



## Pfizer-BioNTech's COVID-19 Vaccine Arrives in Rwanda

March 3, 2021

- *First mRNA vaccine doses delivered to the African continent will be used to vaccinate at-risk, front-line healthcare workers*

**NEW YORK and MAINZ, GERMANY, March 3, 2021** - [Pfizer Inc.](#) (NYSE: PFE) and [BioNTech SE](#) (Nasdaq: BNTX), in partnership with [UNICEF](#), today announced the arrival of the first doses of their COVID-19 vaccine in Rwanda through the COVAX Facility.

This is the companies' first delivery to a COVAX Advanced Market Commitment (AMC) country of their mRNA vaccine. The almost 103,000 doses will be used to vaccinate at-risk, front-line healthcare workers across the country.

"These are the first doses of an mRNA vaccine to arrive on the African continent – an important milestone for the region, for Rwanda, and for the global health partners working tirelessly to fight this pandemic," said Janine Small, Pfizer Global President for Emerging Markets. "The delivery of these doses and the subsequent vaccinations demonstrate that global partners can work together to create the conditions that ensure developing countries can benefit from a new generation of vaccines. We will continue to work closely with COVAX, its partners, and the countries receiving doses of our vaccine to achieve our shared goal of securing equitable access for COVID-19 vaccines for all people around the world."

"SARS-CoV-2 does not differentiate between borders – a global pandemic requires comprehensive solutions and worldwide collaborations between companies, governments and global institutions. Our goal is to make vaccines accessible worldwide and today's delivery to Rwanda is a great step forward. We will continue to work with COVAX to make COVID-19 vaccines available in many more low- and lower-middle-income countries and help protect vulnerable people worldwide," said Ugur Sahin, M.D., CEO and Co-founder of BioNTech.

Pfizer and BioNTech have already supplied doses through COVAX to South Korea and Colombia and will continue supplying doses to a number of diverse economies in all regions of the world, including a number of low and lower-middle income countries, as part of the up to 40 million doses the companies have committed to the Facility through 2021.

The vaccine, which is based on BioNTech's proprietary mRNA technology, was developed by both BioNTech and Pfizer. BioNTech is the Marketing Authorizations Holder in the European Union, 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.

### **AUTHORIZED USE:**

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.

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) and Full EUA Prescribing Information available at [www.cvdvaccine.com](http://www.cvdvaccine.com).

### **IMPORTANT SAFETY 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 Pfizer-BioNTech 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 Pfizer-BioNTech 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 COVID-19 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 <http://vaers.hhs.gov/reportevent.html> or by calling 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 COVID-19 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](https://www.youtube.com/channel/UCv3p00111111111111111111) and like us on Facebook at [Facebook.com/Pfizer](https://www.facebook.com/Pfizer).

#### **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 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, including real-world data gathered; the ability of BNT162b2 to prevent COVID-19 caused by emerging virus variants; the expected time point 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 shelf life 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 production 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](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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