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Real-World Evidence Confirms High Effectiveness of Pfizer-BioNTech COVID-19 Vaccine and Profound Public Health Impact of Vaccination One Year After Pandemic Declared

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- *Dramatically lower COVID-19 disease incidence rates observed in individuals fully vaccinated with the Pfizer-BioNTech vaccine, based on real-world data gathered by the Israel Ministry of Health*
- *Data suggest Pfizer-BioNTech vaccine prevents asymptomatic SARS-CoV-2 infection*
- *Latest data analysis finds unvaccinated individuals were 44 times more likely to develop symptomatic COVID-19 and 29 times more likely to die from COVID-19*
- *Findings represent the most comprehensive real-world evidence to date demonstrating the effectiveness of a COVID-19 vaccine*
- *Data are of global importance to other countries as vaccination campaigns continue worldwide*

JERUSALEM & NEW YORK & MAINZ, Germany--(BUSINESS WIRE)-- The Israel Ministry of Health (MoH), Pfizer Inc. (NYSE: PFE) and BioNTech SE (Nasdaq: BNTX) today announced real-world evidence demonstrating dramatically lower incidence rates of COVID-19 disease in individuals fully vaccinated with the Pfizer-BioNTech COVID-19 Vaccine (BNT162b2), underscoring the observed substantial public health impact of Israel's nationwide immunization program. These new data build upon and confirm previously released data from the MoH demonstrating the vaccine's effectiveness in preventing symptomatic SARS-CoV-2 infections, COVID-19 cases, hospitalizations, severe and critical hospitalizations, and deaths. The latest analysis from the MoH proves that two weeks after the second vaccine dose protection is even stronger – vaccine effectiveness was at least 97% in preventing symptomatic disease, severe/critical disease and death. This comprehensive real-world evidence can be of importance to countries around the world as they advance their own vaccination campaigns one year after the World Health Organization (WHO) declared COVID-19 a pandemic.

This press release features multimedia. View the full release here:
https://www.businesswire.com/news/home/20210311005482/en/

Findings from the analysis were derived from de-identified aggregate Israel MoH surveillance data collected between January 17 and March 6, 2021, when the Pfizer-BioNTech COVID-19 Vaccine was the only vaccine available in the country and when the more transmissible B.1.1.7 variant of SARS-CoV-2 (formerly referred to as the U.K. variant) was the dominant strain. Vaccine effectiveness was at least 97% against symptomatic COVID-19 cases, hospitalizations, severe and critical hospitalizations, and deaths. Furthermore, the analysis found a vaccine effectiveness of 94% against asymptomatic SARS-CoV-2 infections. For all outcomes, vaccine effectiveness was measured from two weeks after the second dose.

“Israel’s strong health system and an unprecedented societal mobilization and awareness allowed us to achieve high national uptake of the COVID-19 vaccine in a short period of time. Thanks to our comprehensive public health surveillance program, we have been able to document the remarkable success of the nationwide vaccination campaign with the COVID-19 vaccine. Incidence rates in the fully vaccinated population have massively dropped compared to the unvaccinated population, showing a marked decline in hospitalized cases due to COVID-19,” said Professor Yeheskel Levy, Israel Ministry of Health Director. “This clearly demonstrates the power of the COVID-19 vaccine to fight this virus and encourages us to continue even more intensively with our vaccination campaign. We aim to achieve even higher uptake in people of all ages, which gives us hope of regaining normal economic and social function in the not so distant future.”

“We are extremely encouraged that the real-world effectiveness data coming from Israel are confirming the high efficacy demonstrated in our Phase 3 clinical trial and showing the significant impact of the vaccine in preventing severe disease and deaths due to COVID-19,” said Luis Jodar, Ph.D., Senior Vice President & Chief Medical Officer, Pfizer Vaccines. “The findings which suggest that the vaccine may also provide protection against asymptomatic SARS-CoV-2 infections are particularly meaningful as we look to disrupt the spread of the virus around the globe. Altogether, these data are critical to understanding the role of vaccination in combatting the pandemic and provide hope to other countries dealing with this devastating disease, which has now afflicted the world for more than a year.”

“When we started our development last year in January, our aim was to make a difference for people worldwide and to help end this pandemic. One year after the declaration of a pandemic by the WHO, we now see that we are on the right track to accomplish our goals,” said Ugur Sahin, M.D., Co-Founder and CEO of BioNTech. “The real-world data reported from Israel demonstrate that BNT162b2 is exceptionally effective in fighting SARS-CoV-2. Our vaccine has been effective in preventing COVID-19 cases, as well as profoundly reducing the rate of COVID-19 related severe diseases, hospitalizations and deaths. These findings are also important, as the data were generated at a time when the SARS-CoV-2 variant B.1.1.7 was the dominant strain.”

In January, Pfizer and the Israel MoH entered into a collaboration agreement to monitor the real-world impact of the Pfizer-BioNTech COVID-19 Vaccine. Detailed findings from this collaboration also will be submitted to a peer-reviewed journal.

About the Israel MoH Vaccination Program and Analysis

Following the authorization for emergency use of the Pfizer-BioNTech COVID-19 Vaccine in Israel on December 6, 2020, the Israel MoH launched a national vaccination program targeting individuals age 16 years or older – a total of 6.4 million people, representing 71% of the population. The vaccination program started at the beginning of a large surge of SARS-CoV-2 infections in Israel, which later resulted in a national lockdown starting on January 8, 2021.

This MoH analysis uses de-identified aggregate Israel MoH public health surveillance data from January 17 through March 6, 2021 (analysis period); the start of the analysis period corresponds to seven days after individuals began receiving second doses of the Pfizer-BioNTech COVID-19 Vaccine. MoH regularly collects comprehensive, real-time data on SARS-CoV-2 testing, COVID-19 cases including date of symptom onset, and vaccination history through a nationally notifiable disease registry and the national medical record database.

Vaccine effectiveness estimates – adjusted to account for variances in age, gender and the week specimens were collected – were determined for the prevention of six laboratory-confirmed SARS-CoV-2 outcomes comparing unvaccinated and fully-vaccinated individuals: SARS-CoV-2 infections (includes symptomatic and asymptomatic infections); asymptomatic SARS-CoV-2 infections; COVID-19 cases (symptomatic only); COVID-19 hospitalizations; severe (respiratory distress, including >30 breaths per minute, oxygen saturation on

room air <94%, and/or ratio of arterial partial pressure of oxygen to fraction of inspired oxygen <300mm mercury) and critical (mechanical ventilation, shock, and/or heart, liver or kidney failure) COVID-19 hospitalizations; and COVID-19 deaths.

The MoH analysis was conducted when more than 80% of tested specimens in Israel were variant B.1.1.7, providing real-world evidence of the effectiveness of BNT162b2 for prevention of COVID-19 infections, hospitalizations, and deaths due to variant B.1.1.7. However, this analysis was not able to evaluate vaccine effectiveness against B.1.351 (formerly referred to as the South African variant) due to the limited number of infections caused by this strain in Israel at the time the analysis was conducted.

The vaccine effectiveness estimates align with the 95% vaccine efficacy of BNT162b2 against COVID-19 demonstrated in the pivotal Randomized Clinical Trial (RCT) of BNT162b2. However, this observational analysis differs from the RCT in several aspects. Vaccine effectiveness estimates may be affected by differences between vaccinated and unvaccinated persons (i.e., different test-seeking behaviors or levels of adherence to preventive measures). In the RCT, randomization minimized the impact of differences between vaccinated and unvaccinated. Despite efforts to adjust for these effects in the available dataset, the possibility remains of unmeasured distortions. For example, findings from the Maccabi HMO indicate that neighborhood may be an important factor. Further vaccine effectiveness analyses investigating the effect of additional covariates such as location, comorbidities, race/ethnicity, and likelihood of seeking SARS-CoV-2 testing are warranted.

About the Pfizer-BioNTech COVID-19 Vaccine (BNT162b2)

The Pfizer-BioNTech COVID-19 Vaccine, which is based on BioNTech proprietary mRNA technology, was developed by both BioNTech and Pfizer. The vaccine has now been granted a conditional marketing authorization, emergency use authorization or temporary authorization in a total of more than 60 countries. BioNTech is the Marketing Authorization Holder in the European Union, and the holder of emergency use authorizations or equivalent in Israel, 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) and Full EUA Prescribing Information available at www.cvdvaccine-us.com.

AUTHORIZED USE IN THE U.S.:

The Pfizer-BioNTech COVID19 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 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 https://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.

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 170 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 and @Pfizer News, LinkedIn, YouTube and like us on Facebook at Facebook.com/Pfizer.

Pfizer Disclosure Notice

The information contained in this release is as of March 11, 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, the anticipated timing of regulatory submissions, regulatory approvals or authorizations, a collaboration with the Israel MoH to monitor the real-world impact of BNT162b2 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 and the real-world evidence), 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 COVID-19 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, 2020 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, 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 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 ability of BNT162b2 to prevent COVID-19 caused by emerging virus variants; 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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