaccine candidates or any future vaccine, in our clinical trials and/or in commercial use based on data observations to date; the ability of BNT162b2, any monovalent or bivalent vaccine candidates or any future vaccine, to prevent COVID-19 caused by emerging virus variants; the uncertainties inherent in research and development, including the ability to meet anticipated clinical endpoints, commencement and/or completion dates for clinical trials, regulatory submission dates, regulatory approval dates and/or launch dates, as well as risks associated with preclinical and clinical data (including Phase 1/2/3 or Phase 4 data), including the data discussed in this release for BNT162b2, any monovalent or bivalent vaccine candidates or any other vaccine candidate in BNT162 program in any of our studies in pediatrics, adolescents, or adults or real world evidence, including the possibility of unfavorable new preclinical, clinical or safety data and further analyses of existing preclinical, clinical or safety data; the expected time point for additional readouts on efficacy data of BNT162b2, or any monovalent or bivalent vaccine candidates or any future vaccine, in our clinical trials; 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; 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; the ability of BioNTech to supply the quantities of BNT162 (including to Hongkong SAR and Macau SAR), any monovalent or bivalent vaccine candidates or any future vaccine, to support clinical development and market demand, including our production estimates for 2022; that demand for any products may be reduced or no longer exist which may lead to reduced revenues or excess inventory; the availability of raw materials to manufacture a vaccine; our vaccine's formulation, dosing schedule and attendant storage, distribution and administration requirements, including risks related to storage and handling after delivery by BioNTech; the ability to successfully develop other vaccine formulations, booster doses or potential future annual boosters or re-vaccinations or new variant-based vaccines; the ability to maintain or scale up manufacturing capacity on a timely basis or maintain access to logistics or supply channels commensurate with global demand for our vaccine, which would negatively impact our ability to supply the estimated numbers of doses of our vaccine within the projected time periods as previously indicated; whether and when additional supply agreements will be reached; the ability to obtain recommendations from vaccine advisory or technical committees and other public health authorities and uncertainties regarding the commercial impact of any such recommendations; challenges related to public vaccine confidence or awareness; and uncertainties regarding the impact of COVID-19 on BioNTech's trials, business and general operations. 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 on Form 6-K for the three and nine months ended September 30, 2022, filed with the SEC on November 7, 2022, 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

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 November 11, 2022. 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, 2021, and Interim Report for the six months ended June 30, 2021, 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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