# Pfizer Announces Positive Top-Line Results from Phase 3 Study of 20-Valent Pneumococcal Conjugate Vaccine in Infants

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Pivotal top-line data demonstrate a four-dose series of 20-valent pneumococcal conjugate vaccine candidate (20vPnC), if approved, would provide the broadest serotype coverage of any pneumococcal conjugate vaccine in infants 20vPnC elicited robust immune responses to all 20 serotypes meeting the statistical non-inferiority criteria for the co-primary objective after Dose 4 20vPnC demonstrated a favorable safety and tolerability profile similar to Prevnar 13 ® Pfizer plans to submit an sBLA by the end of this year, subject to discussions with U.S. FDA

NEW YORK--(BUSINESS WIRE)-- Pfizer Inc. (NYSE:PFE) today announced positive top-line results from its pivotal U.S. Phase 3 study (NCT04382326) in infants evaluating its 20-valent pneumococcal conjugate vaccine candidate (20vPnC) for the prevention of invasive pneumococcal disease (IPD) caused by the 20 Streptococcus pneumoniae (pneumococcus) serotypes contained in the vaccine for the pediatric population.

The study had two co-primary objectives, associated with immunogenicity responses one month after the third and fourth doses of the four-dose vaccination series, respectively: non-inferiority (NI) of the percentage of participants with predefined serotype-specific immunoglobin G (IgG) concentrations after Dose 3 and NI of IgG geometric mean concentrations (GMCs) after Dose 4. All 20 serotypes met the co-primary objective of NI of IgG GMCs after Dose 4. Fourteen of the 20 serotypes met the co-primary objective of NI of the percentage of participants with predefined IgG levels after Dose 3 (two

serotypes missed by a wider margin while four narrowly missed), and all serotypes met noninferiority for the key secondary objective of IgG GMCs after Dose 3. All 20 serotypes elicited robust functional responses (OPA) and increases in antibody responses after Dose 4, with the totality of data supporting the potential benefit of all serotypes in this 20-valent vaccine candidate.

“We are encouraged by today’s data which show that if approved for a pediatric indication, 20vPnC would have the potential to cover more of the clinically significant remaining burden of infant pneumococcal disease than any other available pneumococcal conjugate vaccine,” said Annaliesa Anderson, Ph.D., Senior Vice President and Chief Scientific Officer, Vaccine Research and Development, Pfizer. “We are grateful to everyone who made this study possible, including the study investigators and in particular the trial participants and their parents/guardians for their contribution to this important research.”

Overall, the safety profile of the 20vPnC candidate was consistent with Prevnar 13 given in the same schedule. A similar percentage of infants receiving either vaccine experienced local reactions (pain at the injection site, redness, and swelling), fever, and other systemic events (decreased appetite, drowsiness, and irritability). The study also met non-inferiority objectives for responses to co-administered routinely used pediatric vaccines.

Based on the totality of positive safety and immunogenicity data, Pfizer plans to submit a supplemental Biologics License Application (sBLA) by the end of this year, subject to discussions with the U.S. Food and Drug Administration. Pfizer will seek to present and publish outcomes from this clinical trial at a future date once safety and immunogenicity data have been fully analyzed. Additional top-line results from other pediatric 20vPnC clinical trials are expected to read out in the second half of 2022, with discussions with other regulatory bodies planned once those pivotal data become available.

About the 20vPnC Phase 3 Pediatric Program

In 2020, Pfizer initiated the Phase 3 clinical trial program for the pediatric indication for 20vPnC. Four core Phase 3 pediatric studies will help expand the data on the safety, tolerability, and immunogenicity of 20vPnC. These studies collectively enrolled approximately 4,700 infants and 800 toddlers and children of all ages including:

A Phase 3 study describing the tolerability and safety and comparing immunogenicity of 20vPnC to Prevnar 13® in infants vaccinated at 2, 4, 6, and 12-15 months of age in the U.S. (NCT04382326) A Phase 3 study describing the tolerability and safety of 20vPnC,

with Prevnar 13® serving as the control in infants vaccinated at 2, 4, 6, and 12-15 months of age in multiple countries. (NCT04379713) A Phase 3 study describing the tolerability and safety and comparing immunogenicity of 20vPnC to Prevnar 13® in infant vaccination at approximately 2, 4, and 11-12 months of age in Europe and Australia (NCT04546425) A Phase 3 study in children 15 months through <18 years of age receiving a single dose of 20vPnC in the U.S. (NCT04642079).

About 20vPnC

Pfizer’s 20vPnC pediatric vaccine candidate includes 13 serotypes already included in Prevnar 13® – 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, and 23F. The seven new serotypes included in 20vPnC are global causes of invasive pneumococcal disease (IPD), and are associated with high case-fatality rates, antibiotic resistance, and/or meningitis. Together, the 20 serotypes included in 20vPnC are responsible for the majority of currently circulating pneumococcal disease in the U.S. and globally.

On August 14, 2020, Pfizer’s 20vPnC received the FDA’s Breakthrough Therapy Designation for the prevention of disease caused by Streptococcus pneumoniae serotypes in the vaccine in infants, children, and adolescents.

The FDA previously granted Fast Track Designation for 20vPnC in May 2017 for the pediatric indication.

On June 8, 2021, the FDA approved PREVNAR 20® for the prevention of invasive disease and pneumonia caused by the 20 Streptococcus pneumoniae (pneumococcus) serotypes in the vaccine in adults ages 18 years and older.

INDICATIONS FOR PREVNAR 13 ®

Prevnar 13® is a vaccine approved for adults 18 years and older for the prevention of pneumococcal pneumonia and invasive disease caused by Streptococcus. pneumoniae serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, and 23F Prevnar 13® is also approved for children 6 weeks through 17 years of age (prior to the 18th birthday) for the prevention of invasive disease caused by the 13 strains of S. pneumoniae in the vaccine, and for children 6 weeks through 5 years (prior to the 6th birthday) for the prevention of ear infections caused by 7 of the 13 strains in the vaccine Prevnar 13® is not 100% effective and will only help protect against the 13 strains in the vaccine
IMPORTANT SAFETY INFORMATION

Prevnar 13® should not be given to anyone with a history of severe allergic reaction to any component of Prevnar 13® or any diphtheria toxoid–containing vaccine Children and

adults with weakened immune systems (e.g., HIV infection, leukemia) may have a reduced immune response In adults, the most common side effects were pain, redness, and swelling at the injection site, limitation of arm movement, fatigue, headache, muscle pain, joint pain, decreased appetite, vomiting, fever, chills, and rash A temporary pause of breathing following vaccination has been observed in some infants born prematurely The most commonly reported serious adverse events in infants and toddlers were bronchiolitis (an infection of the lungs) (0.9%), gastroenteritis (inflammation of the stomach and small intestine) (0.9%), and pneumonia (0.9%) In children 6 weeks through 17 years, the most common side effects were tenderness, redness, or swelling at the injection site, irritability, decreased appetite, decreased or increased sleep, and fever Ask your healthcare provider about the risks and benefits of Prevnar 13®. Only a healthcare provider can decide if Prevnar 13® is right for you or your child

INDICATIONS FOR PREVNAR 20 ®

PREVNAR 20® is a vaccine indicated for active immunization for the prevention of pneumonia and invasive disease caused by Streptococcus pneumoniae serotypes 1, 3, 4, 5, 6A, 6B, 7F, 8, 9V, 10A, 11A, 12F, 14, 15B, 18C, 19A, 19F, 22F, 23F, and 33F in adults 18 years of age and older The indication for preventing pneumonia caused by S. pneumoniae serotypes 8, 10A, 11A, 12F, 15B, 22F, and 33F is approved based on immune responses. Continued approval may depend on a supportive study.
IMPORTANT SAFETY INFORMATION

PREVNAR 20® should not be given to anyone with a history of severe allergic reaction to any component of PREVNAR 20® or to diphtheria toxoid Adults with weakened immune systems may have a lower response to PREVNAR 20®. Safety data are not available for these groups. Your healthcare provider can tell you if PREVNAR 20® is right for you In adults 18 years of age and older, the most common side effects were pain at the injection site, muscle pain, fatigue, headache, and joint pain. Additionally, injection site swelling was also common in adults 18 through 59 years of age Ask your healthcare provider about the risks and benefits of PREVNAR 20®. Only a healthcare provider can decide if PREVNAR 20® is right for you
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 August 12, 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 20vPnC vaccine candidate, including its potential benefits, results from the Phase 3 study (NCT04382326) in infants and anticipated clinical trial readouts and regulatory submissions, 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 any biologic license applications may be filed in particular jurisdictions for 20vPnC for any potential indications; whether and when any such applications may be approved by regulatory authorities, which will depend on a 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 such product candidate 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 20vPnC; uncertainties regarding the ability to obtain recommendations from vaccine advisory or technical committees and other public health authorities regarding 20vPnC and uncertainties regarding the commercial impact of any such recommendations; uncertainties regarding the impact of COVID-19 on Pfizer’s 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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