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# Pfizer Announces Top-Line Results of ABRYSVO® for RSV in Immunocompromised Adults

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- *First assessment from an RSV vaccine study in immunocompromised adults show ABRYSVO was well-tolerated and generated strong neutralizing responses after a single dose in adults ? 18 years of age*
- *These results add to the growing body of evidence indicating a single dose of ABRYSVO provides strong immune protection against outcomes caused by RSV*

NEW YORK--(BUSINESS WIRE)-- Pfizer Inc. (NYSE: PFE) today announced positive top-line safety and immunogenicity results from substudy B of the ongoing pivotal Phase 3 clinical trial ( NCT05842967 ) **MONeT** (RSV I **M** munizati **ON** Study for Adul **T** s at Higher Risk of Severe Illness), evaluating two doses of ABRYSVO vaccine in immunocompromised adults aged 18 and older at risk of developing severe respiratory syncytial virus (RSV)-associated lower respiratory tract disease (LRTD).

Adults with immunocompromising conditions have an increased risk of developing RSV-LRTD. Substudy B of the MONeT trial was conducted to assess the safety and immunogenicity of two doses of ABRYSVO, administered one month apart, in four groups of immunocompromised adults: those with non-small cell lung cancer, those on hemodialysis due to end-stage renal disease, those with autoimmune inflammatory disorder receiving active immunomodulator therapy, and solid organ transplant recipients. Of the 203 adults enrolled in the substudy, approximately half were between the ages of 18 to 59, and approximately half were 60 years or older.

ABRYSVO was well-tolerated during the trial, showing a safety profile consistent with findings from other studies of the vaccine. While the company evaluated two doses, a single 120 µg dose of ABRYSVO generated a strong neutralizing response against both subtypes of RSV, RSV-A and RSV-B, across all cohorts and age groups in the study. Pfizer plans to share these findings at an upcoming scientific conference and publish them in a peer-reviewed scientific journal, as well as submit these data to the regulatory agencies for review.

“Immunocompromised adults, such as patients with cancer or autoimmune disorders, have a substantially increased risk of experiencing severe complications from RSV, yet there are currently no vaccines approved for those aged 18 to 59 in the U.S.,” said Annaliesa Anderson, Ph.D., Senior Vice President and Chief Scientific Officer, Vaccine Research and Development, Pfizer. “We are encouraged by the positive top-line data from this study, which provide important evidence that ABRYSVO has the potential to address a significant unmet need in this vulnerable population.”

These most recent data in immunocompromised adults build on the body of evidence supporting the profile of ABRYSVO in high-risk adults. In June of 2024 at the meeting of the Advisory Committee on Immunization Practices ( *ACIP* ), Pfizer presented results from a cohort of adults aged 18-59 with certain chronic medical conditions. In the double-blinded study, 681 adults aged 18 to 59 with chronic conditions were randomized 2:1 to receive a single dose of ABRYSVO or placebo. Participants demonstrated RSV-A and RSV-B subgroup

neutralizing responses non-inferior to the response seen in the Phase 3 (NCT05035212) RENOIR study of ABRYSVO, which previously demonstrated ABRYSVO's efficacy in a population of adults aged 60 or older. These results support previous data presented at the ACIP showing high ABRYSVO clinical effectiveness against lower respiratory tract disease among a population of adults age 60 years and older that included a substantial proportion of immunocompromised persons.

**Approval of ACT-O-VIAL** ®

Additionally and as previously announced, the U.S. Food and Drug Administration (FDA) has approved Pfizer's supplemental Biologics License Application for the ACT-O-VIAL® presentation of ABRYSVO. This approval allows Pfizer to bring a new option to market alongside its existing needle-free reconstitution kits. The ACT-O-VIAL System is a dual-component vial system that simplifies the reconstitution of ABRYSVO within a single, compact device. Designed to support safety, workflow improvements and storage efficiency, the system offers significant storage space savings, which may be appealing to retailers during peak vaccination seasons.

**ABOUT MONeT**
MONeT (RSV I **M** munizati **ON** Study for Adul **T** s at Higher Risk of Severe Illness) is a Phase 3, multicenter clinical trial (NCT05842967) investigating the safety, tolerability and immunogenicity of ABRYSVO in adults at risk of RSV-associated disease, including adults with certain chronic medical conditions (substudy A) and adults who are immunocompromised (substudy B). Substudy A is a double-blinded study that randomized 681 adults aged 18 to 59 with chronic conditions, with 2:1 to receive a single dose of ABRYSVO or placebo. Substudy B is an open-label study that enrolled approximately 200 immunocompromised adults aged 18 or older, roughly half of which were aged 60 or older, who received two doses of ABRYSVO, one month apart.

**ABOUT RSV**
Respiratory syncytial virus (RSV) is a contagious virus and a common cause of respiratory illness. [1] The virus can affect the lungs and breathing passages of an infected individual and can potentially cause severe illness in young infants, older adults, and individuals with certain chronic medical conditions. [2,3,4] In the United States alone, among older adults, RSV infections account for approximately 60,000-160,000 hospitalizations and 6,000-13,000 deaths each year. [5,6,7,8,9,10,11,12,13] 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 older adults, as well as infants through maternal immunization. ABRYSVO is a 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 May 2023, the FDA approved ABRYSVO for the prevention of LRTD caused by RSV in individuals 60 years of age or older. The Advisory Committee on Immunization Practices (ACIP) of the U.S. Centers for Disease Control and Prevention recommends RSV vaccines as a single dose for all adults 75 and older and for adults 60 and older at increased risk of 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 six 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 Medicines Agency (EMA) granted marketing authorization for ABRYSVO for both older adults and maternal immunization to help protect infants. The vaccine has also received approvals from la Administración Nacional de Medicamentos, Alimentos y Tecnología Médica (ANMAT) of Argentina in September 2023; the Medicines and Healthcare products Regulatory Agency (MHRA) of the United Kingdom in November 2023; Health Canada in January 2024 ; the Pharmaceutical Administration Bureau of Macau in February 2024; the Ministry of Health, Labour, and Welfare of Japan for maternal immunization to help protect infants in January 2024 and for older adults in March 2024; and the Therapeutic Goods Administration of Australia in March 2024 for older adults.

In addition to MONeT, Pfizer has initiated a clinical trial evaluating ABRYSVO in children ages two to less than 18 years who are at higher risk for RSV disease. [14]

**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
- 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 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 August 12, 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, plans to share findings from an RSV vaccine study in immunocompromised adults at an upcoming scientific conference and publish them in a peer-reviewed scientific journal, planned regulatory submissions, a potential new indication for ABRYSVO and clinical trials initiated for ABRYSVO 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; 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 .*

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[13] Hansen CL, Chaves SS, Demont C, Viboud C. Mortality Associated With Influenza and Respiratory Syncytial Virus in the US, 1999-2018.JAMA Network Open. 2022 Feb 1;5(2):e220527.
[14] Pfizer Second-Quarter 2023 Earnings Teleconference Presentation, August 1, 2023, page, 24, https://s28.q4cdn.com/781576035/files/doc_financials/2023/q2/Q2-2023-PFE-Earnings-Release.pdf

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