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European Commission Approves Pfizer’s ABRYSVO™ to Help Protect Infants through Maternal Immunization and Older Adults from RSV

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- *ABRYSVO is the first and only RSV vaccine approved in the European Union (EU) for both older adults and for immunization of pregnant individuals to help protect their infants immediately from birth through six months of age*

NEW YORK--(BUSINESS WIRE)-- Pfizer Inc. (NYSE: PFE) announced today that the European Commission (EC) has granted marketing authorization for ABRYSVO™, the company’s bivalent respiratory syncytial virus (RSV) prefusion F (RSVpreF) vaccine, to help protect both infants through maternal immunization and older adults. ABRYSVO is indicated for:

- Passive protection against lower respiratory tract disease (LRTD) caused by RSV in infants from birth through six months of age following maternal immunization during pregnancy
- Active immunization of individuals 60 years of age and older for the prevention of LRTD caused by RSV

“The approval of ABRYSVO in Europe marks significant progress in the scientific community's efforts to provide meaningful protection against RSV, a common respiratory virus that could potentially be severe and even life-threatening, especially for infants and older adults,” said Annaliesa Anderson, Ph.D., Senior Vice President and Head Vaccine Research and Development, Pfizer. “Last year’s significant number of newborns, children, and adults being hospitalized across Europe demonstrated the immense need for protection against severe RSV cases. The approval of the vaccine for both older adults and infants through maternal immunization is a triumph for public health and we hope to see a tremendous impact for future seasons.”

This marketing authorization follows the recent positive opinion from the Committee for Medicinal Products for Human Use (CHMP). The authorization is valid in all 27 EU member states plus Iceland, Liechtenstein, and Norway. ABRYSVO is the first licensed vaccine designed and studied explicitly for maternal immunization and now a single dose of the vaccine could be administered in the EU between weeks 24 and 36 of gestation.[1] In addition, ABRYSVO has been studied in adults 60 years of age and older. The marketing authorization includes single-dose use in this population as well.[1]

The EU marketing authorization for ABRYSVO is based on evidence from two Phase 3 clinical trials – **RENOIR** (**R**SV vaccine **E**fficacy study i**NO**lder adults **I**mmunized against **R**SV disease) and **MATISSE** (**MAT**ernal **I**mmunization **S**tudy for **S**afety and **E**fficacy).

RENOIR (NCT05035212) is a global, randomized, double-blind, placebo-controlled study designed to assess the efficacy, immunogenicity, and safety of a single dose of the vaccinein adults 60 years of age and older.

MATISSE (NCT04424316) is a global, randomized, double-blinded, placebo-controlled study designed to evaluate the efficacy, safety, and immunogenicity of RSVpreF against LRTD and severe LRTD due to RSV in infants born to healthy individuals vaccinated during pregnancy.

The efficacy and safety results of RENOIR and MATISSE were published in *The New England Journal of Medicine*. RENOIR is ongoing, with efficacy data being collected in the second RSV season in the study.

Burden of Disease in Europe

RSV is a contagious virus and a common cause of respiratory illness worldwide.[2] The virus can affect the lungs and breathing passages of an infected individual, potentially causing severe illness or death.[3,4,5] In the EU, approximately 245,000 yearly hospital admissions were associated with RSV in children younger than five years of age, with most cases occurring among children under one year old.[6] The disease burden for older adults is also significant. Each year, the virus causes more than 270,000 hospitalizations and about 20,000 deaths in individuals 60 years and older.[7]

About ABRYSVO

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

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 two to less than 18 years.[8] A second trial is evaluating adults ages 18 to 60 years 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.

U.S. 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

U.S. IMPORTANT SAFETY INFORMATION FOR ABRYSVO

- ABRYSVO should not be given to anyone with a history of severe allergic reaction (e.g., anaphylaxis) to any of its components

- For pregnant individuals: to avoid the potential risk 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, and 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 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 ABRYSVO (RSVpreF) to help protect both infants through maternal immunization and older adults from RSV, applications pending for RSVpreF in other jurisdictions, clinical trials initiated in other populations and plans for post-marketing studies and surveillance programs 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] Abrysvo SmPC, September 15, 2023. Abrysvo, INN-respiratory syncytial virus vaccine (bivalent, recombinant) (europa.eu)
[2] 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
[3] Centers for Disease Control and Prevention. RSV Transmission. https://www.cdc.gov/rsv/about/transmission.html
[4] 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
[5] Centers for Disease Control and Prevention. RSV in Infants and Young Children. https://www.cdc.gov/rsv/high-risk/infants-young-children.html
[6] Del Riccio M, Spreeuwenberg P, Osei-Yeboah R, et al. Defining the Burden of Disease of RSV in the European Union: estimates of RSV-associated hospitalisations in children under 5 years of age. A systematic review and modelling study [published online ahead of print, 2023 May 29]. J Infect Dis. 2023;jiad188. doi:10.1093/infdis/jiad188
[7] Savic M, Penders Y, Shi T, Branche A, Pirçon JY. Respiratory syncytial virus disease burden in adults aged 60 years and older in high-income countries: A systematic literature review and meta-analysis. Influenza Other Respir Viruses. 2023;17(1):e13031. doi:10.1111/irv.13031
[8] Pfizer Second-Quarter 2023 Earnings Teleconference Presentation, August 1, 2023, page, 24, Q2 2023 Earnings Charts (q4cdn.com)

Category: Vaccines

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Media Contact:

EUPress@Pfizer.com
+44 (0) 1737-332-335

Investor Contact:

IR@Pfizer.com
+1 (212) 733-4848

Source: Pfizer Inc.