A Pfizer és a BioNTech COVID-19 vakcinája pozitív véleményt kapott az Európai Gyógyszerügynökség Emberi Felhasználásra Szánt Gyógyszerek Bizottságától (CHMP)

- *Az Európai Bizottság döntése a feltételes forgalomba hozatali engedélyről hamarosan várható*
- *A pozitív CHMP vélemény azt követően érkezett, hogy a vakcina világszerte számos helyen kapott sürgősségi felhasználási engedélyt; a CHMP a teljes tudományos dokumentációt áttekintette, ide sorolva a 3. fázisú klinikai vizsgálat hatékonysági és biztonságossági adatait.*
- *Ha engedélyezik, a BNT162b2 lehet az első elérhető COVID-19 vakcina az Európai Unióban*

NEW YORK és MAINZ, NÉMETORSZÁG, 2020. december 21. — A Pfizer (NYSE: PFE) és a BioNTech SE (Nasdaq: BNTX) ma bejelentették, hogy az Európai Gyógyszerügynökség (EMA) Emberi Felhasználásra Szánt Gyógyszerek Bizottsága (CHMP) pozitív véleménnyel támogatja a Pfizer és a BioNTech COVID-19 vakcinájának (BNT162b2) feltételes forgalomba hozatali engedélyét (CMA) a 16 éves vagy annál idősebb populáció aktív immunizálására, a SARS-CoV-2 vírus okozta COVID-19 fertőzés megelőzésére. A feltételes forgalomba hozatali engedély célja, hogy engedélyezze olyan gyógyászati készítmények alkalmazását, melyek súlyos egészségkárosító vagy életveszélyes betegségek kezelésére, vagy az Európai Unió és a WHO által közegészségügyi fenyegetésként értékelt vészhelyzetek elhárítására szolgálnak.

„A mai egy igazán személyes és felemelő nap számunkra a BioNTech-nél. Az Európai Unió közepén működve nagyon izgatottak vagyunk, hiszen egy lépésssel közelebb kerülhettünk ahhoz, hogy Európa számára biztosíthassuk az első vakcinát, mely segítheti e pusztító világjárvány leküzdését. Készen állunk, hogy megkezdjük az első vakcina adagok szállítását az Európai Unióban, amint megkapjuk a zöld jelzést” – mondta Ugur Sahin, M.D.h, a BioNTech vezérigazgatója és társalapítója

„Örülünk, hogy a CHMP bizalmat szavazott tudományos adatainknak.” – mondta el Dr. Albert Bourla, a Pfizer elnök-vezérigazgatója. “Ha az Európai Bizottság megadja az engedélyt, készen állunk, hogy a vakcinát a kormányzatok által kijelölt helyekre szállítsuk az Európai Unió egész területén, ahol a fertőzéses esetek száma továbbra is emelkedik és több ország küzd lezárásokkal”

A CHMP tanácsadói pozitív véleményüket a Pfizer-BioNTech COVID-19 elleni vakcinájának tudományos dokumentációjára alapozva adták ki, mely dokumentáció tartalmazza a 3-as fáziú klinikai vizsgálatok múlt hónapban bejelentett és 2020. december 10-én a *The New England Journal of Medicine-ben* publikált adatait is. Az Európai Bizottság áttekinti a CHMP ajánlását és várhatóan a közeljövőben döntést hoz a feltételes forgalomba hozatali engedélyről. Amennyiben a Bizottság megadja a feltételes forgalomba hozatali engedélyt, a döntés azonnal az Európai Unió mind a 27 tagállama számára hatályba lép.

Mostanáig a vakcina több mint 15 országban kapott sürgősségi felhasználási engedélyt vagy jóváhagyást. A hatósági folyamatok több országban jelenleg is zajlanak, további engedélyezések várhatóak.

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About Pfizer: Breakthroughs That Change Patients' Lives
At Pfizer, we apply science and our global resources to bring therapies to people that extend and significantly improve their lives. We strive to set the standard for quality, safety and value in the discovery, development and manufacture of health care products, including innovative medicines and vaccines. Every day, Pfizer colleagues work across developed and emerging markets to advance wellness, prevention, treatments and cures that challenge the most feared diseases of our time. Consistent with our responsibility as one of the world's premier innovative biopharmaceutical companies, we collaborate with health care providers, governments and local communities to support and expand access to reliable, affordable health care around the world. For more than 150 years, we have worked to make a difference for all who rely on us. We routinely post information that may be important to investors on our website at www.Pfizer.com. In addition, to learn more, please visit us on www.Pfizer.com and follow us on Twitter at @Pfizer and @Pfizer News, LinkedIn, YouTube and like us on Facebook at Facebook.com/Pfizer.

Pfizer Disclosure Notice
The information contained in this release is as of December 21, 2020. Pfizer assumes no obligation to update forward-looking statements contained in this release as the result of new information or future events or developments.

This release contains forward-looking information about Pfizer's efforts to combat COVID-19, the collaboration between BioNTech and Pfizer to develop a COVID-19 vaccine, the BNT162 mRNA vaccine program and modRNA candidate BNT162b2 (including qualitative assessments of available data, potential benefits, expectations for clinical trials, the pending conditional marketing authorization (CMA) application in the EU, other regulatory submissions, the anticipated timing of regulatory submissions, regulatory approval or authorization and anticipated manufacturing, distribution and supply) involving substantial risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements. Risks and uncertainties include, among other things, 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 clinical data (including the Phase 3 data), including the possibility of unfavorable new preclinical or clinical trial data and further analyses of existing preclinical or clinical trial data; the ability to produce comparable clinical or other results, including the rate of vaccine effectiveness and safety and tolerability profile observed to date, in additional analyses of the Phase 3 trial and additional studies 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; the risk that clinical trial data are subject to differing interpretations and assessments, including during the peer review/publication process, in the scientific community generally, and by regulatory authorities; whether and when additional data from the BNT162 mRNA vaccine program will be published in scientific journal publications and, if so, when and with what modifications; whether regulatory authorities will be satisfied with the design of and results from these and any future preclinical and clinical studies; whether and when other biologics license and/or emergency use authorization applications may be filed in particular jurisdictions for BNT162b2 or any other potential vaccines; whether and when the pending CMA application will be authorized by the EC and whether and when any other 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 and, if approved, whether it will be commercially successful; decisions by regulatory authorities impacting labeling, manufacturing processes, safety and/or other matters that could affect the availability or commercial potential of a vaccine, including development of products or therapies by other companies; 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; challenges related to our vaccine's ultra-low temperature formulation and attendant storage, distribution and administration requirements, including risks related to

handling after delivery by Pfizer; the risk that we may not be able to successfully develop non-frozen formulations; the risk that we may not be able to create or scale up manufacturing capacity on a timely basis or have 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 indicated; whether and when additional supply agreements will be reached; uncertainties regarding the ability to obtain recommendations from vaccine technical committees and other public health authorities and uncertainties regarding the commercial impact of any such recommendations; uncertainties regarding the impact of COVID-19 on Pfizer's business, operations and financial results; and competitive developments.

A further description of risks and uncertainties can be found in Pfizer's Annual Report on Form 10-K for the fiscal year ended December 31, 2019 and in its subsequent reports on Form 10-Q, including in the sections thereof captioned "Risk Factors" and "Forward-Looking Information and Factors That May Affect Future Results", as well as in its subsequent reports on Form 8-K, all of which are filed with the U.S. Securities and Exchange Commission and available at www.sec.gov and www.pfizer.com.

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.

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 Pfizer 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 timepoint 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; the timing for submission of manufacturing data to the FDA; our contemplated shipping and storage plan, including our estimated product shelflife 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 2020 and 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 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 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.

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