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U.S. FDA Approves ABRYSVO™, Pfizer's Vaccine for the Prevention of Respiratory Syncytial Virus (RSV) in Infants Through Active Immunization of Pregnant Individuals 32-36 Weeks of Gestational Age

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- *First and only U.S. approval of a maternal vaccine to help protect infants at birth through six months of life from lower respiratory tract disease (LRTD) and severe LRTD due to RSV*
- *FDA's decision is based on data from the pivotal Phase 3 clinical trial in more than 7,000 pregnant individuals, and including their infants a total greater than 14,000 trial participants*

NEW YORK--(BUSINESS WIRE)-- Pfizer Inc. (NYSE: PFE) announced today that the U.S. Food and Drug Administration (FDA) has approved ABRYSVO™ (*Respiratory Syncytial Virus Vaccine*), the company's bivalent RSV prefusion F (RSVpreF) vaccine, for the prevention of LRTD and severe LRTD caused by RSV in infants from birth up to six months of age by active immunization of pregnant individuals at 32 through 36 weeks gestational age. ABRYSVO is unadjuvanted and composed of two preF proteins selected to optimize protection against RSV A and B strains and was observed to be safe and effective.

"ABRYSVO's approval as the first and only maternal immunization to help protect newborns immediately at birth through six months from RSV marks a significant milestone for the scientific community and for public health," said Annaliesa Anderson, Ph.D., Senior Vice President and Chief Scientific Officer, Vaccine Research and Development, Pfizer. "We are incredibly grateful to the clinical trial participants and study investigator teams around the world, as well as our Pfizer colleagues, for their commitment to making this vaccine available. Today, a long-sought-after goal to deliver a maternal vaccine that will help protect infants six months of age or younger – when they are at greatest risk of possible serious consequences from RSV – has been achieved."

The FDA's decision is based on the data from the pivotal Phase 3 clinical trial (NCT04424316) **MATISSE** (**MAT**ernal **I**mmunization **S**tudy for **S**afety and **E**fficacy), a randomized, double-blinded, placebo-controlled Phase 3 study designed to evaluate the efficacy, safety, and immunogenicity of the vaccine against LRTD and severe LRTD due to RSV in infants born to healthy individuals vaccinated during pregnancy. These results were published in *The New England Journal of Medicine* in April 2023.

"Newborns and young infants – whose immune systems are still developing and are not yet strong enough to defend against infections – may now be protected from RSV from the moment of birth through maternal immunization," said Eric A.F. Simões, M.D., Clinical Professor, Pediatrics-Infectious Diseases, University of Colorado School of Medicine and Children's Hospital Colorado, Aurora. "The approval of Pfizer's ABRYSVO is a major triumph as it helps ensure no delay in potential RSV protection during an infant's most vulnerable first

six months of life and offers healthcare providers a new opportunity to help prevent severe RSV."

RSV is a contagious virus and a common cause of respiratory illness worldwide.[1] The virus can affect the lungs and breathing passages of an infected individual, potentially causing severe illness or death.[2,3,4] The disease burden of RSV in young children is staggering with virtually all children getting an RSV infection by the time they are two years old.[5] In the United States, approximately 500,000 to 600,000 infants experience LRTD due to RSV each year and it is a leading cause of hospitalization in children less than one year of age. [6,7]

About ABRYSVO

On March 2, 2022, Pfizer announced the U.S. Food and Drug Administration (FDA) granted Breakthrough Therapy Designation for ABRYSVO for prevention of RSV-associated lower respiratory tract illness in infants from birth up to six months of age by active immunization of pregnant women. This decision was followed by the FDA's acceptance of ABRYSVO's Biologics License Application (BLA) under priority review for infants in February 2023.

Pfizer currently is the only company with an RSV vaccine to help protect older adults, as well as help protect infants through maternal immunization. In May 2023, the U.S. Food and Drug Administration (FDA) approved RSVpreF under the name ABRYSVO for the prevention of LRTD caused by RSV in individuals 60 years of age or older. The approval was followed in June by the U.S. Centers for Disease Control and Prevention's (CDC) Advisory Committee on Immunization Practices (ACIP) official recommendation for the vaccine for use in adults 60 years of age and older.

In July 2023, Pfizer announced that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) issued a positive opinion to recommend the granting of a marketing authorization for the RSV vaccine candidate, PF-06928316 or RSVpreF, to help protect older adults and infants through maternal immunization from RSV. The CHMP's positive opinion is being reviewed for each indication by the European Commission (EC). The EC will decide whether to approve RSVpreF, whose European Union (EU) trade name will be ABRYSVO.

In February 2023, Pfizer Japan announced an application was filed with the Ministry of Health, Labor and Welfare for RSVPreF as a maternal immunization to help protect infants against RSV. In April 2023, Pfizer Canada announced Health Canada accepted RSVpreF for review for both individuals ages 60 and older and as a maternal immunization to help protect infants against RSV.

Pfizer has initiated two additional clinical trials evaluating ABRYSVO. One trial is being conducted in children at higher risk for RSV disease ages 2-<18.[8] A second trial is evaluating adults ages 18-60 at higher risk for RSV due to underlying medical conditions, such as asthma, diabetes and COPD, and adults ages 18 and older who are immunocompromised and at high-risk for RSV.[8] Pfizer also plans post-marketing studies and surveillance programs to further describe the safety of the vaccine.

INDICATIONS FOR ABRYSVO

ABRYSVO™ is a vaccine indicated for:

- the prevention of lower respiratory tract disease (LRTD) caused by respiratory syncytial virus (RSV) in people 60 years of age and older
- pregnant individuals at 32 through 36 weeks gestational age for the prevention of LRTD and severe LRTD caused by RSV in infants from birth through 6 months of age

IMPORTANT SAFETY INFORMATION FOR ABRYSVO

- ABRYSVO should not be given to anyone with a history of sever allergic reaction (eg, anaphylaxis) to any of its components
- For pregnant individuals: to avoid the potential risks of preterm birth, ABRYSVO should be given during 32 through 36 weeks gestational age
- Fainting can happen after getting injectable vaccines, including ABRYSVO. Precautions should be taken to avoid falling and injury during fainting
- Adults with weakened immune systems, including those receiving medicines that suppress the immune system, may have a reduced immune response to ABRYSVO
- Vaccination with ABRYSVO may not protect all people
- In adults 60 years of age and older, the most common side effects (?10%) were fatigue, headache, pain at the injection site, and muscle pain
- In pregnant individuals, the most common side effects (?10%) were pain at the injection site, headache, muscle pain, nausea
- In clinical trials where ABRYSVO was compared to placebo, infants born to pregnant individuals experienced low birth weight (5.1% ABRYSVO versus 4.4% placebo) and jaundice (7.2% ABRYSVO versus 6.7% placebo

View the full Prescribing Information.

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.

DISCLOSURE NOTICE:

The information contained in this release is as of August 21, 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 ABRYSVO (RSVpreF), including its potential benefits, an approval in the U.S. for the prevention of lower respiratory tract and severe lower respiratory tract disease caused by RSV in infants from birth up to six months of age by active immunization of pregnant individuals at 32 through 36 weeks gestational age , applications pending for RSVpreF in other jurisdictions and clinical trials initiated in other populations, that involves 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, uncertainties regarding the commercial success of ABRYSVO (RSVpreF); the uncertainties inherent in research and development, including the ability to meet anticipated clinical endpoints, commencement and/or completion dates for our clinical trials, regulatory submission dates, regulatory approval

dates and/or launch dates, as well as the possibility of unfavorable new clinical data and further analyses of existing clinical data; risks associated with interim data, including the risk that final results from the Phase 3 trials could differ from the interim data; the risk that clinical trial data are subject to differing interpretations and assessments by regulatory authorities; whether regulatory authorities will be satisfied with the design of and results from our clinical studies; whether and when biologic license applications may be filed in particular jurisdictions for ABRYSVO (RSVpreF) for any potential indications; whether and when any applications that may be pending or filed for ABRYSVO (RSVpreF) may be approved by regulatory authorities, which will depend on myriad factors, including making a determination as to whether the product's benefits outweigh its known risks and determination of the product's efficacy and, if approved, whether ABRYSVO (RSVpreF) for any such indications will be commercially successful; intellectual property and other litigation; decisions by regulatory authorities impacting labeling, manufacturing processes, safety and/or other matters that could affect the availability or commercial potential of ABRYSVO (RSVpreF); uncertainties regarding the ability to obtain recommendations from vaccine advisory or technical committees and other public health authorities regarding ABRYSVO (RSVpreF) and uncertainties regarding the commercial impact of any such recommendations; uncertainties regarding the impact of COVID-19 on our 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 .

[1] World Health Organization. Respiratory Syncytial Virus (RSV) disease. https://www.who.int/teams/health-product-policy-and-standards/standards-and-specifications/vaccine-standardization/respiratory-syncytial-virus-disease
[2] Centers for Disease Control and Prevention. RSV Transmission. https://www.cdc.gov/rsv/about/transmission.html.
[3] Centers for Disease Control and Prevention. Respiratory Syncytial Virus Infection (RSV) – Older Adults are at High Risk for Severe RSV Infection Fact Sheet. https://www.cdc.gov/rsv/factsheet-older-adults.pdf.
[4] Centers for Disease Control and Prevention. RSV in Infants and Young Children. https://www.cdc.gov/rsv/high-risk/infants-young-children.html.
[5] Glezen WP, Taber LH, Frank AL, Kasel JA. Risk of primary infection and reinfection with respiratory syncytial virus. Am J Dis Child. 1986;140(6):543-546. doi:10.1001/archpedi.1986.02140200053026
[6] Rainisch G, Adhikari B, Meltzer MI, Langley G. Estimating the impact of multiple immunization products on medically-attended respiratory syncytial virus (RSV) infections in infants. Vaccine. 2020;38(2):251-257. doi:10.1016/j.vaccine.2019.10.023.
[7] Hall CB, Weinberg GA, Blumkin AK, et al. Respiratory syncytial virus-associated hospitalizations among children less than 24 months of age. Pediatrics. 2013;132(2):e341-e348. doi:10.1542/peds.2013-0303
[8] Pfizer Second-Quarter 2023 Earnings Teleconference Presentation, August 1, 2023, page, 24, https://s28.q4cdn.com/781576035/files/doc_financials/2023/q1/Q1-2023-Earnings-Charts-FINAL.pdf

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