Pfizer and BioNTech Announce Further Details on Collaboration to Accelerate Global COVID-19 Vaccine Development

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Pfizer and BioNTech to jointly develop COVID-19 vaccine, initially in the United States and Europe, and scale-up manufacturing capacity to support global supply. Potential to supply millions of vaccine doses by the end of 2020 subject to technical success of the development program and approval by regulatory authorities, and then rapidly scale up capacity to produce hundreds of millions of doses in 2021. BioNTech will contribute multiple mRNA vaccine candidates as part of its BNT162 COVID-19 vaccine program, which are expected to enter human testing in April 2020. Pfizer will contribute its leading global vaccine clinical research and development, regulatory, manufacturing and distribution infrastructure and capabilities. BioNTech will receive an upfront payment of $185 million, including an equity investment of approximately $113 million, and be eligible to receive future milestone payments of up to $563 million for a potential total consideration of $748 million.

MAINZ, Germany & NEW YORK--(BUSINESS WIRE)-- BioNTech SE (Nasdaq: BNTX, “BioNTech” or “the Company”), and Pfizer Inc. (NYSE: PFE) today disclosed additional details of their collaboration to advance candidates from BioNTech’s mRNA vaccine program, previously announced on March 17, 2020.

This press release features multimedia. View the full release here: https://www.businesswire.com/news/home/20200409005405/en/
The collaboration aims to rapidly advance multiple COVID-19 vaccine candidates into human clinical testing based on BioNTech’s proprietary mRNA vaccine platforms, with the objective of ensuring rapid worldwide access to the vaccine, if approved. The collaboration will leverage Pfizer’s broad expertise in vaccine research and development, regulatory capabilities, and global manufacturing and distribution network.

The two companies plan to jointly conduct clinical trials for the COVID-19 vaccine candidates initially in the United States and Europe across multiple sites. BioNTech and Pfizer intend to initiate the first clinical trials as early as the end of April 2020, assuming regulatory clearance.

During the clinical development stage, BioNTech and its partners will provide clinical supply of the vaccine from its GMP-certified mRNA manufacturing facilities in Europe. BioNTech and Pfizer will work together to scale-up manufacturing capacity at risk to provide worldwide supply in response to the pandemic. BioNTech and Pfizer will also work jointly to commercialize the vaccine worldwide (excluding China, which is already covered by BioNTech’s collaboration with Fosun Pharma) upon regulatory approval.

“Combatting the COVID-19 pandemic will require unprecedented collaboration across the innovation ecosystem, with companies coming together to unite capabilities like never before,” said Mikael Dolsten, Chief Scientific Officer and President, Worldwide Research, Development & Medical, Pfizer. “I am proud of Pfizer’s collaboration with BioNTech and have every confidence in our ability to harness the power of science – together – to bring forth a potential vaccine that the world needs as quickly as possible.”

“We have already started working with Pfizer on our COVID-19 vaccine and are pleased to announce these further details of our ongoing collaboration, which reflects both companies’ strong commitment to move quickly to bring a safe and efficacious vaccine to patients worldwide,” says Co-Founder and CEO of BioNTech, Ugur Sahin, M.D.

Under the terms of the agreement, Pfizer will pay BioNTech $185 million in upfront payments, including a cash payment of $72 million and an equity investment of $113 million. BioNTech is eligible to receive future milestone payments of up to $563 million for a potential total consideration of $748 million. Pfizer and BioNTech will share development costs equally. Initially, Pfizer will fund 100 percent of the development costs, and BioNTech will repay Pfizer its 50 percent share of these costs during the commercialization of the vaccine.

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 April 9, 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, BioNTech’s mRNA vaccine program, BNT162, a collaboration between BioNTech and Pfizer to develop a potential COVID-19 vaccine and manufacturing capacity, including their potential benefits, and the expected timing of clinical trials and potential supply, 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 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 the clinical studies; whether and when any biologics license applications may be filed in any jurisdictions for any potential vaccine candidates under the collaboration; 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 any such vaccine candidates 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 any such vaccine candidates, including development of products or therapies by other companies; manufacturing capabilities or capacity; uncertainties regarding the ability to obtain recommendations from vaccine technical committees and other public health authorities regarding any such vaccine candidates and uncertainties regarding the commercial impact of any such recommendations; 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 (BioNTech) is a next generation immunotherapy company pioneering novel therapies for cancer, infectious diseases and rare diseases. The company exploits a wide array of computational discovery and therapeutic drug platforms for the rapid development of novel biopharmaceuticals. 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. Its broad portfolio of 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. BioNTech has established a broad set of relationships with multiple global pharmaceutical collaborators, including Eli Lilly and Company, Genmab, Sanofi, Bayer Animal Health, Genentech, a member of the Roche Group, 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, BioNTech’s efforts to combat COVID-19, the ability of BioNTech and Pfizer to co-develop and co-commercialize a vaccine for COVID-19, the ability of BioNTech and Pfizer to develop manufacturing capacity, BioNTech’s
potential COVID-19 mRNA vaccine, BNT162, an agreement regarding the co-development and co-commercialization by Pfizer and BioNTech of BNT162, including its potential benefits and the expected timing of a Phase 1 trial of BNT162. 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. These risks and uncertainties include, but are not limited to: competition to create a vaccine for Covid-19 and potential difficulties. For a discussion of these and other risks and uncertainties, see the section entitled “Risk Factors” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” in BioNTech’s Annual Report on Form 20-F filed with the SEC on March 31, 2020 which has been filed with the SEC and 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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Pfizer Contacts Media Relations Amy Rose (U.S.) +1 (212) 733-7410
amy.rose@pfizer.com Lisa O’Neill (UK) +44 7929339560 lisa.o'neill@pfizer.com Investor Relations Ryan Crowe +1 (212) 733-8160 ryan.crowe@pfizer.com BioNTech Contacts: Media Relations Jasmina Alatovic Senior Manager Global External Communications +49 (0)6131 9084 1513 or +49 (0)151 1978 1385 Media@biontech.de Investor Relations Sylke Maas, Ph.D. VP Investor Relations & Business Strategy +49 (0)6131 9084 1074 Investors@biontech.de

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