

Pfizer and BioNTech Achieve Approval by TGA for Their Vaccine Against COVID-19

- Australian drug safety regulator, the Therapeutic Goods Administration (TGA), approves supply of COVID-19 mRNA vaccine, COMIRNATY™.
- Pfizer & BioNTech are ready to deliver the 10 million doses to Australia over 2021, allowing for 5 million Australians to be vaccinated.
- Pfizer has a robust and reliable distribution network to deliver our vaccine to Australians over 2021.

SYDNEY, AUSTRALIA [25 January 2021] — Pfizer Australia and BioNTech today announced that the Therapeutic Goods Administration (TGA) in Australia has granted Provisional Approval for their COVID-19 mRNA vaccine COMIRNATY™. The distribution of the vaccine in Australia will be prioritised by the Department of Health according to the populations identified in guidance from the ATAGI (Australian Technical Advisory Group on Immunisation) COVID-19 Working Group.

“Today’s Provisional Approval in Australia marks an historic moment in the fight against COVID-19. It further affirms Pfizer’s commitment to deliver on its promise to safely bring to Australians a high quality vaccine against this virus,” said Anne Harris, Pfizer Australia and New Zealand Managing Director.

“We commend the TGA for its careful assessment of COMIRNATY™.

“We thank both the Commonwealth Government and the Department of Health for their strong partnership to bring our vaccine to Australians.

“We are proud to be part of this breakthrough which was made possible through unparalleled collaboration between companies, governments, regulators, public health bodies, and the academic and scientific communities coming together urgently to find solutions to the pandemic”, Ms Harris said.

“It is encouraging to see that our mRNA vaccine is now approved in Australia. The number of countries authorising the use of our vaccine is steadily increasing. This is important in order to support addressing this pandemic,” said Sean Marett, Chief Business Officer and Chief Commercial Officer at BioNTech. “Together with our partner Pfizer, we are looking forward to shipping the vaccines to Australia”, Mr Marrett said.

The TGA’s decision is based on a rolling submission including data from the Phase 3 clinical study, which demonstrated a vaccine efficacy rate of 95% ($p < 0.0001$) in participants without prior SARS-CoV-2 infection (first primary objective), and also in participants with and without prior SARS-CoV-2 infection (second primary objective), in each case measured from 7 days after the second dose. The first primary objective analysis is based on 170 cases of COVID-19, as specified in the study protocol. Efficacy was consistent across age, gender, race and ethnicity demographics, with an observed efficacy in adults age 65 and over, of more than 94%. In the trial, COMIRNATY™. was generally well tolerated with no safety concerns reported by the Data Monitoring Committee to date.

Pfizer and BioNTech previously announced an agreement with the Australian government on 5 November 2020 to supply 10 million doses of the mRNA-based vaccine COMIRNATY™. once approved. Dose deliveries will occur throughout 2021 in accordance with the terms of the supply agreement.

The vaccine has now been granted a conditional marketing authorization, emergency use authorization, temporary authorization or provisional approval in a total of more than 50 countries.

Manufacturing and Delivery Capabilities

Pfizer and BioNTech continue to work in collaboration with governments and Ministries of Health around the world that will distribute the vaccine, subject to country authorization or approval, to help ensure it can reach those most in need as quickly as possible. The companies are leveraging leading vaccine manufacturing and distribution capabilities to quickly scale, manufacture and distribute large quantities of the vaccine at high quality, complementing the mRNA manufacturing expertise of BioNTech gained over almost a decade. Pfizer has a 171-year track record of researching, developing, manufacturing and delivering innovative medicines and vaccines to patients in need.

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](https://twitter.com/Pfizer) and [@Pfizer News](https://twitter.com/PfizerNews), [LinkedIn](https://www.linkedin.com/company/pfizer), [YouTube](https://www.youtube.com/channel/UCv31111111111111111111) and like us on Facebook at [Facebook.com/Pfizer](https://www.facebook.com/Pfizer).

Pfizer Disclosure Notice

The information contained in this release is as of 25 January, 2021. 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 COVID-19 vaccine, the BNT162 mRNA vaccine program and modRNA candidate BNT162b2 (including qualitative assessments of available data, potential benefits, expectations for clinical trials, Provisional Approval in Australia, regulatory submissions, including pending requests for emergency use authorization and other marketing applications, the anticipated timing of regulatory submissions, regulatory approvals or authorizations and anticipated manufacturing, distribution and supply), involving 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 clinical data (including the Phase 3 data), including the possibility of unfavorable new preclinical or clinical trial data and further analyses of existing preclinical or clinical trial data; the ability to produce comparable clinical or other results, including the rate of vaccine effectiveness and safety and tolerability profile observed to date, in additional analyses of the Phase 3 trial and additional studies or in larger, more diverse populations upon commercialization; the risk that more widespread use of the vaccine will lead to new information about efficacy, safety, or other developments, including the risk of additional adverse reactions, some of which may be serious; 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 additional 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 any future preclinical and clinical studies; whether and when any other biologics license and/or emergency use authorization applications may be filed in any particular jurisdictions for BNT162b2 or any other potential vaccine candidates; whether and when any applications that may be pending or filed for BNT162b2 may be approved by particular 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; disruptions in the relationships between us and our collaboration partners or third-party suppliers; risks related to the availability of raw materials to manufacture a vaccine; challenges related to our vaccine candidate's ultra-low temperature formulation and attendant storage, distribution and administration requirements, including risks related to handling after delivery by Pfizer; the risk that we may not be able to successfully develop non-frozen formulations; the risk that we may not be able to create or scale up manufacturing capacity on a timely basis or have access to logistics or supply channels commensurate with global demand for any potential approved vaccine, which would negatively impact our ability to supply the estimated numbers of doses of our vaccine candidate within the projected time periods indicated; whether and when additional supply agreements will be reached; uncertainties regarding the ability to obtain recommendations from vaccine technical committees and other public health authorities and uncertainties regarding the commercial impact of any such recommendations; 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, 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, 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, statements concerning: BioNTech's efforts to combat COVID-19; the collaboration between BioNTech and Pfizer regarding a COVID-19 vaccine; our expectations regarding the potential characteristics of BNT162b2 in our Phase 2/3 trial and/or in commercial use based on data observations to date; the expected timepoint for additional readouts on trial data of BNT162b2 in our Phase 2/3 trial; the nature of the clinical data, which is subject to ongoing peer review, regulatory review and market interpretation; the timing for submission of data for, or receipt of, any marketing approval or Emergency Use Authorization; our contemplated shipping and storage plan, including our estimated product shelflife at various temperatures; and the ability of BioNTech to supply the quantities of BNT162 to support clinical development and, if approved, market demand, including our production estimate for 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: the ability to meet the pre-defined endpoints in clinical trials; competition to create a vaccine for COVID-19; the ability to produce comparable clinical or other results, including our stated rate of vaccine effectiveness and safety and tolerability profile observed to date, in the remainder of the trial or in larger, more diverse populations upon commercialization; 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 Quarterly Report for the Three and Nine Months Ended September 30, 2020, filed as Exhibit 99.2 to its Current Report on Form 6-K filed with the SEC on November 10, 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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