Pfizer Logo

Pfizer Announces Positive Top-Line Data from Phase 3 Trial of Older Adults for its Bivalent Respiratory Syncytial Virus (RSV) Vaccine Candidate

Thursday, August 25, 2022 - 06:45am

- *Vaccine efficacy of 85.7% was observed in participants with more severe disease primary endpoint of lower respiratory tract illness (LRTI-RSV) defined by analysis of three or more RSV - associated symptoms*
- *Investigational vaccine was well-tolerated with no safety concerns*
- *Based on the findings of this pre-planned, interim efficacy analysis, Pfizer intends to submit for regulatory approval in fall 2022*

NEW YORK--(BUSINESS WIRE)-- Pfizer Inc. (NYSE: PFE) today announced positive top-line data from the Phase 3 clinical trial (NCT05035212) **RENOIR** (**R**SV vaccine **E**fficacy study i**NO**lder adults **I**mmunized against **R**SV disease) investigating its bivalent RSV prefusion F vaccine candidate, RSVpreF, when administered to adults 60 years of age or older. The bivalent vaccine candidate is composed of two preF proteins selected to optimize protection against RSV A and B strains.

RSV disease is characterized by several respiratory symptoms varying from mild to more severe disease, with more severe disease having more symptoms. A pre-planned, interim analysis of Pfizer's RSVpreF efficacy conducted by an independent, external Data Monitoring Committee (DMC) to assess protection against RSV-associated lower respiratory tract illness (LRTI-RSV) defined by two or more symptoms demonstrated vaccine efficacy: 66.7% (96.66% CI: 28.8%, 85.8%). This positive result enabled Pfizer to look at the more severe disease primary endpoint of LRTI-RSV defined by three or more symptoms, where vaccine efficacy of 85.7% (96.66% CI: 32.0%, 98.7%) was observed. The DMC also indicated the investigational vaccine was well-tolerated, with no safety concerns. Based on these results, Pfizer plans to submit a Biologics License Application (BLA) to the U.S. Food and Drug Administration (FDA) for RSVpreF and to prepare submissions for other regulatory authorities in the coming months.

"We are delighted that this first bivalent RSV vaccine candidate, RSVpreF, was observed to be efficacious in our clinical trial against this disease, which is associated with high levels of morbidity and mortality in older adults," said Annaliesa Anderson, Ph.D., Senior Vice President and Chief Scientific Officer, Vaccine Research and Development, Pfizer. "Scientists and researchers have worked to develop RSV vaccines with little success for over half a century. These findings are an important step in our effort to help protect against RSV disease, and we look forward to working with the FDA and other regulatory agencies to make this vaccine candidate available to help address the substantial burden of RSV disease in older adults."

Pfizer intends to present results of this interim analysis at a future medical congress and will submit the results for peer-review in a scientific journal.

The Phase 3 RENOIR trial is a global, randomized, double-blind, placebo-controlled study designed to assess the efficacy, immunogenicity, and safety of a single dose of RSVpreF in adults 60 years of age and older. To date, RENOIR has enrolled approximately 37,000 participants, randomized to receive 120?g RSVpreF or placebo in a 1:1 ratio. Enrollment up to approximately 40,000 participants continues in the Southern Hemisphere to accumulate cases during their first season.

Burden of RSV in Older Adults

RSV is a contagious virus that in healthy individuals can cause serious respiratory illness.[1] The virus can affect the lungs and breathing passages of an infected individual and can be potentially life-threatening for older adults and adults with certain medical conditions.[2,3,4] Each year it is estimated that 336,000 older adults are hospitalized globally due to RSV.[5] In the United States alone, RSV infections in older adults account for approximately 177,000 hospitalizations and 14,000 deaths each year.[4]

RSV is a disease for which there are currently no prophylactic or therapeutic options for older adults and the medical community is limited to offering only supportive care for adults with the illness.

About RSVpreF

Pfizer's investigational RSV vaccine candidate builds on foundational basic science discoveries including those made at the National Institutes of Health (NIH), which detailed the crystal structure of prefusion F, a key form of the viral fusion protein (F) that RSV uses to enter human cells. The NIH research showed that antibodies specific to the prefusion form were highly effective at blocking virus infection, suggesting a prefusion F-based vaccine may confer optimal protection against RSV. After this important discovery, Pfizer tested numerous versions of a stabilized prefusion F protein and identified a candidate that elicited a strong anti-viral immune response in pre-clinical evaluations. The bivalent vaccine candidate is composed of equal amounts of recombinant RSV prefusion F from subgroups A and B.

In addition to the investigational older adult vaccination program, in March 2022, Pfizer announced RSVpreF received Breakthrough Therapy Designation from the FDA for the prevention of RSV-associated lower respiratory tract disease caused by RSV in infants from birth up to six months of age by active immunization of pregnant women. The FDA designation was primarily informed by the results of the Phase 2b proof-of-concept study of RSVpreF (NCT04032093), a global, double-blinded, placebo-controlled study that assessed the safety and immunogenicity of RSVpreF in healthy pregnant women ages 18 through 49 years old, who were vaccinated between 28- and 36-weeks gestation, and their infants.

In June 2020, Pfizer announced the initiation of a multicenter, international Phase 3 clinical trial (NCT04424316), **MATISSE** (**MAT**ernal **I**mmunization **S**tudy for **S**afety and **E**fficacy), evaluating the efficacy and safety of a single dose of RSVpreF when administered to pregnant individuals to help protect their babies from RSV after birth. This study remains ongoing.

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 August 25, 2022. 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 Pfizer's respiratory syncytial virus vaccine candidate (RSVpreF), including its potential benefits and planned regulatory submissions for the prevention of RSV-associated lower respiratory tract disease in individuals 60 years of age or older, 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, 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 trial could differ from the interim data discussed in this release; 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 any jurisdictions for RSVpreF for any potential indications (including the planned BLA submission in the U.S.) ; whether and when any such applications 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 RSVpreF 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 RSVpreF; uncertainties regarding the ability to obtain recommendations from vaccine advisory or technical committees and other public health authorities regarding 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, 2021 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.

---

[1] Centers for Disease Control and Prevention. Respiratory Syncytial Virus Infection (RSV). https://www.cdc.gov/rsv/index.html. Updated December 18, 2020. Accessed February 22, 2022.
[2] 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. Updated December 18, 2020. Accessed July 22, 2022.
[3] Centers for Disease Control and Prevention. RSV Transmission. https://www.cdc.gov/rsv/about/transmission.html. Updated December 18, 2020. Accessed February 22, 2022.
[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. Accessed

February 10, 2022.
[5] Shi T, Denouel A, Tietjen AK, et al. Global Disease Burden Estimates of Respiratory Syncytial Virus-Associated Acute Respiratory Infection in Older Adults in 2015: A Systematic Review and Meta-Analysis. J Infect Dis. 2020;222(Suppl 7):S577-S583. doi:10.1093/infdis/jiz059.

Category: Vaccines

View source version on businesswire.com: https://www.businesswire.com/news/home/20220825005052/en/

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

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

Source: Pfizer Inc.