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U.S. FDA Approves ABRYSVO™, Pfizer's Vaccine for the Prevention of Respiratory Syncytial Virus (RSV) in Older Adults

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- *FDA's decision is based on the data from the pivotal Phase 3 clinical trial in approximately 37,000 participants*
- *Each year in the U.S., it is estimated that between 60,000 and 160,000 older adults are hospitalized and between 6,000 and 10,000 die due to RSV infection*[1]
- *ABRYSVO's approval will help offer older adults protection in the anticipated RSV season this fall*

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 caused by RSV in individuals 60 years and older. 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.

"A vaccine to help prevent RSV had been an elusive public health goal for more than half a century. Today's approval is a monumental step forward in delivering on Pfizer's commitment to help alleviate the significant burden of RSV in higher-risk populations, which includes older adults," said Annaliesa Anderson, Ph.D., Senior Vice President and Chief Scientific Officer, Vaccine Research and Development, Pfizer. "ABRYSVO will address a need to help protect older adults against the potentially serious consequences of RSV disease. We are extremely grateful to the clinical trial participants, study investigator teams and our dedicated Pfizer colleagues for their roles in making this vaccine available."

The FDA's decision is based on the data from the pivotal Phase 3 clinical trial (NCT05035212) **RENOIR** (**R**SV vaccine **E**fficacy study i**NO**lder adults **I**mmunized against **R**SV disease). RENOIR 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. RENOIR has enrolled approximately 37,000 participants, randomized to receive RSVpreF 120 ?g or placebo in a 1:1 ratio. The results were recently published in *The New England Journal of Medicine*. RENOIR is ongoing, with efficacy data being collected in the second RSV season in the study.

"This past RSV season demonstrated the serious consequences and potential health risks this virus poses for older adults," said Edward E. Walsh, MD, Professor of Medicine, University of Rochester Medical Center, and principal RENOIR investigator. "Today's FDA approval of ABRYSVO recognizes significant scientific progress, and importantly helps provide older adults potential protection against RSV and an opportunity to improve community health by helping prevent the disease."

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 U.S., the burden RSV causes in older adults is considerable. The severity of RSV disease can increase with age and comorbidities, such as chronic obstructive pulmonary disease, asthma, and congestive heart failure.[6]

The U.S. Centers for Disease Control and Prevention's (CDC) Advisory Committee on Immunization Practices (ACIP) will meet on June 21, 2023, to discuss recommendations for the appropriate use of RSV vaccines in older adults. Pending the outcome of this meeting, Pfizer anticipates supply availability in Q3 2023 ahead of the anticipated RSV season this fall.

Earlier this month, Pfizer reported positive top-line results from the Phase 3 study evaluating the safety and immunogenicity of ABRYSVO coadministered with seasonal inactivated influenza vaccine (SIIV) in adults 65 years and older.[7] Pfizer intends to publish these results in a peer-reviewed scientific journal. Earlier this month, Pfizer also announced it would be initiating multiple clinical trials evaluating RSVpreF in healthy children ages 2-5; children ages 5-18 with underlying medical conditions; adults ages 18-60 at high-risk due to underlying medical conditions; and adults ages 18 and older who are immunocompromised and at high-risk for RSV.[8]

About ABRYSVO Regulatory Review
On March 24, 2022, Pfizer announced the FDA granted Breakthrough Therapy Designation for ABRYSVO for the prevention of lower respiratory tract disease caused by RSV in individuals 60 years of age and older. This decision was followed by the FDA's acceptance of ABRYSVO's Biologics License Application (BLA) under priority review for older adults in November 2022.

Pfizer is currently the only company pursuing regulatory applications for an RSV investigational vaccine candidate for both an indication to help protect older adults, as well as an indication to help protect infants through maternal immunization. Previously, Pfizer announced that the FDA had granted priority review for a BLA for RSVpreF 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. Earlier this month, Pfizer announced that the FDA's Vaccines and Related Biological Products Advisory Committee voted that available data support the efficacy and safety of RSVpreF for the maternal indication. The FDA has set a Prescription Drug User Fee Act (PDUFA) action date in August 2023.

In February 2023, it was announced that the European Medicines Agency (EMA) accepted for review Pfizer's Marketing Authorization Application (MAA) under accelerated assessment for RSVpreF, as submitted for both older adults and maternal immunization to help protect infants against RSV. The formal review process by the EMA's Committee for Medicinal Products for Human Use (CHMP) currently is ongoing. Also 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.

INDICATION FOR ABRYSVO

ABRYSVO is a vaccine indicated for the prevention of lower respiratory tract disease caused by respiratory syncytial virus (RSV) in people 60 years of age and older.

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

- Fainting can happen after getting injectable vaccines, including ABRYSVO. Precautions should be taken to avoid falling and injury due to 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 pain at the injections site, fatigue, headache, and muscle pain

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 May 31, 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 disease caused by RSV in individuals 60 years and older, an application pending in the U.S. for RSVpreF 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, applications pending for RSVpreF in other jurisdictions and plans to initiate clinical trials 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; 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.

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[1] Centers for Disease Control and Prevention. RSV in Older Adults and Adults with Chronic Medical Conditions. https://www.cdc.gov/rsv/high-risk/older-adults.html.
[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] Centers for Disease Control and Prevention. Older Adults Are at High Risk for Severe RSV Infection. https://www.cdc.gov/rsv/factsheet-older-adults.html
[7] Pfizer First Quarter 2023 Earnings Press Release, May 2, 2023, page 11, https://s28.q4cdn.com/781576035/files/doc_financials/2023/q1/Q1-2023-PFE-Earnings-Release.pdf
[8] Pfizer First Quarter 2023 Earnings Teleconference Presentation, May 2, 2023, page 22, https://s28.q4cdn.com/781576035/files/doc_financials/2023/q1/Q1-2023-Earnings-Charts-FINAL.pdf

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