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European Commission Approves Pfizer's RSV Vaccine ABRYSVO® to Help Protect Adults Aged 18-59 Against RSV Lower Respiratory Tract Disease

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- *ABRYSVO is the first and only RSV vaccine approved in the European Union (EU) for non-pregnant adults aged 18-49*

NEW YORK--(BUSINESS WIRE)-- Pfizer Inc. (NYSE: PFE) announced today that the European Commission (EC) has issued a decision amending the marketing authorization for ABRYSVO®, the company's bivalent respiratory syncytial virus (RSV) prefusion F (RSVpreF) vaccine, to extend the indication to include prevention of lower respiratory tract disease (LRTD) caused by RSV in individuals 18 through 59 years of age. This expands the previous authorization for individuals aged 60 and older, and ABRYSVO now offers in the EU the broadest RSV vaccine indication, which includes:

- Active immunization of individuals 18 years of age and older for the prevention of LRTD caused by RSV
- Passive protection against lower respiratory tract disease (LRTD) caused by RSV in infants from birth through 6 months of age following maternal immunization during pregnancy

"We are thrilled that ABRYSVO is now approved in the EU to help prevent RSV in adults aged 18 and older, which causes approximately 158,000 adult hospital admissions annually from RSV disease, a common respiratory virus with symptoms that can be severe or even life-threatening," said Alexandre de Germay, Chief International Commercial Officer, Executive Vice President, Pfizer. "With an indication that also includes pregnant individuals between weeks 24 and 36 gestation to help protect infants from birth up to 6 months of age, ABRYSVO's expanded authorization for adults aged 18 to 59 in the EU signifies another step for public health by offering the potential to substantially reduce the burden of RSV in future seasons."

The amended 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. The approval is based on results from the pivotal phase 3 clinical trial (NCT05842967) **MONeT** (RSV I**M**munizati**ON** Study for Adul**T**s at Higher Risk of Severe Illness), which investigated the safety, tolerability, and immunogenicity of ABRYSVO in adults 18 through 59 years of age at risk of RSV-associated LRTD due to certain chronic medical conditions. It was also supported by the thousands of persons vaccinated in clinical trials involving ABRYSVO in this age group.[1,2,3,4] The results of MONeT and other studies have been published in peer-reviewed journals.

ABOUT RSV

Respiratory Syncytial Virus (RSV) is a contagious virus and a common cause of respiratory illness worldwide.[5] The virus can affect the lungs and breathing passages of an infected individual, potentially causing severe illness

or death.[6,7,8] There are two major subgroups of RSV: RSV-A and RSV-B.[9] Both subgroups cause disease and can co-circulate or alternate predominance from season to season. In total, RSV causes approximately 158,000 hospital admissions annually among adults aged 18 and older across the EU, with an estimated 13,000 hospitalizations in those aged 18 to 64 years.[10]

ABOUT ABRYSVO

ABRYSVO is an unadjuvanted, bivalent vaccine that was designed to provide protection against RSV-LRTD, regardless of the virus subgroup. In the prefusion state, the RSV fusion protein (F) is a major target of neutralizing antibodies, serving as the basis of Pfizer's RSV vaccine. Variations in the F protein sequence among RSV-A and RSV-B subgroups are clustered in a key antigenic site, a target for potent neutralizing antibodies.

In August 2023, Pfizer announced that the European Commission granted marketing authorization for ABRYSVO for both adults aged 60 years and older and maternal immunization to help protect infants.

In the U.S in October 2024, the FDA approved ABRYSVO for the prevention of lower respiratory tract disease caused by RSV in individuals 18 through 59 years of age who are at increased risk for LRTD caused by RSV. Prior, in May 2023, the FDA approved ABRYSVO for the prevention of LRTD caused by RSV in individuals 60 years of age and older. In August 2023, the FDA approved ABRYSVO for the prevention of LRTD and severe LRTD caused by RSV in infants from birth up to 6 months of age by active immunization of pregnant individuals at 32 through 36 weeks gestational age.

In addition to the most recent EU approval, ABRYSVO has received approvals for both indications in multiple countries worldwide.

U.S. INDICATIONS FOR ABRYSVO

ABRYSVO® is a vaccine indicated in the U.S. for:

- the prevention of lower respiratory tract disease (LRTD) caused by respiratory syncytial virus (RSV) in people 60 years of age and older
- the prevention of LRTD caused by RSV in people 18 through 59 years of age who are at increased risk for LRTD caused by RSV
- 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 U.S. 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
- An increased risk of Guillain-Barré syndrome (severe muscle weakness) was observed after vaccination with ABRYSVO
- 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 adults 18 through 59 years of age, the most common side effects (?10%) were pain at the injection site, muscle pain, joint pain, and nausea
- 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 ABRYSVO 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 175 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 X 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 April 1, 2025. 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, including its potential benefits and an approval in the EU to extend the indication to include prevention of LRTD caused by RSV in individuals 18 through 59 years of age, 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; 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; 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 for any potential indications; whether and when any applications that may be pending or filed for ABRYSVO 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 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; uncertainties regarding the ability to obtain or maintain recommendations from vaccine advisory or technical committees and other public health authorities regarding ABRYSVO 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, 2024, 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] Walsh EE, Falsey AR, Scott DA, et al. A Randomized Phase 1/2 Study of a Respiratory Syncytial Virus Prefusion F Vaccine. J Infect Dis. 2022 Apr 19;225(8):1357-1366.

[2] Schmoele-Thoma B, Zareba AM, Jiang Q, et al. Vaccine Efficacy in Adults in a Respiratory Syncytial Virus Challenge Study. N Engl J Med. 2022 Jun 23;386(25):2377-2386. doi: 10.1056/NEJMoa2116154.

[3] Baker J, Aliabadi N, Munjal I, et al. Equivalent immunogenicity across three RSVpreF vaccine lots in healthy adults 18-49 years of age: Results of a randomized phase 3 study. Vaccine. 2024 May 10;42(13):3172-3179. doi: 10.1016/j.vaccine.2024.03.070. Epub 2024 Apr 16.

[4] Peterson JT, Zareba AM, Fitz-Patrick D, et al. Safety and Immunogenicity of a Respiratory Syncytial Virus Prefusion F Vaccine When Coadministered With a Tetanus, Diphtheria, and Acellular Pertussis Vaccine. J Infect Dis. 2022 Jun 15;225(12):2077-2086. doi: 10.1093/infdis/jiab505.

[5] 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

[6] World Health Organization. Respiratory Syncytial Virus (RSV). https://www.who.int/news-room/fact-sheets/detail/respiratory-syncytial-virus-(rsv)

[7] 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

[8] Centers for Disease Control and Prevention. RSV in Infants and Young Children. https://www.cdc.gov/rsv/high-risk/infants-young-children.html

[9] Nuttens C, Moyersoen J, Curcio D, et al. Differences Between RSV A and RSV B Subgroups and Implications for Pharmaceutical Preventive Measures. *Infect Dis Ther*. 2024;13(8):1725-1742. doi:10.1007/s40121-024-01012-2

[10] Del Riccio M, Spreeuwenberg P, Osei-Yeboah R, et al. Estimation of the Number of Respiratory Syncytial Virus–Associated Hospitalizations in Adults in the European Union. J Infect Dis 2023 May 29;228(11):1539–1548. doi: 10.1093/infdis/jiad189.

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