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Pfizer Announces Positive Top-Line Results from Phase 3 Study of ABRYSVO® in Adults Aged 18 to 59 at Increased Risk for RSV Disease

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- *ABRYSVO met its trial primary endpoints in adults aged 18 to 59 with an increased respiratory syncytial virus (RSV) disease risk. The vaccine was well-tolerated and demonstrated an immune response non-inferior to adults aged 60 years and older*
- *Pfizer intends to submit these findings to regulatory agencies to seek approval of ABRYSVO in adults 18 to 59 years of age*

NEW YORK--(BUSINESS WIRE)-- Pfizer Inc. (NYSE: PFE) today announced positive top-line immunogenicity and safety data from 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 a single dose of ABRYSVO versus placebo in adults 18 to 59 years of age at risk of developing severe respiratory syncytial virus (RSV)-associated lower respiratory tract disease (LRTD).

Adults with certain underlying chronic conditions are at increased risk of developing, and being hospitalized for, RSV-associated LRTD[1,2]. Among US adults 18 to 49 years of age, 9.5 percent have a chronic condition that puts them at risk of severe RSV disease and this percentage rises to 24.3 percent among persons 50 to 64 years of age[1]. However, no RSV vaccines have been approved for use in adults 18 to 59 years of age. The MONeT study was initiated to address this significant unmet need by investigating the immunogenicity and safety of ABRYSVO in adults aged 18 to 59 at increased risk for RSV disease, such as those with asthma, diabetes, and chronic obstructive pulmonary disease.

The MONeT study achieved its co-primary immunogenicity endpoints and primary safety endpoint:

- 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 in more than 34,000 adults aged 60 or older where vaccine efficacy was previously demonstrated.[3]
- Participants also achieved at least a four-fold increase in serum neutralizing titers for RSV-A and RSV-B one month following receipt of ABRYSVO compared to pre-vaccination.
- During the trial, ABRYSVO was well-tolerated, and safety findings were consistent with those from previous investigations of ABRYSVO in other populations. [4]

Pfizer also met its diversity recruitment goals for the study providing data from participants that mirror the diverse U.S. population and had a balanced representation across underlying medical conditions.

Pfizer intends to submit these data to regulatory agencies and request expansion of the age group from the current indication to 18 years of age and older. The use of immunobridging studies to extrapolate efficacy from older to younger adults is an established regulatory pathway.[4] The company also intends to publish these findings in a peer-reviewed scientific journal and share them at an upcoming scientific conference.

“These encouraging results provide evidence that ABRYSVO can help protect adults with increased risk against RSV-associated illness,” said Annaliesa Anderson, Ph.D., Senior Vice President and Head, Vaccine Research and Development, Pfizer. “We are excited to address a significant unmet need, pending regulatory authority approval, as ABRYSVO has the potential to become the first and only RSV vaccine for adults 18 years and older.”

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.[5] 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.[6,7,8] 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.[9,10,11,12,13,14,15,16,17] RSV disease is caused by the respiratory syncytial virus. 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 broad protection against all 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. This was followed by the ACIP’s recommendation of the vaccine for use in adults 60 years of age and older based on shared clinical decision making, which occurred in June 2023. 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.[18]

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 April 9, 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 submit MONeT data to regulatory authorities, 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.

Category: Vaccines

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[1] Weycker, D., Averin, A., Houde, L. et al. Rates of Lower Respiratory Tract Illness in US Adults by Age and Comorbidity Profile. Infect Dis Ther 2024;13: 207–220. doi: 10.1007/s40121-023-00904-z. Epub 2024 Jan 18. PMID: 38236516; PMCID: PMC10828164.

[2] Centers for Disease Control and Prevention. "Epidemiology of Respiratory Syncytial Virus Hospitalizations in Adults — RSV-NET." https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2023-10-25-26/03-Patton-Adult-RSV-508.pdf. Presented October 25, 2023. Last Accessed April 2024.

[3] Walsh EE, Gonzalo PM, et al. "Efficacy and Safety of a Bivalent RSV Prefusion F Vaccine in Older Adults." The New England Journal of Medicine. April 20, 2023.

https://www.nejm.org/doi/full/10.1056/NEJMoa2213836?query=featured_home.
[4] Fink D. Immunobridging to Evaluate Vaccines. https://cdn.who.int/media/docs/default-source/blue-print/doran-fink_4_immunobridging_vrconsultation_6.12.2021.pdf. Published June 2021, Last Accessed April 2024.
[5] Centers for Disease Control and Prevention. Respiratory Syncytial Virus Infection (RSV). https://www.cdc.gov/rsv/index.html. Updated December 18, 2020.
[6] Centers for Disease Control and Prevention. RSV Transmission. https://www.cdc.gov/rsv/about/transmission.html. Updated December 18, 2020.
[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] Centers for Disease Control and Prevention. RSV Surveillance & Research. https://www.cdc.gov/rsv/research/index.html.
[10] Widmer K, Zhu Y, Williams JV, et al. Rates of Hospitalizations for Respiratory Syncytial Virus, Human Metapneumovirus, and Influenza Virus in Older Adults. J Infect Dis. 2012; 206(1):56-62.
[11] Branche AR, Saiman L, Walsh EE, et al. Incidence of Respiratory Syncytial Virus Infection Among Hospitalized Adults, 2017–2020. CID. 2022;74(6):1004-1011.
[12] McLaughlin JM, Khan F, Begier E, et al. Rates of Medically Attended RSV among US Adults: A Systematic Review and Meta-analysis. Open Forum Infect Dis. 2022; 9(7): ofac300.
[13] Zheng Z, Warren JL, Shapiro ED, et al. Estimated Incidence of Respiratory Hospitalizations Attributable to RSV Infections across Age and Socioeconomic Groups. Pneumonia. 2022;14(1):6.
[14] Centers for Disease Control and Prevention. October 2022 ACIP Meeting Slides. ACIP Adult RSV Work Group Considerations. Available at: www.cdc.gov/vaccines/acip/meetings/downloads/slides-2022-10-19-20/04-RSV-Adults-Melgar-508.pdf.
[15] Thompson WW, Shay DK, Weintraub E, et al. Mortality Associated with Influenza and Respiratory Syncytial Virus in the United States. JAMA. 2003; 289(2): 179.186.
[16] Matias G, Taylor R, Haguinet F, et al. Estimates of Mortality Attributable to Influenza and RSV in the United States during 1997–2009 by Influenza Type or Subtype, Age, Cause of Death, and Risk Status. Influenza Other Respir Viruses. 2014; 8(5):507-15.
[17] 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
[18] Pfizer Second-Quarter 2023 Earnings Teleconference Presentation, August 1, 2023, page, 24, https://s28.q4cdn.com/781576035/files/doc_financials/2023/q2/Q2-2023-Earnings-Charts-FINAL.pdf.

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