

# President Biden Visits Pfizer's Kalamazoo Manufacturing Facility

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**New York, NY, February 19, 2021** — Today President Biden visited Pfizer's Kalamazoo, MI facility, the largest manufacturing site in Pfizer's network and the largest employer in the city of Kalamazoo. Established in 1948, Pfizer's Kalamazoo site is one of three manufacturing plants in the U.S. that is currently engaged in the manufacture of the Pfizer-BioNTech COVID-19 Vaccine. Pfizer's Kalamazoo facility is responsible for the formulation of the vaccine, and fill and finish activities.

The U.S. government and Pfizer currently have agreements in place for the company to supply 300 million doses of the Pfizer-BioNTech COVID-19 vaccine. As of February 17, 2021, Pfizer has supplied more than 40 million doses to the U.S. government, with a shipment accuracy rate of 99.9%. Pfizer expects to deliver a total of 120 million doses to the U.S. government by the end of March 2021, to reach 200 million doses by the end of May 2021, and deliver the remaining 100 million doses by the end of July 2021, in total enabling the vaccination of up to 150 million Americans.

"Pfizer has been a proud American company for more than 170 years, and we were honored to have hosted President Biden in Kalamazoo and demonstrate how our colleagues have been working around the clock throughout the pandemic to ensure not only a continuous supply of critical hospital medicines, but also the production and shipment of the Pfizer-BioNTech COVID-19 vaccine," said Albert Bourla, Chairman and Chief Executive Officer, Pfizer. "There remains a dire need to vaccinate more people more quickly, and Pfizer is working tirelessly, scaling up manufacturing to increase the number of doses and decrease our production timelines. We look forward to our continued partnership with the government to more quickly bring an end to the pandemic and restore a new state of normalcy to the United States."

Pfizer is expanding and enhancing its manufacturing capabilities to increase the number of doses it's able to produce globally by the end of 2021. As part of this expansion, Pfizer is adding new formulation suites in Kalamazoo, lipid production capabilities both in Kalamazoo and at its research and development site in Groton, CT, and fill/finish lines at its McPherson, KS site. In addition, the company has engaged two U.S. contract manufacturers and is also increasing the supply of raw materials from existing suppliers and bringing on new suppliers. Pfizer has also improved its processes to double its batch size to increase yield and deploy more efficient lab test methods to reduce release times. As such, we have reduced our timelines from approximately 110 days from start to vial-ready, and we are now approaching an average of 60 days – an almost 50% improvement.

Consequently, Pfizer and BioNTech believe they can potentially deliver at least two billion doses globally by the end of 2021. In the U.S., to date in 2021, Pfizer has been shipping on average five million doses per week. As a result of these process improvements and the expansion of capabilities, by the end of March the company expects to more than double the number of doses per week.

The vaccine, which is based on BioNTech proprietary mRNA technology, was developed by both BioNTech and Pfizer. BioNTech is the Marketing Authorizations Holder in the EU, and the holder of emergency use authorizations or equivalent in the United States, United Kingdom, Canada and other countries in advance of a planned application for full marketing authorizations in these countries.

The Pfizer-BioNTech COVID-19 Vaccine has not been approved or licensed by the U.S. Food and Drug Administration (FDA), but has been authorized for emergency use by FDA under an Emergency Use Authorization (EUA) to prevent Coronavirus Disease 2019 (COVID-19) for use in individuals 16 years of age and older. The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of the medical product under Section 564 (b) (1) of the FD&C Act unless the declaration is terminated or authorization revoked sooner. Please see Emergency Use Authorization (EUA) Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) including Full EUA Prescribing Information available at [www.cvdvaccine-us.com](http://www.cvdvaccine-us.com).

#### **AUTHORIZED USE IN THE U.S.:**

The Pfizer-BioNTech COVID-19 Vaccine is authorized for use under an Emergency Use Authorization (EUA) for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 16 years of age and older.

#### **IMPORTANT SAFETY INFORMATION FROM U.S. FDA EMERGENCY USE AUTHORIZATION PRESCRIBING INFORMATION:**

- Do not administer Pfizer-BioNTech COVID-19 Vaccine to individuals with known history of a severe allergic reaction (e.g., anaphylaxis) to any [component](#) of the PfizerBioNTech COVID-19 Vaccine
- Appropriate medical treatment used to manage immediate allergic reactions must be immediately available in the event an acute anaphylactic reaction occurs following administration of Pfizer-BioNTech COVID-19 Vaccine

**Monitor Pfizer-BioNTech COVID-19 Vaccine recipients for the occurrence of immediate adverse reactions according to the Centers for Disease Control and Prevention guidelines ( <https://www.cdc.gov/vaccines/covid-19/> )**

- Immunocompromised persons, including individuals receiving immunosuppressant therapy, may have a diminished immune response to the Pfizer-BioNTech COVID-19 Vaccine
- The Pfizer-BioNTech COVID-19 Vaccine may not protect all vaccine recipients
- In clinical studies, adverse reactions in participants 16 years of age and older included pain at the injection site (84.1%), fatigue (62.9%), headache (55.1%), muscle pain (38.3%), chills (31.9%), joint pain (23.6%), fever (14.2%), injection site swelling (10.5%), injection site redness (9.5%), nausea (1.1%), malaise (0.5%), and lymphadenopathy (0.3%)
- Severe allergic reactions, including anaphylaxis, have been reported following the PfizerBioNTech COVID-19 Vaccine during mass vaccination outside of clinical trials. Additional adverse reactions, some of which may be serious, may become apparent with more widespread use of the Pfizer-BioNTech COVID-19 Vaccine

- Available data on Pfizer-BioNTech COVID-19 Vaccine administered to pregnant women are insufficient to inform vaccine-associated risks in pregnancy
- Data are not available to assess the effects of Pfizer-BioNTech COVID-19 Vaccine on the breastfed infant or on milk production/excretion
- There are no data available on the interchangeability of the Pfizer-BioNTech COVID19 Vaccine with other COVID-19 vaccines to complete the vaccination series. Individuals who have received one dose of Pfizer-BioNTech COVID-19 Vaccine should receive a second dose of Pfizer-BioNTech COVID-19 Vaccine to complete the vaccination series
- Vaccination providers must report Adverse Events in accordance with the Fact Sheet to VAERS at <https://vaers.hhs.gov/reportevent.html> or by calling [1-800-822-7967](tel:1-800-822-7967). The reports should include the words “Pfizer-BioNTech COVID-19 Vaccine EUA” in the description section of the report
- Vaccination providers should review the Fact Sheet for Information to Provide to Vaccine Recipients/Caregivers and Mandatory Requirements for Pfizer-BioNTech COVID19 Vaccine Administration Under Emergency Use Authorization

Please see Emergency Use Authorization (EUA) Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) including Full EUA Prescribing Information available at [www.cvdvaccine-us.com](http://www.cvdvaccine-us.com).

#### 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](http://www.Pfizer.com). In addition, to learn more, please visit us on [www.Pfizer.com](http://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 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 February 19, 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 the Pfizer-BioNTech COVID-19 Vaccine (BNT162b2) (including qualitative assessments of available data, potential benefits, expectations for clinical trials, supply agreements with the U.S. government and the timing of delivery of doses thereunder, the anticipated timing of regulatory submissions, regulatory approval or authorization 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 preclinical and clinical data (including the in vitro and Phase 3 data), including the possibility of unfavorable new preclinical, clinical or safety data and further analyses of existing preclinical, clinical or safety 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 ability of BNT162b2 to prevent COVID19 caused by emerging virus variants; 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 preclinical and 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 and interpretations; whether regulatory authorities will be satisfied with the design of and results from these and any future preclinical and clinical studies; whether and when a Biologics License Application for BNT162b2 may be filed in the U.S. and whether and when other biologics license and/or emergency use authorization applications may be filed in particular jurisdictions for BNT162b2 or any other potential vaccines that may arise from the BNT162 program, and if obtained, whether or when such emergency use authorization or licenses will expire or terminate; whether and when any applications that may be pending or filed for BNT162b2 (including a potential Biologics License Application in the U.S.) or other vaccines that may result from the BNT162 program may be approved by particular regulatory authorities, which will depend on myriad factors, including making a determination as to whether the vaccine's benefits outweigh its known risks and determination of the vaccine's efficacy and, if approved, whether it will be commercially successful; decisions by regulatory authorities impacting labeling or marketing, 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's ultra-low temperature formulation, two-dose schedule and attendant storage, distribution and administration requirements, including risks related to storage and handling after delivery by Pfizer; the risk that we may not be able to successfully develop other vaccine formulations; the risk that we may not be able to create or scale up manufacturing capacity on a timely basis or maintain access to logistics or supply channels commensurate with global demand for our vaccine, which would negatively impact our ability to supply the estimated numbers of doses of our vaccine within the projected time periods as previously 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](http://www.sec.gov) and [www.pfizer.com](http://www.pfizer.com). Pfizer Contacts: Media Relations Amy Rose +1 (212) 733-1226 [PfizerMediaRelations@pfizer.com](mailto:PfizerMediaRelations@pfizer.com) Investor Relations Chuck Triano +1 (212) 733-3901 [Charles.E.Triano@Pfizer.com](mailto:Charles.E.Triano@Pfizer.com)