Pfizer and BioNTech Sign New Global Collaboration Agreement to Develop First mRNA-based Shingles Vaccine

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- Third mRNA vaccine collaboration between the companies aims to accelerate development of an improved vaccine for shingles, a debilitating, disfiguring and painful disease that affects people all over the world
- Product candidates will be based on BioNTech's proprietary mRNA technology and on Pfizer's antigen technology
- Clinical trials are expected to start in the second half of 2022
- BioNTech will receive $225 million upfront, including an upfront cash payment of $75 million and an equity investment of $150 million, and will be eligible to receive future approval and sales milestone payments totaling up to $200 million as well as a share of gross profits arising from future product sales
- Pfizer will receive an upfront payment of $25 million from BioNTech for its proprietary antigen sequences identified by Pfizer

NEW YORK and MAINZ, Germany, January 5, 2022 — Pfizer Inc. (NYSE: PFE) and BioNTech SE (Nasdaq: BNTX) today announced a new research, development and commercialization collaboration to develop a potential first mRNA-based vaccine for the prevention of shingles (herpes zoster virus, or HZV), a debilitating, disfiguring and painful disease that impacts about one in three people in the United States during their lifetime. The collaboration builds on the companies’ success in developing the first approved and most widely used mRNA vaccine to help prevent COVID-19. This is the third collaboration between Pfizer and BioNTech in the infectious diseases field, following the influenza vaccine collaboration initiated in 2018 and the COVID-19 vaccine collaboration initiated in 2020.

Under the terms of the agreement, the companies will leverage a proprietary antigen technology identified by Pfizer's scientists and BioNTech's proprietary mRNA platform technology used in the companies' COVID-19 vaccine. The parties will share development costs. Clinical trials are planned to start in the second half of 2022. Pfizer will have rights to commercialize the potential vaccine on a global basis, with the exception of Germany, Turkey and certain developing countries where BioNTech will have commercialization rights. The companies will share gross profits from commercialization of any product.

“Pfizer and BioNTech co-developed the world’s first mRNA vaccine, providing a well-tolerated and effective tool to help address COVID-19 – the most devastating pandemic in a century – and demonstrating consistent, agile and high-quality manufacturing on an unprecedented scale,” said Mikael Dolsten, M.D., Ph.D., Chief Scientific Officer and President, Worldwide Research, Development & Medical, Pfizer. "With this agreement, we continue on our journey of discovery together, by advancing mRNA technology to tackle another health challenge ripe for scientific innovation, supported by our world-class manufacturing network.”

“The collaboration aims to develop a new mRNA-based vaccine against shingles, leveraging the expertise and resources of both companies,” said Ugur Sahin, M.D., CEO and Co-Founder of BioNTech. “Adults aged 50 years and older as well as vulnerable populations like cancer patients are at an increased risk of shingles. Our goal is to develop an mRNA vaccine with a favorable safety profile and high efficacy, which is at the same time more easily scalable to support global access.”

Under the terms of the agreement, Pfizer will pay BioNTech $225 million in upfront payments, including a cash payment of $75 million and an equity investment of $150 million. BioNTech is eligible to receive future regulatory and sales milestone payments of up to $200 million. BioNTech will pay Pfizer $25m for the company’s proprietary antigen technology.

About Shingles (Herpes Zoster Virus)

Shingles (HZV) is a chronic form of the varicella zoster virus (VZV), which causes an initial chickenpox infection. After chickenpox disease, the virus remains dormant in human nerve cells and can re-activate later in life, due to a trigger such as stress or immunocompromise. This attack can lead to extremely painful, disfiguring patches, which may continue to be painful after the episode has resolved, a condition known as postherpetic neuralgia (PHN). In rare conditions, shingles can also lead to facial paralysis, deafness and blindness.

According to the U.S. Centers for Disease Control and Prevention, studies show that more than 99 percent of Americans 40 years and older have had chickenpox, even if they don’t remember having the disease.

While there are currently approved vaccines for shingles, there is an opportunity to develop an improved vaccine that potentially shows high efficacy and better tolerability, and is more efficient to produce globally, by utilizing mRNA technology.

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 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 January 5, 2022. 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 a potential preventative Herpes Zoster Virus (HZV) mRNA vaccine candidate and a strategic research, development and commercialization collaboration between Pfizer and BioNTech for the development of such HZV mRNA vaccine candidate, 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 a HZV mRNA vaccine candidate; 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 a HZV mRNA 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 a HZV mRNA vaccine candidate; whether the collaboration between Pfizer and BioNTech will be successful; 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, 2020 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, the ability of BioNTech to develop and commercialize a vaccine for the Herpes Zoster Virus (HZV), the ability of BioNTech to achieve the collaboration milestone payments and the timing to commence clinical trials. 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 the section entitled “Risk Factors” in BioNTech's Annual Report on Form 20-F filed with the SEC on March 30, 2021, 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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