

## **Pfizer and BioNTech to Supply New Zealand with 1.5 million doses of their BNT162 mRNA-based Vaccine Candidate Against SARS-CoV-2**

- *Supply of 1.5 million doses to be provided over the course of 2021, subject to Medsafe approval*
- *Agreement is part of Pfizer's and BioNTech's global commitment to help address the COVID-19 pandemic*
- *Pfizer and BioNTech began a Phase 2/3 safety and efficacy trial and assuming positive data, plan to initiate regulatory applications in the fourth quarter of 2020 and manufacture globally up to 100 million doses by the end of 2020 and approximately 1.3 billion doses by the end of 2021*

**AUCKLAND, NEW ZEALAND and MAINZ, GERMANY, 12 October 2020** — Pfizer New Zealand and BioNTech SE today announced an agreement with the Ministry of Health in New Zealand to supply 1.5 million doses of their BNT162 mRNA-based vaccine candidate against SARS-CoV-2, subject to clinical success and regulatory approval, in 2021.

Financial details of the agreement were not disclosed, but the terms were based on the timing of delivery and the volume of doses. As requested by the Government of New Zealand, deliveries are planned in 2021, subject to clinical success and local regulatory approval.

"We are deeply honored to work with the New Zealand government and to marshal our scientific and manufacturing resources toward our shared goal of bringing a potential COVID-19 vaccine to the New Zealand people as quickly as possible," said Anne Harris, Pfizer New Zealand Country Manager. "In the face of this global health crisis, Pfizer's purpose – breakthroughs that change patients' lives – has taken on an even greater urgency. Our hope is that, subject to clinical and regulatory success, our vaccine will help make this happen."

"I would like to thank the New Zealand government for its support and putting trust in our ability to develop a vaccine that, we believe, has the potential to help address this global pandemic threat. Our goal remains to create a global supply of a safe and effective COVID-19 vaccine for many people around the world, as quickly as we can," said Sean Marett, Chief Business and Chief Commercial Officer at BioNTech.

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, including those in the emerging markets, 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 the BNT162 Candidate**

The BNT162 program is based on BioNTech's proprietary mRNA technology and supported by Pfizer's global vaccine development and manufacturing capabilities. In July, 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.

On July 27, Pfizer and BioNTech announced that following extensive review of preclinical and clinical data from Phase 1/2 clinical trials, and in consultation with the FDA's Center for Biologics Evaluation and Research (CBER) and other global regulators, the companies selected the BNT162b2 vaccine candidate to move forward into a Phase 2/3 study. BNT162b2 encodes an optimized SARS-CoV-2 full length spike glycoprotein (S), which is the target of virus neutralizing antibodies.

### **About the Phase 2/3 Study**

In the late-stage trial, the companies will study a 30 micrograms dose level in a 2-dose regimen. In September, Pfizer submitted an amended protocol to the FDA for the Phase 3 pivotal trial to expand recruitment from 30,000 to approximately 44,000 participants that allows for the enrollment of new populations and include adolescents as young as 16 years of age and people with chronic, stable HIV (human immunodeficiency viruses), Hepatitis C, or Hepatitis B infection, as well as provide additional safety and efficacy data.

Based on current infection rates, we continue to expect that a readout on efficacy for the trial's primary endpoint could be as early as the end of October. It is expected to include approximately 120 sites globally including in regions with significant expected SARS-CoV-2 transmission.

Assuming clinical success, Pfizer and BioNTech plan to initiate regulatory applications for BNT162b2 in the fourth quarter of 2020 and, if regulatory authorization or approval is obtained, plan to supply up to 100 million doses worldwide by the end of 2020 and approximately 1.3 billion doses by the end of 2021.

The BNT162 vaccine candidate is not currently approved for distribution anywhere in the world. Both collaborators are committed to developing these novel vaccines with pre-clinical and clinical data at the forefront of all their decision-making.

**About Pfizer New Zealand: Breakthroughs That Change Patients' Lives™** At Pfizer, we apply science and our global resources to improve health and well-being at every stage of life. We strive to set the standard for quality, safety and value in the discovery, development and manufacturing of medicines. Our diversified global health care portfolio includes biologic and small molecule medicines and vaccines. Consistent with our responsibility as one of the world's leading biopharmaceutical companies, we also collaborate with healthcare 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. For more information please visit: [www.pfizer.co.nz](http://www.pfizer.co.nz)

**Pfizer Disclosure Notice** The information contained in this release is as of 12 October, 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 potential COVID-19 vaccine, an agreement with the government of New Zealand to supply BNT162 and other potential agreements, the BNT162 mRNA vaccine program, and modRNA candidates BNT162b2 and BNT162b1 (including qualitative assessments of available data, potential benefits, expectations for clinical trials and timing of regulatory submissions, anticipated manufacturing, supply and distribution), 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 risks associated with preliminary data, including the possibility of unfavorable new preclinical or clinical trial data and further analyses of existing preclinical or clinical trial data that may be inconsistent with the data used

for selection of the BNT162b2 vaccine candidate and dose level for the Phase 2/3 study; 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 and/or emergency use authorization applications may be filed in any jurisdictions for BNT162b2 or any other potential vaccine candidates; 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 vaccine candidate's benefits outweigh its known risks and determination of the vaccine candidate'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; manufacturing capabilities or capacity, including whether the estimated numbers of doses can be manufactured within the projected time periods indicated; whether and when additional supply agreements will be reached; uncertainties regarding the ability to obtain commendations from vaccine technical committees and other public health authorities 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](http://www.sec.gov) and [www.pfizer.com](http://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](http://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 production 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](http://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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