Pfizer and BioNTech Initiate Phase 1/2 Study of First mRNA-based Shingles Vaccine Program

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- *Phase 1/2 trial will enroll up to 900 healthy U.S. volunteers ages 50 through 69*
- *As the global population ages, there is a need for highly effective, well tolerated, and efficiently produced shingles vaccines which Pfizer and BioNTech aim to address by utilizing mRNA technology*
- *Without vaccination, about half of the people who live to age 85 are expected to develop shingles,[1] a painful, localized rash caused by reactivation of the varicella zoster virus*

NEW YORK and MAINZ, GERMANY, February 10, 2023 —Pfizer Inc. (NYSE: PFE) and BioNTech SE (Nasdaq: BNTX) today announced the start of a Phase 1/2 trial exploring the safety, tolerability, and immunogenicity of the companies' mRNA vaccine candidates against shingles (also known as herpes zoster, or "HZ"), a debilitating disease caused by the varicella zoster virus ("VZV"). Shingles affects millions of people around the world each year.[2]

The companies' Phase 1/2 multicenter, randomized, controlled, dose-selection study (NCT05703607) will evaluate the safety, tolerability, and immunogenicity of mRNA vaccine candidates against shingles. The study is aiming to enroll up to 900 healthy volunteers 50 through 69 years of age and is being conducted in the United States. Phase 1 will help select the optimal mRNA vaccine candidate, dose level, dosing schedule, and formulation for advancement to Phase 2. Participants in the study will be followed to determine how long protection may last.

While there are currently approved vaccines for shingles, Pfizer and BioNTech aim to utilize mRNA technology to potentially develop a vaccine that demonstrates high efficacy, is well tolerated, and is efficient to produce globally. The companies will leverage Pfizer's proprietary antigen technology and BioNTech's proprietary mRNA platform technology used in the companies' COVID-19 vaccine. The mRNA shingles vaccine candidates encode different versions of glycoprotein E ("gE") on the surface of the varicella zoster virus. The gE protein is important for viral replication and the cell-to-cell spread after reactivation of the virus in the nerve cells.[3]

Pfizer and BioNTech announced a shingles vaccine collaboration in January 2022. The companies are also working together on COVID-19, and a COVID-19 and influenza combination vaccine program.

About Shingles (Herpes Zoster)
Shingles (also known as herpes zoster or "HZ") is an infectious disease caused by the reactivation of varicella zoster virus ("VZV"). Primary infection with VZV causes chickenpox, usually during childhood. After chickenpox, the virus remains dormant in human nerve cells and can reactivate later in life due to stress or immunosuppression.[4] Shingles manifests as an extremely painful localized rash, which may cause persistent pain after resolution, a condition known as postherpetic neuralgia ("PHN"). [5] In rare cases, shingles can also lead to hearing loss, brain inflammation (encephalitis) or blindness.[6]

Globally, about 95% of individuals older than 50 years of age have been exposed to VZV, placing them at risk of developing shingles.[7] Furthermore, both the incidence and severity of shingles rise with age, with a marked increase after age 50.[8] With an aging global population, shingles vaccination is an important global health priority.[9]

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 170 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 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 February 10, 2023. 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 mRNA-based vaccine candidates against shingles (herpes zoster) and a collaboration between Pfizer and BioNTech, including their potential benefits, that involves 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 our clinical trials, regulatory submission dates, regulatory approval dates and/or launch dates, as well as the possibility of unfavorable new clinical data and further analyses of existing clinical data; the risk that clinical trial data are subject to differing interpretations and assessments by regulatory authorities; whether regulatory authorities will be satisfied with the design of and results from our clinical studies; whether and when drug applications may be filed in any jurisdictions for an mRNA-based vaccine candidate against shingles; whether and when any such applications may be approved by regulatory authorities, which will depend on myriad factors, including making a determination as to whether the product's benefits outweigh its known risks and determination of the product's efficacy and, if approved, whether such vaccine candidate 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 an mRNA-based vaccine candidate against shingles; whether the collaboration between Pfizer and BioNTech will be successful; 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, 2021 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, 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: the collaboration between BioNTech and Pfizer, including the program to develop and commercialize a mRNA vaccine candidate against shingles (also known as herpes zoster, or "HZ") caused by the varicella zoster virus ("VZV"); timing for commencement of the Phase 1/2 trial of the companies' mRNA vaccine candidates against shingles and the number of anticipated volunteers to be enrolled in the U.S.; the ability of a mRNA vaccine candidate against shingles to show high efficacy, being well tolerated, and being efficient to produce globally; 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; the nature and characterization of and timing for release of clinical data across BioNTech's platforms, which is subject to peer review, regulatory review and market interpretation; the planned next steps in BioNTech's pipeline programs and specifically including, but not limited to, statements regarding timing or plans for initiation of clinical trials, enrolment or submission for and receipt of product approvals with respect to BioNTech's product candidates; the ability of BioNTech's mRNA technology to demonstrate clinical efficacy outside of the Pfizer-BioNTech COVID-19 Vaccine; the potential safety and efficacy of our other product candidates; BioNTech's anticipated market opportunity and size for its product candidates; and the success of BioNTech's collaboration with Pfizer on a shingles vaccine and the ability of BioNTech to achieve the collaboration milestone payments. Any forward-looking statements in this press release are based on BioNTech'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.

For a discussion of these and other risks and uncertainties, see BioNTech's Quarterly Report on Form 6-K for the quarter 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.

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