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U.S. FDA Approves Pfizer's RSV Vaccine ABRYSVO® for Adults Aged 18 to 59 at Increased Risk for Disease

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- *First and only respiratory syncytial virus (RSV) vaccine indicated for adults younger than 50*
- *Approval based on data from pivotal Phase 3 trial in adults at increased risk of lower respiratory tract disease caused by RSV*

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 lower respiratory tract disease (LRTD) caused by RSV in individuals 18 through 59 years of age who are at increased risk for LRTD caused by RSV. ABRYSVO now offers the broadest RSV vaccine indication for adults, which previously included those 60 years and older. Additionally, it remains the only RSV immunization approved for pregnant individuals at 32 through 36 weeks of gestation to protect infants from birth up to 6 months of age.

"RSV represents a significant threat to younger adults with certain chronic conditions. After decades of vaccine research by the scientific community and Pfizer, we now have the opportunity to help alleviate the burden of RSV in this high-risk adult population," said Aamir Malik, Chief U.S. Commercial Officer and Executive Vice President, Pfizer. "With this approval, we are proud that ABRYSVO is now the only RSV vaccine indicated for adults aged 18 to 49 at increased risk for the disease, expanding on its existing indications for older adults and pregnant women."

The FDA's decision is based on inferred efficacy [1] 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 at risk of RSV-associated disease due to certain chronic medical conditions. The company intends to submit results from MONeT for publication in a peer-reviewed scientific journal and for presentation at an upcoming scientific conference.

Among U.S. adults 18 to 49 years of age, 9.5% have an underlying chronic condition, such as obesity, diabetes, chronic obstructive pulmonary disease (COPD), heart failure, chronic kidney disease, and asthma [2] that puts them at increased risk of developing, and being hospitalized for, RSV-associated LRTD, and this rises to 24.3% among those 50 to 64 years of age. [3,4]

ABOUT RSV

Respiratory syncytial virus (RSV) is a contagious virus and a common cause of respiratory illness. [5] The virus can affect the lungs and breathing passages of an infected individual, potentially causing severe illness or death. [6,7] Chronic cardiovascular disease, chronic lung disease, moderate or severe immune compromise, diabetes with complications, and severe obesity are among the conditions that increase an individual's risk for severe RSV. [8] There are two major subgroups of RSV: RSV-A and RSV-B. Both subgroups cause disease and can co-circulate or alternate predominance from season to season.

ABOUT ABRYSVO
Pfizer currently is the only company with an RSV vaccine to help protect adults aged 60 and older, and adults 18 and older at increased risk of lower respiratory tract disease caused by RSV (RSV-LRTD), as well as infants through maternal immunization. ABRYSVO is an unadjuvanted, bivalent vaccine that was designed to provide broad 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 May 2023, the FDA approved ABRYSVO for the prevention of LRTD caused by RSV in individuals 60 years of age or older. In June 2024, the Advisory Committee on Immunization Practices (ACIP) voted to update its recommendation of RSV vaccines for use in adults aged ?75 years and adults age 60-74 years who are increased risk for severe RSV disease. 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. This was followed in September 2023 with ACIP's recommendation for maternal immunization to help protect newborns from RSV seasonally where the vaccine should be administered from September through January in most of the continental United States.

Also in August 2023, Pfizer announced that the European Commission granted marketing authorization for ABRYSVO for both older adults and maternal immunization to help protect infants. Additionally, ABRYSVO has received approvals for both indications in multiple countries worldwide.

INDICATIONS FOR ABRYSVO

ABRYSVO ® is a vaccine indicated in the US 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 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 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 October 22, 2024. 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 U.S. for the prevention of LRTD caused by RSV in individuals 18 through 59 years of age who are at increased risk for LRTD caused by RSV, 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 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, 2023, 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 .

REFERENCES

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[2] U.S. Centers for Disease Control and Prevention. "Morbidity and Mortality Weekly Report." August 15, 2024. https://www.cdc.gov/mmwr/volumes/73/wr/mm7332e1.htm

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[5] World Health Organization. Respiratory Syncytial Virus (RSV) disease. https://www.who.int/teams/health-product-policy-and-standards/standards-and-specifications/norms-and-standards/vaccine-standardization/respiratory-syncytial-virus-disease. Accessed October 2024.

[6] U.S. Centers for Disease Control and Prevention. How RSV Spreads. https://www.cdc.gov/rsv/causes/index.html. Updated August 30, 2024. Accessed October 2024.

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[8] U.S. Centers for Disease Control and Prevention. Clinical Overview of RSV. https://www.cdc.gov/rsv/hcp/clinical-overview/index.html. Updated August 30, 2024. Accessed October 2024.

Category: Vaccines

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

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

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