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Pfizer Announces Top-Line Results from Phase 3 Study of 20-Valent Pneumococcal Conjugate Vaccine in Pneumococcal Vaccine-Naïve Adults Aged 18 Years or Older

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20-valent pneumococcal conjugate vaccine demonstrated comparable safety and immunogenicity profile to licensed pneumococcal vaccines

NEW YORK--(BUSINESS WIRE)-- Pfizer Inc. (NYSE:PFE) today announced top-line results from one of its Phase 3 studies (NCT03760146), which evaluated the safety and immunogenicity of its 20-valent pneumococcal conjugate vaccine (20vPnC) candidate in adults 18 years of age or older not previously vaccinated against pneumococcal disease. The primary immunogenicity objectives of non-inferiority for the 20 serotypes included in 20vPnC in adults 60 years of age and older at one month after vaccination were met for all serotypes in common with licensed Prevnar 13® (pneumococcal 13-valent Conjugate Vaccine [Diphtheria CRM197 Protein]) and six of the seven additional serotypes when compared to a licensed pneumococcal polysaccharide vaccine (PPSV23); one of the new seven serotypes missed noninferiority criteria by a small margin.[1] Secondary immunogenicity objectives for adults 18-59 years old compared to those 60-64 years old met non-inferiority for all 20 serotypes. The safety objectives were met in adults 18 years of age or older demonstrating that the safety and tolerability of 20vPnC were comparable to licensed pneumococcal vaccines. Based on prior discussions with regulators, these data are expected to meet licensure criteria.

“We are encouraged by the results from this study and remain on track to file the adult 20vPnC indication with the FDA by the end of 2020. 20vPnC builds on a well-established and trusted foundation of pneumococcal conjugate experience and science that Pfizer has accumulated for more than 20 years,” said Kathrin U. Jansen, Ph.D., Senior Vice President and Head of Vaccine Research & Development, Pfizer. “The results from this pivotal study provide evidence that the 20vPnC vaccine is expected to have a comparable safety profile and likely be as effective as Prevnar 13 in helping prevent invasive pneumococcal disease and pneumonia due to the 13 serotypes in Prevnar 13, and also effective against disease due to the seven additional pneumococcal serotypes in adults 18 years of age or older.”

Pfizer’s 20vPnC vaccine candidate includes 13 serotypes already included in Prevnar 13. The seven new serotypes included in 20vPnC are global causes of invasive pneumococcal disease (IPD),[2,3,4,5,6] and are associated with high case-fatality rates,[7,8,9,10] antibiotic resistance,[5,11,12] and/or meningitis.[13,14] Globally, pneumococcal pneumonia is estimated to cause about 500,000 deaths and 30 million episodes in adults 70 years and older annually.[15] Together, the 20 serotypes included in 20vPnC are responsible for the majority of currently circulating pneumococcal disease in the U.S. and globally.[16,17,18,19,20,21,22]

“The 20-valent pneumococcal conjugate vaccine was developed to overcome the limitations attributed to pneumococcal plain polysaccharide vaccines. 20vPnC, like its predecessor Prevnar 13, is expected to provide immunological memory against the 20 serotypes included in the vaccine and to afford protection against non-bacteremic pneumonia for those 20 serotypes,” said Luis Jodar, Ph.D., Chief Medical and Scientific Affairs Officer, Pfizer Vaccines. “This is particularly important for the seven additional pneumococcal serotypes due to the burden of pneumonia caused by the new serotypes and the lack of herd protection for adults since the current pediatric vaccine does not protect against the seven additional strains.”

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.

20vPnC Phase 3 Adult Program
Pfizer’s phase 3 pivotal development program for 20vPnC includes three clinical trials (NCT03760146, NCT03828617, and NCT03835975) evaluating the vaccine candidate for the prevention of invasive disease and pneumococcal pneumonia in adults 18 years or older. Combined, these three trials have enrolled more than 6,000 adult subjects, including populations of vaccine-naïve adults and adults with prior pneumococcal vaccination.[23,24] All three trials have been completed and the data for two remaining studies will be reading out over the next few months.

- This press release refers to **NCT03760146**: Phase 3 randomized, double-blind trial including 3,880 adults aged 18 or older with no history of pneumococcal vaccination. The study was designed to compare immune responses in patients ?60 years old after 20vPnC administration to responses in a control group receiving Prevnar 13 or PPSV23. The study also evaluated immune responses of 20vPnC in adults 18 to 59 years (secondary endpoints) and described the safety profile of 20vPnC in all adults ?18 years old (primary endpoint). Additional information about the study can be found at www.clinicaltrials.gov under the identifier NCT03760146.

Additional trials include:

- **NCT03828617**: Phase 3 randomized, double-blind trial, designed to provide additional safety data and evaluate three different lots of 20vPnC in adults 18 through 49 years of age with no history of pneumococcal vaccination. More on the study can be found on www.clinicaltrials.gov under the identifier NCT03828617.
- **NCT03835975**: Phase 3 randomized, open-label trial, designed to describe the safety and immune response of 20vPnC in an estimated 875 adults aged 65 years or older with prior pneumococcal vaccination. More on the study can be found on www.clinicaltrials.govunder the identifier NCT03835975.

About 20vPnC
On September 20, 2018, Pfizer announced the U.S. Food and Drug Administration (FDA) granted Breakthrough Therapy Designation for 20vPnC for the prevention of invasive disease and pneumonia in adults age 18 years or older. Breakthrough Therapy Designation is designed to expedite the development and review of drugs and vaccines that are intended to treat or prevent serious conditions and preliminary clinical evidence indicates that the drug or vaccine may demonstrate substantial improvement over available therapy on a clinically significant endpoint(s).[25] Drugs and vaccines that receive Breakthrough Therapy Designation are eligible for all features of the FDA’s Fast Track designation, which may include more frequent communication with the FDA about the drug’s development plan and eligibility for Accelerated Approval and Priority Review, if relevant criteria are met.[26]

The FDA previously granted Fast Track designation for 20vPnC in September 2017 for use in adults aged 18 years or older.[27] The FDA’s Fast Track approach is a process designed to facilitate the development and

expedite the review of new drugs and vaccines intended to treat or prevent serious conditions and address an unmet medical need.[26]

Additionally, in May 2017 the FDA granted Fast Track status for a pediatric indication for 20vPnC.[28]

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

Pfizer Inc: 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 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 March 18, 2020. 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 20-valent pneumococcal conjugate vaccine (20vPnC) candidate, including potential regulatory submission and timing, expected licensure criteria and 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 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 biologics license applications may be filed in any jurisdictions for 20vPnC for any indications; whether and when any such 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 20vPnC 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 technical committees and other public health authorities regarding 20vPnC and uncertainties regarding the commercial impact of any such recommendations; 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, 2019 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] Lower bound of the 2-sided 95% confidence interval for the opsonophagocytic activity (OPA) assay geometric mean ratio of serotype 8 contained in 20vPnC compared to PPSV23 equals 0.49. The predefined noninferiority criterion is >0.5.

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[28] Data on file. Pfizer Inc., New York, NY

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