Pfizer Logo

Pfizer and BioNTech Submit Supplemental Biologics License Application for U.S. FDA Approval of Omicron BA.4/BA.5-Adapted Bivalent COVID-19 Vaccine for Ages 12 Years and Older as Primary Series or Booster

Friday, February 24, 2023 - 07:00am

NEW YORK and MAINZ, GERMANY, FEBRUARY 24, 2023 — Pfizer Inc. (NYSE: PFE) and BioNTech SE (Nasdaq: BNTX) today announced they have submitted a supplemental Biologics License Application (sBLA) to the U.S. Food and Drug Administration (FDA) for approval of their Omicron BA.4/BA.5-adapted bivalent COVID-19 vaccine as a primary series and booster dose(s) for individuals 12 years of age and older.

On January 26, 2023, the U.S. FDA's Vaccines and Related Biological Products Advisory Committee (VRBPAC) voted to harmonize the composition of COVID-19 vaccines across booster and primary series doses. If this sBLA is approved, people 12 years or older would be able to receive the companies' Omicron BA.4/BA.5-adapted bivalent COVID-19 vaccine for their primary series, rather than completing their primary series with the original vaccine (COMIRNATY® (COVID-19 Vaccine, mRNA)) before having access to the bivalent vaccine. Individuals in this age group who completed their primary series with the original vaccine or will complete it with the bivalent vaccine would still be eligible to receive a booster dose of the bivalent vaccine.

The original BLA for COMIRNATY as the primary series was approved in August 2021 for ages 16 years and older and later extended through an sBLA to include ages 12 through 15 years of age. Currently, the bivalent vaccine is available in the U.S. under Emergency Use Authorization (EUA) as a single booster dose for ages 5 years and older and as the third dose in the three-dose primary series for children 6 months through 4 years of age. As EUA is not meant to be a long-term status, this sBLA is the next step toward full regulatory approval of the bivalent vaccine.

This sBLA submission is supported by clinical, pre-clinical, and manufacturing data demonstrating the safety, tolerability, and immunogenicity of the bivalent vaccine. Among study participants over 55 years of age (n=~300 per group (individuals receiving the bivalent vaccine vs. comparator group receiving the original vaccine)), the bivalent vaccine met criteria for superiority over the original vaccine with respect to Omicron BA.4/BA.5-neutralizing antibodies elicited. Measured at one-month post-vaccination, the geometric mean ratio (GMR) of Omicron BA.4/BA.5-neutralizing antibodies was 2.91 (95% CI: 2.45, 3.44). For study participants aged 18 to 55 (n=~300) who received the bivalent vaccine, GMR was 0.98 (95% CI: 0.83, 1.16), which met criteria for non-inferiority compared to participants over 55 years of age who received the bivalent vaccine. For both age groups, the pattern of results was the same regardless of prior SARS-CoV-2 infection. The safety and tolerability profile of the bivalent vaccine remained similar to that of the original vaccine.[1]

The bivalent vaccine also induced a stronger neutralizing antibody response against newer Omicron sublineages in participants 55 years of age and older, including BA.4.6, BA.2.75.2, BQ.1.1 and XBB.1, compared to the original vaccine. For XBB.1, neutralizing antibody titers increased 4.8-fold (95% CI: 3.3,6.9) following a booster dose of the companies' bivalent vaccine and 1.5-fold (95% CI: 1.3,1.8) following a booster dose of the companies' original vaccine.[1] This subset of individuals included those with and without evidence of prior infection. Similar results have been observe for XBB.1.5, which currently accounts for more than 80% of COVID-19 cases in the U.S.[2,3]

In the European Union (EU), the Omicron BA.4/BA.5-adapted bivalent COVID-19 vaccine was granted full marketing authorization (MA) for administration as a booster dose in individuals 5 years of age and older who have completed a primary vaccination course against COVID-19. The companies also plan to submit applications to the European Medicines Agency (EMA) for a variation of the MA to also include the bivalent vaccine as a primary course of vaccination in individuals 5 years of age and older and a line extension for the bivalent vaccine as a primary course of vaccination and booster for individuals 6 months of age through 4 years.

The Pfizer-BioNTech COVID-19 Vaccines (COMIRNATY) are based on BioNTech's proprietary mRNA technology and were developed by both BioNTech and Pfizer. BioNTech is the Marketing Authorization Holder for BNT162b2 (Original) and BNT162b2 Bivalent (Original/Omicron BA.4/BA.5) in the United States, the European Union, the United Kingdom, Canada and other countries, and the holder of emergency use authorizations or equivalents in the United States (jointly with Pfizer) and other countries.

U.S. INDICATION & AUTHORIZED USE

Pfizer-BioNTech COVID-19 Vaccine, Bivalent, (Original and Omicron BA.4/BA.5)

AUTHORIZED USE

Pfizer-BioNTech COVID-19 Vaccine, Bivalent (Original and Omicron BA.4/BA.5) is FDA authorized under Emergency Use Authorization (EUA) for use in individuals 5 years of age and older as a single booster dose administered at least 2 months after either:

- completion of primary vaccination with any authorized or approved COVID-19 vaccine; or
- receipt of the most recent booster dose with any authorized or approved monovalent* COVID-19 vaccine

*Monovalent refers to any authorized and approved COVID-19 vaccine that contains or encodes the spike protein of only the Original SARS-CoV-2 virus.

COMIRNATY® (COVID-19 Vaccine, mRNA)

INDICATION
COMIRNATY® (COVID-19 Vaccine, mRNA) is an FDA-approved COVID-19 vaccine for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 12 years of age and older.

AUTHORIZED USE
COMIRNATY® (COVID-19 Vaccine, mRNA) is authorized under Emergency Use Authorization (EUA) to provide:

Primary Series

- a third primary series dose to individuals 12 years of age and older who have certain kinds of immunocompromise

Pfizer-BioNTech COVID-19 Vaccine

AUTHORIZED USES

Pfizer-BioNTech COVID-19 Vaccine is FDA authorized under Emergency Use Authorization (EUA) for use in individuals 5 years of age and older to provide:

Primary Series

- a 2-dose primary series to individuals 5 years of age and older
- a third primary series dose to individuals 5 years of age and older with certain kinds of immunocompromise

Pfizer-BioNTech COVID-19 Vaccine and Pfizer-BioNTech COVID-19 Vaccine, Bivalent

AUTHORIZED USES

Pfizer-BioNTech COVID-19 Vaccine and Pfizer-BioNTech COVID-19 Vaccine, Bivalent are FDA authorized under Emergency Use Authorization (EUA) for use in individuals 6 months to 4 years of age to provide:

Primary Series

- a 3-dose primary series as follows:
    - Dose 1: Pfizer-BioNTech COVID-19 Vaccine
    - Dose 2: Pfizer-BioNTech COVID-19 Vaccine
    - Dose 3: Pfizer-BioNTech COVID-19 Vaccine, Bivalent

EMERGENCY USE AUTHORIZATION
Emergency uses of the vaccines have not been approved or licensed by FDA but have been authorized by FDA under an Emergency Use Authorization (EUA) to prevent Coronavirus Disease 2019 (COVID-19) in individuals aged 6 months and older. The emergency uses are 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.

PFIZER-BIONTECH COVID-19 VACCINE, BIVALENT (ORIGINAL AND OMICRON BA.4/BA.5), COMIRNATY® (COVID-19 VACCINE, MRNA), AND PFIZER-BIONTECH COVID-19 VACCINE IMPORTANT SAFETY INFORMATION

Tell your vaccination provider about all of your medical conditions, including if you:

- have any allergies
- have had myocarditis (inflammation of the heart muscle) or pericarditis (inflammation of the lining outside the heart)
- have a fever
- have a bleeding disorder or are on a blood thinner
- are immunocompromised or are on a medicine that affects the immune system
- are pregnant, plan to become pregnant, or are breastfeeding

- have received another COVID-19 vaccine
- have ever fainted in association with an injection

- The vaccine may not protect everyone

- You should not get COMIRNATY (COVID-19 Vaccine, mRNA), the Pfizer-BioNTech COVID-19 Vaccine, or the Pfizer-BioNTech COVID-19 Vaccine, Bivalent if you have had a severe allergic reaction after a previous dose of COMIRNATY or the Pfizer-BioNTech COVID-19 Vaccine or any ingredient in these vaccines

- There is a remote chance that these vaccines could cause a severe allergic reaction. A severe allergic reaction would usually occur within a few minutes to 1 hour after getting a dose of the vaccine. For this reason, your vaccination provider may ask you to stay at the place where you received the vaccine for monitoring after vaccination. If you experience a severe allergic reaction, call 9-1-1 or go to the nearest hospital

Seek medical attention right away if you have any of the following symptoms:
- difficulty breathing, swelling of the face and throat, a fast heartbeat, a bad rash all over the body, dizziness, and weakness

- Myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the lining outside the heart) have occurred in some people who have received COMIRNATY® (COVID-19 Vaccine, mRNA) or Pfizer-BioNTech COVID-19 Vaccine or Pfizer-BioNTech COVID-19 Vaccine, Bivalent. The observed risk is higher among adolescent males and adult males under 40 years of age than among females and older males, and the observed risk is highest in males 12 through 17 years of age. In most of these people, symptoms began within a few days following receipt of the second dose of vaccine. The chance of having this occur is very low

Side effects that have been reported with these vaccines include:

- Severe allergic reactions
- Non-severe allergic reactions such as rash, itching, hives, or swelling of the face
- Myocarditis (inflammation of the heart muscle)
- Pericarditis (inflammation of the lining outside the heart)
- Injection site pain
- Tiredness
- Headache
- Muscle pain
- Chills
- Joint pain
- Fever
- Injection site swelling
- Injection site redness
- Nausea
- Feeling unwell
- Swollen lymph nodes (lymphadenopathy)
- Decreased appetite
- Diarrhea
- Vomiting
- Arm pain
- Fainting in association with injection of the vaccine
- Unusual and persistent irritability
- Unusual and persistent poor feeding

- Unusual and persistent fatigue or lack of energy
- Unusual and persistent cool, pale skin
- Dizziness

These may not be all the possible side effects of these vaccines. Call the vaccination provider or healthcare provider about bothersome side effects or side effects that do not go away.

- Individuals should always ask their healthcare providers for medical advice about adverse events. Report vaccine side effects to the US Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC) Vaccine Adverse Event Reporting System (VAERS). The VAERS toll-free number is 1?800?822?7967 or report online to www.vaers.hhs.gov/reportevent.html. In addition, individuals can report side effects to Pfizer Inc. at www.pfizersafetyreporting.com or by calling 1-800-438-1985

COMIRNATY® Full Prescribing Information and EUA Fact Sheets for Vaccination Providers and Recipients and Caregivers Fact Sheets:

COMIRNATY® Full Prescribing Information (12 years of age and older), DO NOT DILUTE, Gray Cap

EUA Fact Sheet for Vaccination Providers (12 years of age and older), BIVALENT (Original and Omicron BA.4/BA.5), DO NOT DILUTE, Gray Cap

EUA Fact Sheet for Vaccination Providers (5 through 11 years of age), BIVALENT (Original and Omicron BA.4/BA.5), DILUTE BEFORE USE, Orange Cap

EUA Fact Sheet for Vaccination Providers (12 years of age and older), DO NOT DILUTE, Gray Cap

EUA Fact Sheet for Vaccination Providers (5 through 11 years of age), DILUTE BEFORE USE, Orange Cap

EUA Fact Sheet for Vaccination Providers (6 months through 4 years of age), DILUTE BEFORE USE, Maroon Cap

EUA Fact Sheet for Recipients and Caregivers (12 years of age and older)

EUA Recipients and Caregivers Fact Sheet (5 through 11 years of age)

EUA Recipients and Caregivers Fact Sheet (6 months through 4 years of age)

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 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 February 24, 2023. 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 BNT162b2 mRNA vaccine program, and the Pfizer-BioNTech COVID-19 Vaccine, also known as COMIRNATY (COVID-19 Vaccine, mRNA) (BNT162b2) (including the Pfizer-BioNTech COVID-19 Vaccine, Bivalent (Original and Omicron BA.4/BA.5), including a submission of a supplemental Biologics License Application (sBLA) to the U.S. Food and Drug Administration (FDA) to extend the approval of COMIRNATY to include the Omicron BA.4/BA.5-adapted bivalent COVID-19 vaccine (Pfizer-BioNTech COVID-19 Vaccine, Bivalent (Original and Omicron BA.4/BA.5)) as the primary series or a booster dose for individuals 12 years of age and older, planned regulatory submissions, qualitative assessments of available data, potential benefits, expectations for clinical trials, potential regulatory submissions, the anticipated timing of data readouts, 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 preclinical and clinical data (including Phase 1/2/3 or Phase 4 data), including the data discussed in this release for BNT162b2, any monovalent, bivalent or variant-adapted vaccine candidates or any other vaccine candidate in the BNT162 program in any of our studies in pediatrics, adolescents, or adults or real world evidence, including the possibility of unfavorable new preclinical, clinical or safety data and further analyses of existing preclinical, clinical or safety data, including the risk that additional data against newer Omicron sublineages could differ from the data discussed in this release; 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, in real world data studies or in larger, more diverse populations following commercialization; the ability of BNT162b2, any monovalent, bivalent or variant-adapted vaccine candidates or any future vaccine 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 submissions to request emergency use or conditional marketing authorizations for BNT162b2 in additional populations, for a potential booster dose for BNT162b2, any monovalent or bivalent vaccine candidates or any potential future vaccines (including potential future annual boosters or re-vaccinations), and/or other biologics license and/or emergency use authorization applications or amendments to any such applications may be filed in particular jurisdictions for BNT162b2, any monovalent or bivalent vaccine candidates or any other potential vaccines that may arise from the BNT162 program, including a potential variant-based, higher dose, or bivalent vaccine, and if obtained, whether or when such emergency use authorizations or licenses will expire or terminate; whether and when any applications that may be pending or filed for BNT162b2 (including any requested amendments to the emergency use or conditional marketing authorizations), any monovalent, bivalent or variant-adapted vaccine candidates (including the sBLA submission to the FDA to extend the approval of COMIRNATY to include the Omicron BA.4/BA.5-adapted bivalent COVID-19 vaccine), 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 the authorization or approval of products or therapies developed by other companies; disruptions in the relationships between us and our collaboration partners, clinical trial sites or third-party suppliers; the risk that other companies produce superior or competitive products; risks related to the availability of raw materials to manufacture or test a vaccine; challenges related to our vaccine's formulation, dosing 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, booster doses or potential future annual boosters or re-vaccinations or new variant-based or next generation vaccines; the risk that we may not be able to maintain manufacturing capacity or access to logistics or supply channels commensurate with global demand for our vaccines, which would negatively impact our ability to supply our vaccines within the projected time periods; whether and when additional supply agreements will be reached or existing agreements will be completed or renegotiated; uncertainties regarding the ability to obtain recommendations from vaccine advisory or technical committees and other public health authorities and uncertainties regarding the commercial impact of any such recommendations; challenges related to public vaccine confidence or awareness; 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, 2022 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, bispecific immune checkpoint 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, Genentech, a member of the Roche Group, Regeneron, Genevant, Fosun Pharma, and Pfizer. For more information, please visit www.BioNTech.com.

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 including the program to develop a COVID-19 vaccine and COMIRNATY (COVID-19 vaccine, mRNA) (BNT162b2) (including the submission of a supplemental Biologics License Application to the FDA to extend the approval of COMIRNATY to include the Omicron BA.4/BA.5-adapted bivalent COVID-19 vaccine as a primary series or booster dose for individuals 12 years of age and older, [plans to submit an application to the European Medicines Agency for a variation of the Marketing Authorization for the Omicron BA.4/BA.5-adapted bivalent COVID-19 vaccine to also include the bivalent vaccine as a primary course of

vaccination in individuals 5 years of age and older] and planned regulatory submissions, qualitative assessments of available data, potential benefits, expectations for clinical trials, the anticipated timing of regulatory submissions, regulatory approvals or authorizations and anticipated manufacturing, distribution and supply); our expectations regarding the potential characteristics of BNT162b2, any monovalent or bivalent vaccine candidates or any future vaccine, in our clinical trials and/or in commercial use based on data observations to date; the ability of BNT162b2, any monovalent or bivalent vaccine candidates or any future vaccine, to prevent COVID-19 caused by emerging virus variants; 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 Phase 1/2/3 or Phase 4 data), including the data discussed in this release for BNT162b2, any monovalent or bivalent vaccine candidates or any other vaccine candidate in BNT162 program in any of our studies in pediatrics, adolescents, or adults or 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 expected time point for additional readouts on efficacy data of BNT162b2, any monovalent or bivalent vaccine candidates or any future vaccine, in our clinical trials; 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 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; the ability of BioNTech to supply the quantities of BNT162, any monovalent or bivalent vaccine candidates or any future vaccine, to support clinical development and market demand, including our production estimates for 2023; that demand for any products may be reduced or no longer exist which may lead to reduced revenues or excess inventory; the availability of raw materials to manufacture a vaccine; our vaccine's formulation, dosing schedule and attendant storage, distribution and administration requirements, including risks related to storage and handling after delivery by BioNTech or Pfizer; the ability to successfully develop other vaccine formulations, booster doses or potential future annual boosters or re-vaccinations or new variant-based vaccines; the ability to maintain 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; the ability to obtain recommendations from vaccine advisory or technical committees and other public health authorities and uncertainties regarding the commercial impact of any such recommendations; challenges related to public vaccine confidence or awareness; and uncertainties regarding the impact of COVID-19 on BioNTech's trials, business and general operations. Any forward-looking statements in this press release are based on BioNTech's 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 as Form 6-K for the quarter ended September 30, 2022, filed with the SEC on November 7, 2022, 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.

Pfizer:
Media Relations
+1 (212) 733-1226
PfizerMediaRelations@pfizer.com

Investor Relations
+1 (212) 733-4848
IR@pfizer.com

BioNTech:
Media Relations
Jasmina Alatovic
+49 (0)6131 9084 1513
Media@biontech.de

Investor Relations
Sylke Maas, Ph.D.
+49 (0)6131 9084 1074
Investors@biontech.de

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[1] Zou J, Kurhade C, Patel S, et al. Neutralization of BA.4-BA.5, BA.4.6, BA.2.75.2, BQ.1.1, and XBB.1 with Bivalent Vaccine [published online ahead of print, 2023 Jan 25]. N Engl J Med. 2023;NEJMc2214916. doi:10.1056/NEJMc2214916

[2] Centers for Disease Control and Prevention. COVID Data Tracker. Available at: https://covid.cdc.gov/covid-data-tracker

[3] Centers for Disease Control and Prevention. Early Estimates of Bivalent mRNA Booster Dose Vaccine Effectiveness in Preventing Symptomatic SARS-CoV-2 Infection Attributable to Omicron BA.5– and XBB/XBB.1.5–Related Sublineages Among Immunocompetent Adults — Increasing Community Access to Testing Program, United States, December 2022–January 2023. Available at: https://www.cdc.gov/mmwr/volumes/72/wr/mm7205e1.htm