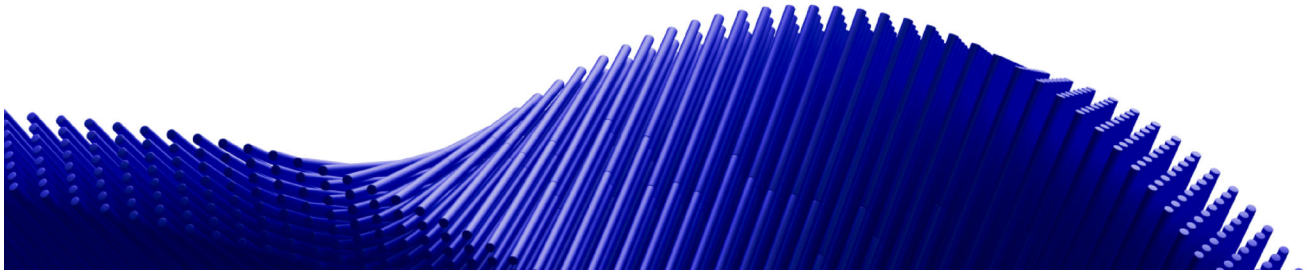
Pfizer and BioNTech Announce an Agreement with U.S. Government for up to 600 Million Doses of mRNA-based Vaccine Candidate Against SARS-CoV-2

pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-announce-agreement-us-government-600



- *U.S. government placed an initial order of 100 million doses for $1.95 billion and can acquire up to 500 million additional doses*
- *Americans to receive the vaccine for free consistent with U.S. government's commitment for free access for COVID-19 vaccines*
- *Pfizer and BioNTech remain on track to begin an anticipated Phase 2b/3 safety and efficacy trial later this month, seek regulatory review as early as October 2020, and manufacture globally up to 100 million doses by the end of 2020 and potentially more than 1.3 billion doses by the end of 2021*

NEW YORK & MAINZ, Germany--(BUSINESS WIRE)-- Pfizer Inc. (NYSE: PFE) and BioNTech SE (Nasdaq: BNTX) today announced the execution of an agreement with the U.S. Department of Health and Human Services and the Department of Defense to meet the U.S. government's Operation Warp Speed program goal to begin delivering 300 million doses of a vaccine for COVID-19 in 2021. Under the agreement, the U.S. government will receive 100 million doses of BNT162, the COVID-19 vaccine candidate jointly developed by Pfizer and BioNTech, after Pfizer successfully manufactures and obtains approval or emergency use authorization from U.S. Food and Drug Administration (FDA).

This press release features multimedia. View the full release here: https://www.businesswire.com/news/home/20200722005438/en/

The U.S. government will pay the companies $1.95 billion upon the receipt of the first 100 million doses, following FDA authorization or approval. The U.S. government also can acquire up to an additional 500 million doses.

Americans will receive the vaccine for free consistent with U.S. government's commitment for free access for COVID-19 vaccines.

"We've been committed to making the impossible possible by working tirelessly to develop and produce in record time a safe and effective vaccine to help bring an end to this global health crisis," said Dr. Albert Bourla, Pfizer Chairman and CEO. "We made the early decision to begin clinical work and large-scale manufacturing at our own risk to ensure that product would be available immediately if our clinical trials prove successful and an Emergency Use Authorization is granted. We are honored to be a part of this effort to provide Americans access to protection from this deadly virus."

"Expanding Operation Warp Speed's diverse portfolio by adding a vaccine from Pfizer and BioNTech increases the odds that we will have a safe, effective vaccine as soon as the end of this year," said HHS Secretary Alex Azar. "Depending on success in clinical trials, today's agreement will enable the delivery of approximately 100 million doses of this vaccine to the American people."

The BNT162 program is based on BioNTech's proprietary mRNA technology and supported by Pfizer's global vaccine development and manufacturing capabilities. The BNT162 vaccine candidates are undergoing clinical studies and are not currently approved for distribution anywhere in the world. BioNTech is the market authorization holder worldwide and will hold all trademarks for the potential product. Both collaborators are committed to developing these novel vaccines with pre-clinical and clinical data at the forefront of all their decision-making.

"We are pleased to have signed this important agreement with the U.S. government to supply the initial 100 million doses upon approval as part of our commitment to address the global health threat. This agreement is one of many steps towards providing global access to a safe and efficacious vaccines for COVID-19. We are also in advanced discussions with multiple other government bodies and we hope to announce additional supply agreements soon. Our goal remains to bring a safe and effective COVID-19 vaccine to many people around the world, as quickly as we can," said Ugur Sahin, M.D., CEO and Co-founder of BioNTech.

The Pfizer/BioNTech vaccine development program is evaluating at least four experimental vaccines, each of which represents a unique combination of messenger RNA (mRNA) format and target antigen. On July 1st, Pfizer and BioNTech announced preliminary data from BNT162b1, the most advanced of the four mRNA formulations. The early data demonstrates that BNT162b1 is able to produce neutralizing antibodies in humans at or above the levels observed in the plasma from patients who have recovered from COVID-19, and this was shown at relatively low dose levels. Local reactions and systemic events were dose-dependent, generally mild to moderate, and transient. No serious adverse events were reported. On July 20th, the companies announced early positive update from German Phase 1/2 COVID-19 vaccine study, including first T Cell response data.

Recently, two of the companies' four investigational vaccine candidates (BNT162b1 and BNT162b2) received Fast Track designation from the U.S. Food and Drug Administration (FDA). This designation was granted based on preliminary data from Phase 1/2 studies that are currently ongoing in the United States and Germany as well as animal immunogenicity studies. Further data from the ongoing Phase 1/2 clinical trials of the four vaccine candidates will enable the selection of a lead candidate and dose level for an anticipated large, global Phase 2b/3 safety and efficacy study that may begin as early as later this month, pending regulatory approval.

If the ongoing studies are successful, Pfizer and BioNTech expect to be ready to seek Emergency Use Authorization or some form of regulatory approval as early as October 2020. The companies currently expect to manufacture globally up to 100 million doses by the end of 2020 and potentially more than 1.3 billion doses by the end of 2021, subject to final dose selection from their clinical trial.

In addition to engagements with governments, Pfizer and BioNTech have provided an expression of interest for possible supply to the COVAX Facility, a mechanism established by Gavi, the Vaccine Alliance, the Coalition for Epidemic Preparedness Innovations (CEPI) and World Health Organization (WHO) that aims to provide governments with early access to a large portfolio of COVID-19 candidate vaccines using a range of technology platforms, produced by multiple manufacturers across the world.

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 July 22, 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 BNT162 mRNA vaccine program, a collaboration between BioNTech and Pfizer to develop a potential COVID-19 vaccine, an agreement with the United States to manufacture and deliver BNT162 and other potential agreements, including their potential benefits, manufacturing and distribution and the expected timing of clinical trials and regulatory submissions, 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 preclinical or clinical trial data and further analyses of existing preclinical or clinical trial data; risks associated with preliminary data; 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 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 future preclinical and 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, including whether the estimated numbers of doses can be manufactured within the projected time periods indicated; whether and when a future production agreement with the United States will be reached; whether and when other supply agreements will be reached; 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 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, 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 timing to initiate clinical trials of BNT162 and anticipated publication of data from these clinical trials; the timing for any potential emergency use authorizations or approvals; the potential to enter into additional supply agreements with other jurisdictions or the COVAX Facility; the potential safety and efficacy of BNT162; the collaboration between BioNTech and Pfizer to develop a potential COVID-19 vaccine; 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: competition to create a vaccine for COVID-19; the ability to produce comparable clinical results in larger and more diverse clinical trials; 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 Annual Report on Form 20-F filed with the SEC on March 31, 2020, 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.

View source version on businesswire.com : https://www.businesswire.com/news/home/20200722005438/en/

Pfizer:
Media Relations
Amy Rose
+1 (212) 733-7410
Amy.Rose@pfizer.com

Investor Relations
Chuck Triano
+1 (212) 733-3901
Charles.E.Triano@Pfizer.com

BioNTech:
Media Relations
Jasmina Alatovic
+49 (0)6131 9084 1513 or +49 (0)151 1978 1385
Media@biontech.de

Investor Relations
Sylke Maas, Ph.D.
+49 (0)6131 9084 1074
Investors@biontech.de

Source: Pfizer Inc.