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Pfizer Granted FDA Breakthrough Therapy Designation for Respiratory Syncytial Virus Vaccine Candidate for the Prevention of RSV in Older Adults

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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 U.S. Food and Drug Administration (FDA) for the prevention of lower respiratory tract disease caused by RSV in individuals 60 years of age or older.

The FDA decision is primarily informed by the positive results of a proof-of-concept, Phase 2a study evaluating the safety, immunogenicity, and efficacy of a single dose of 120µg RSVpreF in a human viral challenge model in healthy adults 18 to 50 years of age.

“Today’s decision is a significant step forward in our efforts to help protect vulnerable populations, particularly older adults, against certain potentially serious respiratory illnesses, including RSV,” said Kathrin U. Jansen, Ph.D., Senior Vice President and Head of Vaccine Research & Development at Pfizer Inc. “The clinical and economic burden of RSV represents a critical need, and we look forward to our ongoing dialogue with the FDA to accelerate the development of our RSV vaccine candidate.”

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. This study remains ongoing.

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]

Burden of 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 be potentially life-threatening for young infants, children with chronic medical conditions, and older adults.[3,4,5,6] In the United States alone, among older adults, RSV infections account for approximately 177,000 hospitalizations and 14,000 deaths each year.[7] For children younger than five years old in the U.S., approximately 2.1 million outpatient visits and 58,000 hospitalizations occur each year.[8,9]

RSV is a disease for which there are currently no prophylactic, therapeutic, or vaccine 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 attack 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 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.

Earlier this month, Pfizer announced RSVpreF received Breakthrough Therapy Designation from the U.S. Food and Drug Administration (FDA) for the prevention of RSV-associated lower respiratory tract disease in infants from birth up to six months of age by active immunization of pregnant women. The FDA designation was informed by the results of the Phase 2b proof-of-concept study of RSVpreF (NCT04032093), which evaluated the safety, tolerability and immunogenicity of RSVpreF in vaccinated pregnant women ages 18 through 49 and their infants. This followed the FDA's November 2018 decision to grant Fast Track status to RSVpreF.

In June 2020, Pfizer announced the initiation of a multicenter, international Phase 3 clinical trial (NCT04424316) evaluating the efficacy and safety of RSVpreF when administered to pregnant women 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 March 24, 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.

Category: Vaccines

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[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] 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.

[3] 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.

[4] Centers for Disease Control and Prevention. RSV Transmission. https://www.cdc.gov/rsv/about/transmission.html. Updated December 18, 2020. Accessed February 22, 2022.

[5] 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.

[6] 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.

[7] 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

[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.

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