



## Pfizer and BioNTech Submit Request to Expand Conditional Marketing Authorization of COMIRNATY® in the EU to Adolescents

April 30, 2021

**NEW YORK and MAINZ, GERMANY, April 30, 2021 (GLOBE NEWSWIRE)** —[Pfizer Inc.](#) (NYSE: PFE) and [BioNTech SE](#) (Nasdaq: BNTX) today announced they have submitted a variation to the Conditional Marketing Authorization (CMA) in the European Union (EU) to the European Medicines Agency (EMA) for the Pfizer-BioNTech vaccine COMIRNATY® (BNT162b2) to request an extension of the indication for use in adolescents 12 to 15 years of age. If EMA approves the variation, the amended CMA will be valid in all 27 member states of the EU. The companies have already submitted a similar request to the U.S. Food and Drug Administration (FDA) for the Emergency Use Authorization (EUA) and plan to request additional amendments with other regulatory authorities worldwide.

This submission is based on data from a pivotal Phase 3 clinical trial, which enrolled 2,260 participants aged 12 to 15 years. Topline results from this trial, [announced](#) on March 31, 2021, showed a vaccine efficacy of 100% in participants with or without prior SARS-CoV-2 infection and robust antibody responses. In the trial, the vaccine also was generally well tolerated. Participants will continue to be monitored for long-term protection and safety for an additional two years after their second dose.

The Pfizer-BioNTech COVID-19 vaccine, which is based on BioNTech proprietary mRNA technology, was developed by both BioNTech and Pfizer. BioNTech is the Marketing Authorization Holder in the European Union, and the holder of emergency use authorizations or equivalent in the United States (jointly with Pfizer), United Kingdom, Canada and other countries in advance of a planned application for full marketing authorizations in these countries.

### AUTHORIZED USE IN THE EU:

**COMIRNATY®** ▼ (the Pfizer-BioNTech COVID-19 vaccine) has been granted conditional marketing authorisation by the by the European Commission to prevent coronavirus disease 2019 (COVID-19) in people from 16 years of age. The European Medicines Agency's (EMA's) human medicines committee (CHMP) has completed its rigorous evaluation of COMIRNATY®, concluding by consensus that sufficiently robust data on the quality, safety and efficacy of the vaccine are now available.

### IMPORTANT SAFETY INFORMATION:

- Events of anaphylaxis have been reported. Appropriate medical treatment and supervision should always be readily available in case of an anaphylactic reaction following the administration of the vaccine.
- The efficacy, safety and immunogenicity of the vaccine has not been assessed in immunocompromised individuals, including those receiving immunosuppressant therapy. The efficacy of COMIRNATY® may be lower in immunosuppressed individuals.
- As with any vaccine, vaccination with COMIRNATY® may not protect all vaccine recipients. Individuals may not be fully protected until 7 days after their second dose of vaccine.
- In clinical studies, adverse reactions in participants 16 years of age and older were injection site pain (> 80%), fatigue (> 60%), headache (> 50%), myalgia and chills (> 30%), arthralgia (> 20%), pyrexia and injection site swelling (> 10%) and were usually mild or moderate in intensity and resolved within a few days after vaccination. A slightly lower frequency of reactogenicity events was associated with greater age.
- There is limited experience with use of COMIRNATY® in pregnant women. Administration of COMIRNATY® in pregnancy should only be considered when the potential benefits outweigh any potential risks for the mother and fetus.
- It is unknown whether COMIRNATY® is excreted in human milk.
- Interactions with other medicinal products or concomitant administration of COMIRNATY® with other vaccines has not been studied.
- For complete information on the safety of COMIRNATY® always make reference to the approved Summary of Product Characteristics and Package Leaflet available in all the languages of the European Union on the EMA website.

The black equilateral triangle denotes that additional monitoring is required to capture any adverse reactions. This will allow quick identification of new safety information. Individuals can help by reporting any side effects they may get. Side effects can be reported to [EudraVigilance](#) or directly to BioNTech using email [medinfo@biontech.de](mailto:medinfo@biontech.de), telephone +49 6131 9084 0, or via the website [www.biontech.de](http://www.biontech.de).

### 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



statements in this press release are based on BioNTech's current expectations and beliefs of future events. The forward-looking statements in this press release are neither promises nor guarantees, and you should not place undue reliance on these forward-looking statements because they involve known and unknown risks, uncertainties, and other factors, many of which are beyond BioNTech's control and which could cause actual results to differ materially from those expressed or implied by these forward-looking statements. You should review the risks and uncertainties described under the heading "Risk Factors" in BioNTech's Annual Report on Form 20-F for the Year Ended December 31, 2020, filed with the SEC on March 30, 2021, 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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