Pfizer Logo

Pfizer Announces Positive Top-Line Results from Phase 3 Study in 20-Valent Pneumococcal Conjugate Vaccine in Infants in the European Union

Monday, September 19, 2022 - 06:45am

- *Positive pivotal top-line data demonstrates 20-valent pneumococcal conjugate vaccine candidate (20vPnC), if approved, can likely help protect against all 20 vaccine serotypes in three-dose series and potentially offer the broadest serotype coverage of any available pneumococcal conjugate vaccine (PCV)*
- *The safety profile of 20vPnC was favorable and similar to Prevenar 13® (or Prevnar 13® in the U.S.) in this schedule, and concomitant use with common pediatric vaccines was supported and well tolerated*
- *20vPnC also showed robust functional antibody responses to the vaccine serotypes post Dose 2 and 3 similar to Prevenar® and Prevenar 13®*
- *The company intends to file for regulatory approval in the EU in the next few months*

NEW YORK--(BUSINESS WIRE)-- Pfizer today announced positive top-line results from its pivotal E.U. Phase 3 study in infants (NCT04546425) evaluating its 20-valent pneumococcal conjugate vaccine candidate (20vPnC) for the prevention of invasive pneumococcal disease (IPD), pneumonia, and acute otitis media caused by the 20 *Streptococcus pneumoniae* (pneumococcus) serotypes contained in the vaccine for the pediatric population.

The study had three coprimary outcomes, associated with immunogenicity responses one month after the second and third doses of a three-dose vaccination series given at approximately 2, 4, and 11-12 months of age of 20vPnC compared to Prevenar 13®. For the non-inferiority (NI) co-primary objective of immunoglobulin G (IgG) geometric mean concentrations (GMCs) one month after Dose 3 at 11-12 months of age, 19 of the 20 serotypes met the NI criteria with only one serotype narrowly missing. For the NI co-primary objective of IgG GMCs one month after Dose 2, 16 of the 20 serotypes met NI. Finally, for the third NI co-primary objective of the percentage of participants with predefined serotype-specific IgG concentrations one month after Dose 2, nine of the 20 serotypes met the NI criteria. All 20 serotypes showed increased booster responses from post dose 2 to post dose 3 which are indicative of immunological memory and long-term protection. All 20 vaccine serotypes also showed strong functional antibody responses as measured by the opsonophagocytic assay (OPA) post-dose 2 and post dose 3 similar to Prevenar® and Prevenar 13®. The totality of data is therefore directionally consistent with prior clinical experience with Prevenar® and Prevenar 13® after 2 and 3 infant doses, both of which have demonstrated effectiveness in a three-dose schedule against the serotypes contained in the vaccine in post-licensure studies.

In summary, the totality of these positive 20vPnC data, combined with the experience with Prevenar 13® in this schedule, demonstrates that the 20vPnC candidate, if approved, is likely to help protect against all 20 vaccine serotypes in a three-dose vaccine series.

“Today marks another important milestone in the 20vPnC pediatric program, with these data demonstrating 20vPnC’s potential to provide the most comprehensive pneumococcal serotype coverage of any available pneumococcal conjugate vaccine,” said Annaliesa Anderson, Ph.D., Senior Vice President and Chief Scientific Officer, Vaccine Research and Development, Pfizer. “Based on the totality of immunogenicity and safety data, we feel confident that 20vPnC is likely to be protective against all vaccine serotypes in a three-dose series. We are thankful to everyone who worked on or participated in this study, and we look forward to hopefully being able to provide infants with more robust and meaningful protection against more pneumococcal disease-causing serotypes in the near future.”

The safety profile of 20vPnC was similar to Prevenar 13® in this schedule, and concomitant use with common pediatric vaccines were supported.

Pfizer plans to file these data by the end of this year with the European Medicines Agency (EMA). These positive data mark the conclusion of pivotal topline readouts for the 20vPnC pediatric program. Pfizer will also seek to present and publish outcomes from this clinical trial at a future date once safety and immunogenicity data have been fully analyzed.

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 Prevenar 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 Prevenar 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 Prevenar 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 Prevenar 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 EU and globally.

On Feb 14, 2022, the European Commission Decision was adopted for APEXXNAR ® (20vPnC) 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 PREVENAR 13 ®

- Active immunisation for the prevention of invasive disease, pneumonia and acute otitis media caused by Streptococcus pneumoniae in infants, children and adolescents from 6 weeks to 17 years of age.

- Active immunisation for the prevention of invasive disease and pneumonia caused by Streptococcus pneumoniae in adults ?18 years of age and the elderly.
- The use of Prevenar 13 should be determined on the basis of official recommendations taking into consideration the risk of invasive disease and pneumonia in different age groups, underlying comorbidities as well as the variability of serotype epidemiology in different geographical areas.

IMPORTANT SAFETY INFORMATION

- Prevenar 13® should not be given to anyone with a history of severe allergic reaction to any component of Prevenar 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 Prevenar 13®. Only a healthcare provider can decide if Prevenar 13® is right for you or your child

INDICATIONS FOR APEXXNAR ®

- Active immunisation for the prevention of invasive disease and pneumonia caused by Streptococcus pneumoniae in individuals 18 years of age and older. APEXXNAR ® should be used in accordance with official recommendations.

IMPORTANT SAFETY INFORMATION

- APEXXNAR should not be given to anyone with a history of severe allergic reaction to any component of APEXXNAR or to diphtheria toxoid
- Adults with weakened immune systems may have a lower response to APEXXNAR ®. Safety data are not available for these groups. Your healthcare provider can tell you if APEXXNAR ® 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 49 years of age
- Ask your healthcare provider about the risks and benefits of APEXXNAR ®. Only a healthcare provider can decide if APEXXNAR ® 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 September 19, 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 (NCT04546425) in infants and anticipated 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.

View source version on businesswire.com: https://www.businesswire.com/news/home/20220919005238/en/

Media Relations
US Contact:
+1 (212) 733-1226

EU Contact:
+44 (0) 1737 332 335
EUPress@pfizer.com

Investor Relations
+1 (212) 733-4848
IR@pfizer.com

Source: Pfizer Inc.