Pfizer Receives Positive FDA Advisory Committee Votes Supporting Potential Approval for Vaccine Candidate to Help Combat RSV in Older Adults

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FDA decision expected by PDUFA goal date in May 2023 The positive votes are based on compelling scientific evidence presented by the company, including Phase 3 efficacy and safety data If authorized, vaccine candidate would help address the substantial burden of RSV in adults 60 years of age and older

NEW YORK--(BUSINESS WIRE)-- Pfizer Inc. (NYSE: PFE) announced today that the U.S. Food and Drug Administration’s (FDA) Vaccines and Related Biological Products Advisory Committee (VRBPAC) voted that available data is adequate to support the safety and effectiveness of its respiratory syncytial virus (RSV) bivalent vaccine candidate PF-06928316 or RSVpreF. The Committee voted 7 to 4 on safety and 7 to 4 on effectiveness. The vaccine candidate is currently under FDA review for the prevention of acute respiratory disease and lower respiratory tract disease caused by RSV in adults 60 years of age and older.

“In older adults, RSV can result in serious illness, hospitalization, or even death, so there is a significant need to protect this at-risk population,” said Annaliesa Anderson, Ph.D., Senior Vice President and Chief Scientific Officer, Vaccine Research and Development, Pfizer. “We are encouraged by the outcome of today’s VRBPAC meeting as it is a testament to the strength of our science and dedication to bringing this important

vaccine candidate to the market. We look forward to working with the FDA as it completes the review of our application.”

The VRBPAC based its recommendation on the scientific evidence shared by Pfizer, including interim data from the pivotal Phase 3 clinical trial (NCT05035212) RENOIR (RSV vaccine Efficacy study iN Older adults Immunized against RSV disease) announced with top-line results in August 2022 and presented at IDWeek 2022. Pfizer intends to publish these results in a peer-reviewed scientific journal.

The role of the VRBPAC is to provide recommendations to the FDA; however, these recommendations are not binding. The FDA’s decision on whether or not to approve RSVpreF for the prevention of acute respiratory disease and lower respiratory tract disease caused by RSV in individuals 60 years of age and older is expected by the Prescription Drug User Fee Act (PDUFA) goal date in May 2023.

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 60,000-160,000 hospitalizations and 6,000-13,000 deaths each year.5,6,7,8,9,10,11,12,13 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.8,14,15

RSV is a disease for which there are currently no targeted 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 is currently the only company pursuing regulatory applications for an RSV investigational vaccine candidate for both an indication to help protect older adults, as well as a maternal indication to help protect infants through maternal immunization. Regarding the maternal indication, earlier this month Pfizer announced that the FDA had granted priority review to a biologics license application for RSVpreF for the prevention of lower respiratory tract and severe lower respiratory tract disease caused by RSV in infants from birth up to six months of age by active immunization of pregnant individuals. A Prescription Drug User Fee Act (PDUFA) action date in August 2023 was set.

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.

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 28, 2023. 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 BLAs pending with the FDA, 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 trials could differ from the interim data; t he 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 BLAs pending with the FDA and any such other applications that may be pending or filed for any indications for RSVpreF 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, 2022, 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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