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FDA Advisory Committee Votes in Support of Approval for Pfizer's Vaccine Candidate to Help Prevent RSV in Infants Through Maternal Immunization

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- *The positive vote is based on compelling scientific evidence presented, including Phase 3 efficacy and safety data in pregnant individuals and their infants*
- *FDA decision expected in August 2023*
- *If authorized, the vaccine candidate would help protect infants at first breath through six months of life against RSV disease and its potential complications*

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 the available data support the efficacy and safety of its unadjuvanted bivalent respiratory syncytial virus (RSV) prefusion F vaccine candidate RSVpreF or PF-06928316. The Committee voted 14 to 0 on effectiveness and 10 to 4 on safety. The vaccine candidate is currently under FDA review for the prevention of medically attended lower respiratory tract disease (MA-LRTD) and severe MA-LRTD caused by RSV in infants from birth up to six months of age by active immunization of pregnant individuals.

"We are encouraged by the outcome of today's VRBPAC meeting as it is a critical step forward in the scientific community's long-sought-after goal to help prevent RSV disease in infants during their most vulnerable first six months of life," said Annaliesa Anderson, Ph.D., Senior Vice President and Chief Scientific Officer, Vaccine Research and Development, Pfizer. "If approved, our RSV vaccine candidate has the potential to be the first maternal immunization vaccine to help protect infants at first breath through their first six months of life from this potentially serious infection."

The VRBPAC based its recommendation on the scientific evidence shared by Pfizer, including primary analysis results from the pivotal Phase 3 clinical trial (NCT04424316) **MATISSE** (**MAT**ernal **I**mmunization **S**tudy for **S**afety and **E**fficacy) announced in November 2022. These results were also recently published in *The New England Journal of Medicine*.

The role of the VRBPAC is to provide recommendations to the FDA; however, these recommendations are not binding. The FDA's decision on the potential approval of RSVpreF for the prevention of MA-LRTD and severe MA-LRTD caused by RSV in infants by active immunization of pregnant individuals is expected by the Prescription Drug User Fee Act (PDUFA) goal date in August 2023.

Burden of RSV in Infants
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, approximately 500,000 to 600,000 cases of MA-LRTD due to RSV occur annually in infants less than 12 months of age.[5] Worldwide, there are an estimated 6.6 million cases of RSV annually in infants less than six months of age, with approximately 45,000 dying each year from complications associated with the infection, and the vast majority in developing countries.[6,7,8]

About RSVpreF
Pfizer is currently the only company pursuing regulatory applications for an RSV investigational vaccine candidate for both an older adult indication, as well as a maternal indication to help protect infants through maternal immunization.

In December 2022, Pfizer announced that the FDA had granted priority review to a biologics license application for RSVpreF for the prevention of RSV disease in older adults with a decision on whether or not to approve RSVpreF expected by thePDUFA goal date later this month. This was followed by the February 2023 vote by VRBPAC in support of the safety and effectiveness of RSVpreF in adults 60 years of age and older. The FDA's VRBPAC based its recommendation on the scientific evidence shared by Pfizer, including interim data from the pivotal Phase 3 clinical trial (NCT05035212) **RENOIR** (**R**SV vaccine **E**fficacy study i**N O**lder adults **I** mmunized against **R**SV disease). Top-line results for **RENOIR** were previously announced by Pfizer in August 2022 and presented at IDWeek and the CDC's Advisory Committee on Immunization Practices (ACIP) in October 2022, as well as recently published in *The New England Journal of Medicine*.

In February 2023, it was announced that the European Medicines Agency (EMA) accepted for review Pfizer's Marketing Authorization Application (MAA) under accelerated assessmentfor RSVpreF, as submitted for both older adults and maternal immunization to help protect infants against RSV. The formal review process by the EMA's Committee for Medicinal Products for Human Use (CHMP) currently is ongoing. Also in February 2023, Pfizer Japan announced an application was filed with the Ministry of Health, Labor and Welfare for RSVPreF as a maternal immunization to help protect infants against RSV. In April 2023, Pfizer Canada announced Health Canada accepted RSVpreF for review for both individuals ages 60 and older and as a maternal immunization to help protect infants against RSV.

Earlier this month, Pfizer also announced it would be initiating multiple clinical trials evaluating RSVpreF in healthy children ages 2-5; children ages 5-18 with underlying medical conditions; adults ages 18-60 at high-risk due to underlying medical conditions; and adults ages 18 and older who are immunocompromised and at high-risk for RSV.[9]

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 May 18, 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 regulatory applications pending with the FDA, the EMA, and other regulatory authorities for a maternal indication to help protect infants through maternal immunization and an older adult indication , 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 regulatory applications pending with the FDA and the EMA, and other regulatory authorities 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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[3] 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

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[9] Pfizer First Quarter 2023 Earnings Teleconference Presentation, May 2, 2023, page 22, https://s28.q4cdn.com/781576035/files/doc_financials/2023/q1/Q1-2023-Earnings-Charts-FINAL.pdf

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