Pfizer Logo

Pfizer Granted FDA Breakthrough Therapy Designation for Respiratory Syncytial Virus (RSV) Vaccine Candidate for the Prevention of RSV in Infants from Birth up to Six Months of Age by Active Immunization of Pregnant Women

Wednesday, March 02, 2022 - 06:45am

NEW YORK--(BUSINESS WIRE)-- Pfizer Inc. (NYSE:PFE) today announced that its respiratory syncytial virus (RSV) vaccine candidate, PF-06928316 or RSVpreF, received Breakthrough Therapy Designation from the US Food and Drug Administration (FDA) for prevention of RSV-associated lower respiratory tract illness in infants from birth up to six months of age by active immunization of pregnant women.

The FDA decision is 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. Pfizer will publish outcomes from this clinical trial at a future date.

“Today’s decision is a pivotal next step in our path towards potential regulatory approval for our maternal RSV vaccine candidate and is an important milestone in our efforts to help address the detrimental impact RSV disease has on infants,” said Kathrin U. Jansen, Ph.D., Senior Vice President and Head of Vaccine Research & Development at Pfizer Inc. “If approved by the FDA, this maternal immunization has the potential to be the first vaccine candidate to help protect infants in their vulnerable first months of life from disease caused by this highly-contagious virus. We look forward to our ongoing dialogue with the FDA to accelerate the development of our maternal RSV vaccine candidate.”

The FDA’s Breakthrough Therapy Designation is designed to expedite the development and review of drugs and vaccines that are intended to treat or prevent serious conditions and preliminary clinical evidence indicates that the drug or vaccine may demonstrate substantial improvement over available therapy on a clinically significant endpoint(s).[1] This decision follows the FDA’s November 2018 decision to grant Fast Track status to RSVpreF. Fast Track status is a process designed to facilitate the development and expedite the review of new drugs and vaccines intended to treat or prevent serious conditions and address a medical need.[2]

Burden of RSV

RSV is a contagious virus and a common cause of respiratory illness.[3] The virus can affect the lungs and breathing passages of an infected individual and can be potentially life-threatening for young infants, the immunocompromised, and older adults.[4,5,6,7] In the United States alone, approximately 2.1 million outpatient

visits and 58,000 hospitalizations occur each year among children younger than five years old.[8,9] For older adults in the U.S., RSV infections account for approximately 177,000 hospitalizations and 14,000 deaths each year.[10] There is no vaccine to prevent RSV, and the medical community is limited to offering only supportive care for those 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 a key form of the viral fusion protein (F) that RSV uses to attack human cells, prefusion F. 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 the viral protein, and identified those that elicited a strong anti-viral immune response in pre-clinical evaluation. The vaccine candidate is composed of two preF proteins selected to optimize protection against RSV A and B and is currently being evaluated in ongoing late-stage human trials.

In April 2020, positive top-line results were achieved for a Phase 2b proof-of-concept study of RSVpreF, which evaluated the safety, tolerability and immunogenicity of RSVpreF in vaccinated pregnant women ages 18 through 49 and their infants. Pfizer will publish outcomes from this clinical trial at a future date.

In June 2020, Pfizer announced the initiation of a multicenter, international Phase 3 clinical trial (NCT04424316) evaluating the efficacy, immunogenicity and safety of RSVpreF when administered to pregnant women to help protect their babies from the disease after they are born. This study remains ongoing, but Pfizer expects the trial to readout in the first half of 2022 (1H22) and will seek to present and publish the results of MATISSE (**MAT**ernal **I**mmunization **S**tudy for **S**afety and **E**fficacy) at a later date.

In September 2021, Pfizer announced the initiation of RENOIR (**R**SV vaccine **E**fficacy study i**NO**lder adults **I** mmunized against **R**SV disease), a Phase 3 clinical trial (NCT05035212) evaluating the efficacy, immunogenicity and safety of a single dose of RSVpreF, in adults ages 60 years or older. Top-line data for the trial are expected in 1H22, and Pfizer will seek to present and publish the results at a later date. The initiation of this trial followed the company's July 2021 update on a Phase 2a study evaluating the safety, immunogenicity and efficacy of RSVpreF in a virus challenge model in healthy adults 18 to 50 years of age. The results of the study supported proceeding to Phase 3.

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 March 2, 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, 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; 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; 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] U.S. Food and Drug Administration (FDA). Breakthrough Therapy. https://www.fda.gov/forpatients/approvals/fast/ucm405397.htm. Updated January 4, 2018. Accessed February 10, 2022.
[2] U.S. Food and Drug Administration. Fast Track https://www.fda.gov/ForPatients/Approvals/Fast/ucm405399.htm. Updated January 4, 2018. Accessed February 10, 2022.
[3] 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.
[4] Centers for Disease Control and Prevention. Disease or Condition of the Week - Respiratory Syncytial Virus Infection (RSV). https://www.cdc.gov/dotw/rsv/index.html. Updated September 14, 2021. Accessed February 22, 2022.
[5] Centers for Disease Control and Prevention. RSV Transmission. https://www.cdc.gov/rsv/about/transmission.html. Updated December 18, 2020. Accessed February 22, 2022.
[6] 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.
[7] Centers for Disease Control and Prevention. RSV in Infants and Young Children. https://www.cdc.gov/rsv/high-risk/infants-young-children.html. Updated December 18, 2020. Accessed February 22, 2022.
[8] Hall CB, et al. The Burden of Respiratory Syncytial Virus Infection in Young Children. N Engl J Med. 2009; 360:588-598. DOI: 10.1056/NEJMoa0804877
[9] Rha B, et al. Respiratory Syncytial Virus-Associated Hospitalizations Among Young Children: 2015-2016 Pediatrics. 2020 Jul;146(1):e20193611. doi: 10.1542/peds.2019-3611. Epub 2020 Jun 16.

[10] Falsey AR, et al. Respiratory Syncytial Virus Infection in Elderly and High-Risk Adults. N Engl J Med 2005; 352:1749-1759. DOI: 10.1056/NEJMoa043951

View source version on businesswire.com: https://www.businesswire.com/news/home/20220302005162/en/

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

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

Source: Pfizer Inc.