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Pfizer Announces Positive Top-Line Data for Full Season Two Efficacy of ABRYSVO® for RSV in Older Adults

Thursday, February 29, 2024 - 08:00am

- *ABRYSVO, a bivalent vaccine, maintained consistently high protective efficacy for both RSV A and RSV B disease through two seasons after a single dose.*
- *ABRYSVO efficacy was 77.8% against RSV lower respiratory tract disease with three or more symptoms in a second full RSV season in adults 60 years of age or older.*

NEW YORK--(BUSINESS WIRE)-- Pfizer Inc. (NYSE: PFE) today announced top-line ABRYSVO® vaccine efficacy and safety data for respiratory syncytial virus (RSV) in adults 60 years of age and older following a second season in the Northern and Southern Hemispheres from the ongoing pivotal Phase 3 clinical trial (NCT05035212) **RENOIR** (**R**SV vaccine **E**fficacy study i**N** **O**lder adults **I**mmunized against **R**SV disease). Vaccine efficacy against RSV-associated lower respiratory tract disease (LRTD), defined by three or more symptoms, after disease surveillance in season two was 77.8% (95.0% CI: 51.4, 91.1); vaccine efficacy following season one was 88.9% (95.0% CI: 53.6%, 98.7%)[1], which demonstrates durable efficacy after two seasons.

Consistent vaccine efficacy was demonstrated for both RSV A and RSV B after season two with vaccine efficacy against each subtype of ?80% for LRTD with three or more symptoms. Vaccine efficacy was also sustained against less severe LRTD, defined by two or more symptoms, from 65.1% (95.0%% CI: 35.9%, 82.0%)1 after season one to 55.7% (95.0% CI: 34.7%, 70.4%) after the end of season two. Vaccine efficacy against RSV-associated LRTD, defined by three or more symptoms, across both seasons after approximately 16.4 months of disease surveillance was 81.5% (95.0% CI: 63.3, 91.6).

No new adverse events were reported through the second RSV season beyond what was reported by subjects in the clinical trial during the first season. Pfizer is conducting post-marketing studies and surveillance programs to inform the safety profile of ABRYSVO.

“We are encouraged by the level of protection that we observed after two full RSV seasons for ABRYSVO,” said Annaliesa Anderson, Ph.D., Senior Vice President and Chief Scientific Officer, Vaccine Research and Development, Pfizer. “This new data indicate that broad and durable protection against both types of RSV that cause disease, RSV A and RSV B, is the potential benefit to having a bivalent vaccine.”

Pfizer intends to submit these data to regulatory authorities and vaccine technical committees. The company also intends to publish these findings in a peer-reviewed scientific journal and share them at an upcoming scientific congress.

ABOUT RSV

RSV is a contagious virus and a common cause of respiratory illness.[2] 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.[3,4,5] 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.[6,7,8,9,10,11,12,13,14] 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. The RSV fusion protein (F) in the prefusion conformation is a major target of virus infection blocking antibodies and is the basis of Pfizer's RSV vaccine. Sequence variability in F between RSV subgroup A and B strains clusters in potent neutralizing antibody binding sites on prefusion F.

In May 2023, the FDA approved ABRYSVO for the prevention of LRTD caused by RSV in individuals 60 years of age or older. ABRYSVO is a bivalent vaccine that was designed to provide broad protection regardless whether strain. This was followed by the ACIP's recommendation of the vaccine for use in adults 60 years of age and older with 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 of Canada in January 2024; the Pharmaceutical Administration Bureau of Macau in February 2024; and for maternal immunization to help protect infants by the Ministry of Health, Labour, and Welfare of Japan in January 2024.

Pfizer has also initiated two additional clinical trials evaluating ABRYSVO. One trial is being conducted in children ages two to less than 18 years who are at higher risk for RSV disease.[15] A second trial is evaluating adults ages 18 to 59 years at higher risk for RSV due to underlying medical conditions such as asthma, diabetes and chronic obstructive pulmonary disease (COPD), and adults ages 18 and older who are immunocompromised and at high risk for RSV.

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 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 February 29, 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 season two data to regulatory authorities and vaccine technical committees, clinical trials initiated for ABRYSVO in other populations and post-marketing studies and surveillance programs for ABRYSVO, 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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[2] Centers for Disease Control and Prevention. Respiratory Syncytial Virus Infection (RSV). https://www.cdc.gov/rsv/index.html. Updated December 18, 2020.

[3] Centers for Disease Control and Prevention. RSV Transmission. https://www.cdc.gov/rsv/about/transmission.html. Updated December 18, 2020.

[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. RSV Surveillance & Research. https://www.cdc.gov/rsv/research/index.html.

[7] 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.

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[11] 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.

[12] 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.

[13] 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.

[14] 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.

[15] 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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Source: Pfizer Inc.