Pfizer Begins a Phase 1/2 Study to Evaluate Respiratory Syncytial Virus (RSV) Vaccine

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RSV affects 33 million children globally and leads to approximately 120,000 childhood deaths every year 1 In the United States approximately 177,000 older adults are hospitalized annually because of RSV 2 The clinical program aims to develop a vaccine for populations at highest risk of infection: infants through maternal immunization, and older adults through direct vaccination

Pfizer Inc. (NYSE:PFE) today announced that it has started a Phase 1/2 trial of its respiratory syncytial virus (RSV) vaccine candidate in healthy adult volunteers. RSV is a common respiratory virus that affects the lungs and airways, with significant impact on young children and older adults. The highest risk of severe outcome from RSV occurs in the first months of life.3

“A successful RSV vaccine has been an elusive goal for the global health community for decades, but recent scientific achievements have prepared the field to potentially tackle this important pathogen,” said Kathrin Jansen, Ph.D., senior vice president and head of Vaccine Research and Development at Pfizer Inc. “By pursuing a vaccine candidate to help protect both infants and older adults, we hope to make an impact for those most at risk for RSV disease.”

Currently available prophylactic treatments for RSV are limited for use in high risk young children and infants, including very premature infants. If successful, Pfizer’s investigational RSV vaccine could help protect young infants through the immunity created following vaccination of pregnant women. The maternal vaccine candidate is intended to raise RSV neutralizing antibody levels in pregnant women who then pass these protective antibodies to their unborn child and provide immunity during the early months of an infant’s life. Pfizer is also advancing a maternal vaccine candidate against

Group B streptococcus (GBS), currently in Phase 1/2 trials.

“RSV is the most frequent cause of serious respiratory tract infection in infants and young children, and also significantly impacts older adults and those with a compromised immune system,” said Edward E. Walsh, M.D., Principal Investigator, Professor of Medicine at the University of Rochester, and Head of Infectious Diseases at the Rochester General Hospital in New York. “There is an urgent global need to develop a safe and effective vaccine as a preventative option to reduce the incidence and severity of this infection in these populations.”

For older adults, RSV is the second leading cause of moderate to severe respiratory illness, following influenza.4 The risk of serious infection increases with age and for those with chronic heart or lung disease or a weakened immune system.5 There is no specific treatment for RSV and currently no licensed vaccine to prevent the disease.6

Clinical Development Program

The trial is designed as a Phase 1/2 randomized, placebo-controlled, observer-blind, dose-ranging study with two age groups enrolled in parallel to support both the maternal and older adult indications.

One age group includes males and females 18-49 years of age; the other includes males and females 50-85 years of age. The study’s primary endpoints are safety and tolerability, and its secondary endpoint is immunogenicity.

Pfizer’s 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 viral protein that RSV uses to attack human cells. They showed that the antibodies that protect humans from RSV target one form of this viral protein. Applying insights from this important work, Pfizer engineered and tested numerous candidates and identified those that elicited a strong and stable immune response in pre-clinical evaluation, which led to the vaccine candidate which Pfizer is evaluating in human trials.

Global Burden of RSV

Globally, there are an estimated 33 million cases of RSV annually in children less than 5 years of age, with about 3 million hospitalized and up to approximately 120,000 dying each year from complications associated with the infection. About half of the pediatric hospitalizations and deaths occur in infants less than 6 months of age.7

More than 90% of all RSV-associated deaths occur in low- and middle-income countries (LMIC);8 the World Health Organization has indicated that the development of an RSV vaccine is a high priority.9

It is estimated that in the United States approximately 177,000 older adults are hospitalized annually because of RSV.10

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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. Our global portfolio includes medicines and vaccines as well as many of the world's best-known consumer health care products. 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 150 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 22, 2018. 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 vaccine candidate against Respiratory Syncytial Virus (RSV), 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 study commencement and completion dates and regulatory submission dates, as well as the possibility of unfavorable study results, including unfavorable new clinical data and additional analyses of existing data; the risk that clinical trial data are subject to differing interpretations, and, even when we view data as sufficient to support the safety and/or effectiveness of a product candidate, regulatory authorities may not share our views and may require additional data or may

deny approval altogether; whether regulatory authorities will be satisfied with the design of and results from our clinical studies; whether and when drug applications may be filed in any jurisdictions for Pfizer's vaccine candidate against RSV; whether and when any such applications may be approved by regulatory authorities, which will depend on the assessment by such regulatory authorities of the benefit-risk profile suggested by the totality of immunogenicity and safety information submitted and, if approved, whether Pfizer's vaccine candidate against RSV will be commercially successful; decisions by regulatory authorities regarding labeling and other matters that could affect the availability or commercial potential of Pfizer's vaccine candidate against RSV; 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, 2017 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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1 Shi et al. Global, regional, and national disease burden estimates of acute lower respiratory infections due to respiratory syncytial virus in young children in 2015: a systematic review and modelling study. Lancet. 2017 Sep 2; 390(10098): 946–958: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5592248/ 2 Centers for Disease Control and Prevention. Respiratory Syncytial Virus Infection. https://www.cdc.gov/rsv/research/us-surveillance.html. Accessed April 17, 2018. 3 World Health Organization. RSV Vaccine Research and Development Technology Roadmap. http://apps.who.int/iris/bitstream/handle/10665/258706/WHO-IVB-17.12-eng.pdf;jsessionid=5C2C837DFDE5E9A0C6507B728475779D?sequence=1. Accessed April 17, 2018. 4 Collins PL, Melero JA. Progress in understanding and controlling respiratory syncytial virus: still crazy after all these years. Virus Res. 2011; 162 (1-2): 80-99. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3221877/pdf/nihms326799.pdf. Accessed April 19, 2018. 5 Centers for Disease Control and Prevention. RSV in Older Adults or Adults with Chronic Medical Conditions. https://www.cdc.gov/rsv/high-risk/older-adults.html. Accessed April 19, 2018. 6 Centers for Disease Control and Prevention. RSV in Older Adults or Adults with Chronic Medical Conditions. https://www.cdc.gov/rsv/high-risk/older-adults.html. Accessed April 19, 2018. 7 Shi et al. Global, regional, and national disease burden estimates of acute lower respiratory infections due to respiratory syncytial virus in young children in 2015: a systematic review and modelling study.

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Pfizer Inc. Media: Jessica Smith, 212-733-6213jessica.a.smith@pfizer.com or Investors: Ryan Crowe, 212-733-8160ryan.crowe@pfizer.com