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U.S. FDA Accepts for Priority Review the Biologics License Application for Pfizer's Respiratory Syncytial Virus Vaccine Candidate for the Prevention of RSV Disease in Older Adults

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If approved, RSVpreF would help address the substantial burden of RSV disease in individuals 60 years of age or older

NEW YORK--(BUSINESS WIRE)-- Pfizer Inc. (NYSE: PFE) today announced that the U.S. Food and Drug Administration (FDA) accepted for priority review a Biologics License Application (BLA) for its respiratory syncytial virus (RSV) vaccine candidate, PF-06928316 or RSVpreF, as submitted for the prevention of lower respiratory tract disease caused by RSV in individuals 60 years of age and older.

Priority Review designation by the FDA reduces the standard BLA review period by four months. The Prescription Drug User Fee Act (PDUFA) goal date for a decision by the FDA on the RSVpreF application is in May 2023. This decision follows the FDA's Breakthrough Therapy Designation of RSVpreF in older adults in March 2022.

"With no RSV vaccines currently available, older adults remain at-risk for RSV disease and potential severe outcomes, including serious respiratory symptoms, hospitalization, and in some cases, even death," said Annaliesa Anderson, Ph.D., Senior Vice President and Chief Scientific Officer, Vaccine Research & Development, Pfizer. "The FDA's acceptance of the BLA for our RSV vaccine candidate is an important regulatory milestone in Pfizer's efforts to help protect older adults against RSV and demonstrates additional progress toward what has been an elusive public health goal – reducing the overall burden associated with this infectious disease."

The regulatory submission is supported by results of the Phase 3 clinical trial (NCT05035212) **RENOIR** (**R**SV vaccine **E**fficacy study i**NO**lder adults **I**mmunized against **R**SV disease). RENOIR 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. RENOIR has enrolled approximately 37,000 participants, randomized to receive RSVpreF 120 ?g or placebo in a 1:1 ratio. In August 2022, Pfizer announced positive top-line results of an interim efficacy analysis for RENOIR.

Burden of RSV

RSV is a contagious virus and a common cause of respiratory illness.[1] 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. [2,3,4] In the United States alone, among older adults, RSV infections account for approximately 60,000–120,000 hospitalizations and 6,000–14,000 deaths each year.[5,6,7,8] Among children younger than five years old in the U.S., RSV infections account for approximately 2.1 million outpatient visits and 58,000–80,000 hospitalizations occur each year.[9,10,11] RSV incidence can vary dramatically from one year to the next, and this year there has been a large resurgence in cases following an evolution of masking and isolation measures.

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 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.

Pfizer is currently the only company with an investigational vaccine being prepared for regulatory applications for both infants through maternal immunization and older adults to help protect against RSV. In November 2022, Pfizer announced a positive interim analysis of its Phase 3 clinical trial (NCT04424316) **MATISSE** (**MAT**ernal **I**mmunization **S**tudy for **S**afety and **E**fficacy) investigating its bivalent RSV prefusion vaccine candidate, RSVpreF or PF-06928316, when administered to pregnant participants to help protect their infants from RSV disease after birth.

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 December 7, 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 a BLA pending with the FDA f or the prevention of lower

respiratory tract disease caused by RSV in individuals 60 years of age and 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 cl inical data; risks associated with interim data, including the risk that final results from the Phase 3 trials could differ from the 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 RSVpreF for any potential indications; whether and when the BLA pending with the FDA for RSVpreF f or the prevention of lower respiratory tract disease caused by RSV in individuals 60 years of age and older or any such other 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 .

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