BioNTech and Fosun Pharma Announce Full Regulatory Approval of their Mono- and Bivalent COVID-19 Vaccine COMIRNATY® in Individuals 12 Years and Older in Hong Kong

December 23, 2022

- *COMIRNATY® Original/Omicron BA.4/BA.5 is the first and currently only variant-adapted vaccine available for individuals 12 years and older which was granted a Biologics License Application equivalent in Hong Kong*
- *Individuals 12 years and older can now receive COMIRNATY® vaccines at medical institutions or clinics in Hong Kong with a medical prescription, in addition to vaccine access via governmental vaccination centers*
- *Clinical data from an ongoing Phase 2/3 trial demonstrated a booster dose of the Omicron BA.4/BA.5-adapted bivalent vaccine elicited substantially higher immune responses against Omicron BA.4/BA.5 sublineages as well as emerging Omicron sublineages compared to the companies' monovalent COVID-19 vaccine encoding for the spike-protein of the wild-type of SARS-CoV-2, suggesting that a bivalent booster may induce a higher level of protection against emerging Omicron sublineages than the original vaccine*
- *Safety and tolerability profile of bivalent booster remains favorable and similar to the companies' monovalent COVID-19 vaccine*

MAINZ, GERMANY, and SHANGHAI, CHINA, December 23, 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 Fosun Industrial Co., Limited (as a sub-licensee of Fosun Pharmaceutical Industrial) has received the certificates of registration as pharmaceutical product in relation to the official registration (the ''Registration'') of the monovalent COVID-19 vaccine (also known as BNT162b2 or COMIRNATY ® Original) and the Omicron BA.4/BA.5-adapted bivalent COVID-19 vaccine (also known as COMIRNATY® Original/Omicron BA.4/BA.5) by the Health Bureau of the Hong Kong Special Administrative Region of the People's Republic of China ("Hong Kong") which is equivalent to a Biologics License Application.

The full regulatory approval of both the companies' monovalent and Omicron *BA.4/BA.5-adapted bivalent COVID-19 vaccine follows the emergency use authorization of* the companies' monovalent COVID-19 vaccine in Hong Kong in March 2021. This makes COMIRNATY ® the first and currently only variant-adapted vaccine available as a booster dose for individuals 12 years and older which has been granted approval in Hong Kong. The companies' monovalent COVID-19 vaccine is approved as a primary course of vaccination for individuals 12 years of age. In addition to vaccine access via governmental vaccination centers, individuals 12 years and older can now receive COMIRNATY® vaccines at medical institutions or clinics in Hong Kong, with a local medical prescription.

While the companies' monovalent COVID-19 vaccine for individuals 12 years and older contains 30-µg of mRNA encoding for the spike-protein of the wild-type of SARS-CoV-2, the bivalent COVID-19 vaccine contains 15-µg of mRNA encoding for the spike-protein of the wild-type of SARS-CoV-2 and 15-µg of mRNA encoding for the spike protein of the Omicron BA.4/BA.5 sublineages of SARS-CoV-2. Apart from the addition of the mRNA sequence of the Omicron BA.4/BA.5 spike protein, all other components of the vaccine remain unchanged.

Clinical data from an ongoing Phase 2/3 trial *demonstrated a robust neutralizing immune response one-month after a booster dose of the companies' Omicron BA.4/BA.5-adapted bivalent COVID-19 vaccine. Immune responses against BA.4/BA.5 sublineages, which are currently the prevalent sublineages in Hong Kong and many regions in Asia, were substantially higher for those who received the bivalent vaccine compared to the companies' monovalent COVID-19 vaccine, with a similar safety and tolerability profile between both vaccines. One-month after a booster dose of the bivalent vaccine, Omicron BA.4/BA.5-neutralizing antibody titers increased 13.2-fold from pre-booster levels in adults older than 55 years of age and 9.5-fold in adults 18 to 55 years of age, compared to a 2.9-fold increase in adults older than 55 years or age who received the original booster vaccine. These results suggest that a booster dose of the Omicron BA.4/BA.5-adapted bivalent vaccine may induce a higher level of protection against the Omicron BA.4 and BA.5 sublineages than the companies' monovalent COVID-19 vaccine.*

Further, an analysis *examining the immune response induced by the companies' Omicron BA.4/BA.5-adapted bivalent COVID-19 vaccine against newer Omicron sublineages, including BA.4.6, BA.2.75.2, BQ.1.1 and XBB.1., showed that neutralizing* antibody titers against emerging Omicron sublineages increased 3.2- to 4.8-fold compared to the companies' monovalent COVID-19 vaccine.

COMIRNATY® Original has been authorized for emergency use ("EUA") for the government vaccination program in the Hong Kong Special Administrative Region and Macau Hong Kong Special Administrative Region since March 2021; vaccination was commenced in the Taiwan region since September 2021. COMIRNATY® Original/Omicron BA.4/BA.5 was available to citizens in Hong Kong and Macau through the government vaccination program since December 1, 2022.

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 Mainland China, Hong Kong Special Administrative Region and Macau Hong Kong Special Administrative Region and Taiwan region.

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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 the Omicron BA.4/BA.5-adapted bivalent COVID-19 vaccine, the receipt of the registration as pharmaceutical product of the Omicron BA.4/BA.5-adapted bivalent COVID-19 in Hong Kong SAR, 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 COVID-19 vaccine 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 COVID-19 vaccine to meet market demands, including our production estimates for 2022. 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 COVID-19 vaccine; whether and when any applications that may be pending or filed for COVID-19 vaccine 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 December 20, 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, 2022, 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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Fosun Pharma
Fosun Pharma has appointed Halo PR as its PR agency for the COVID-19 vaccine in Hong Kong
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