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Pfizer Advances Pivotal Pediatric Pneumococcal Vaccine Program Following Strong Positive Phase 2 Results

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- *Phase 2 data demonstrate robust immunogenicity, including enhanced response against serotype 3, alongside expanded protection across 25 serotypes; to achieve potential vaccine serotype coverage of 90% in the pediatric population*
- *An oral presentation at ISPPD highlighted an approximately 9 to 15-fold higher serotype 3 immunogenicity response after Dose 3 and 4 in infants receiving Pfizer's 25-valent vaccine candidate (25vPnC) compared to PREVNAR 20®*
- *The investigational vaccine candidate was well-tolerated with no safety concerns identified in a Phase 2 study*
- *Based on these encouraging results from the Phase 2 program across serotypes and discussions with regulatory authorities, Pfizer initiated its Phase 3 25vPnC pediatric program*
- *Company advances adult program to fifth generation 35-valent vaccine candidate*

NEW YORK--(BUSINESS WIRE)-- Pfizer Inc. (NYSE: PFE) today announced data from its Phase 2 study (NCT06524414) evaluating the safety, tolerability and immunogenicity of a four-dose series of its investigational 25-valent pneumococcal conjugate vaccine candidate PF-07872412 (25vPnC) in infants compared to four doses of PREVNAR 20 at months 2, 4, 6 and 12-15. Based on the strong immune responses observed for all 25vPnC serotypes from Phase 2, compared to PREVNAR 20, Pfizer is confident that the required non-inferiority thresholds may be achieved for the 25vPnC pediatric Phase 3 program.

Key preliminary data from the broader Phase 2 study were presented today in an oral presentation at the 14th meeting of the International Society of Pneumonia & Pneumococcal Diseases in Copenhagen, Denmark (ISPPD). Results found:

- **One month after Dose 3**, geometric mean titers for serotype 3 were **8.8-fold higher** with 25vPnC than with PREVNAR 20 (**4.22 vs. 0.48**).
- **One month after Dose 4**, geometric mean titers for serotype 3 were approximately **15-fold higher** with 25vPnC than with Prevnar 20 (**13.85 vs. 0.92**).
- This vaccine candidate is expected to cover up to **90% of disease-causing serotypes** in children under 5 years of age, which includes approximately 15% from serotype 3.

"For more than 25 years, our vaccines have helped protect children from pneumococcal disease, yet significant disease burden remains," said Annaliesa Anderson, Ph.D., Senior Vice President and Chief Vaccines Officer, Pfizer. "These Phase 2 results reinforce our confidence in a next-generation vaccine designed to expand protection across serotypes while improving responses to key residual disease drivers such as serotype 3. We are advancing our Phase 3 program with the goal of delivering broader and more durable protection for children."

The Phase 2 study is a randomized trial in healthy infants, with initial enrolment beginning in July 2024, evaluating 25vPnC compared with PREVNAR 20. Participants were randomized to receive 25vPnC or PREVNAR 20 at months 2, 4, 6 and 12–15 assessing the safety and tolerability, including local and systemic reactogenicity within seven days after each vaccination, as well as adverse events and serious adverse events in participants who receive at least one dose. The trial also assessed immunogenicity one month after Dose 3 and one month after Dose 4, compared to one month after Dose 3 and Dose 4 with PREVNAR 20.

The safety and tolerability profile of 25vPnC was consistent with the currently approved and available pneumococcal vaccine. The most common local reactions were redness, swelling or pain at injection site similar to existing vaccines.

Advancing Pediatric and Adult into Pivotal Phase 3 Studies

Despite significant reduction in pneumococcal disease burden by the currently available 20-valent standard-of-care-vaccine, serotype 3 remains a notable cause of invasive pneumococcal disease and complicated pneumonia in children. Therefore, based on this Phase 2 data and discussions with regulatory authorities, Pfizer began a pivotal pediatric Phase 3 program in May 2026. The studies evaluate safety, tolerability and immunogenicity of 25vPnC in healthy children where participants receive either 25vPnC or PCV20 at 2, 4, 6 and 12 to 15 months of age. Participants will receive the same vaccine for all four vaccinations for up to 2,400 individuals comparing 25vPnC to the currently licensed 20-valent standard-of-care vaccine.

The vaccine candidate covers 25 serotypes including serotype 3, adding five new serotypes to the established vaccine coverage for infants. If successful, this has the potential to broaden protection to about 90% of disease-causing serotypes in US children.

Meanwhile, as the strongest opportunity to maintain the company’s current leadership in the adult market over the long term, Pfizer has decided to move directly to a fifth-generation vaccine candidate covering 35 serotypes. This fifth-generation adult candidate has the potential to increase serotype coverage while also improving immunogenicity for critical serotypes including serotype 3 with Pfizer’s proprietary next generation technology. The adult vaccine candidate is expected to enter clinical development by the end of 2026, pending alignment with regulatory authorities.

About 25vPnC (25-valent pneumococcal conjugate vaccine candidate)

Pfizer's 4th-generation pneumococcal conjugate vaccine candidate builds on the 20 serotypes already covered by PCV20 (PREVNAR 20). It adds five additional serotypes — 15A, 23A, 23B, 24F, and 35B that represents additional 25% coverage of IPD cases compared with PCV20 to broaden coverage to 25 serotypes total, including cross-reactivity. Beyond expanding serotype coverage, 25vPnC also aims to enhance protection against serotype 3, which remains a key driver of residual pneumococcal disease. To achieve this, 25vPnC utilizes next-generation technology specifically designed to elicit a more robust immune response against serotype 3.

U.S. INDICATION AND IMPORTANT SAFETY INFORMATION FOR PREVNAR 20

INDICATION

PREVNAR 20 is a vaccine approved for:

- the prevention of invasive disease caused by 20 *Streptococcus pneumoniae* strains (1, 3, 4, 5, 6A, 6B, 7F, 8, 9V, 10A, 11A, 12F, 14, 15B, 18C, 19A, 19F, 22F, 23F, and 33F) in individuals 6 weeks of age and

older.
- the prevention of otitis media (middle ear infection) caused by 7 of the 20 strains in individuals 6 weeks through 5 years.
- active immunization for the prevention of pneumonia caused by *Streptococcus pneumoniae* strains 1, 3, 4, 5, 6A, 6B, 7F, 8, 9V, 10A, 11A, 12F, 14, 15B, 18C, 19A, 19F, 22F, 23F, and 33F in individuals 18 years of age and older.

The indication for the prevention of pneumonia caused by *S. pneumoniae* serotypes 8, 10A, 11A, 12F, 15B, 22F, and 33F in individuals 18 years of age and older 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 who has had a severe allergic reaction to any component of Prevnar 20 or to diphtheria toxoid.
- Individuals with weakened immune systems may have a lower immune response. Safety data are not available for these groups.
- A temporary pause in breathing after getting a vaccine has been observed in some infants who were born prematurely. For premature infants, talk to your healthcare provider about the infant's medical status when deciding to get vaccinated with Prevnar 20.
- In individuals 2, 4, 6, and 12 through 15 months of age vaccinated with a 4-dose schedule, the most common side effects reported at a rate of >10% were irritability, pain at the injection site, drowsiness, decreased appetite, injection site redness, injection site swelling, and fever.
- In individuals 15 months through 17 years of age vaccinated with a single dose, the most common side effects reported at a rate of >10% were irritability, pain at the injection site, drowsiness, fatigue, muscle pain, decreased appetite, injection site swelling, injection site redness, headache, and fever.
- In individuals 18 years and older, the most common side effects reported at a rate of >10% were pain at the injection site, muscle pain, fatigue, headache, and joint pain. Also, injection site swelling was common in individuals 18 years 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 or your child.

Please click for PREVNAR 20 Full Prescribing Information.

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 175 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 X 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 20, 2026. 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 an investigational pediatric 25-valent pneumococcal conjugate vaccine candidate PF-07872412 (25vPnC) and an investigational adult fifth-generation vaccine candidate covering 35 serotypes (35vPnC), including their potential benefits, results from a Phase 2 study of 25vPvC in infants and clinical development plans and timing for 25vPnC and 35vPnC, 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 initial, preliminary or interim 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 applications may be filed in any jurisdictions for 25vPnC or 35vPnC; 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 25vPnC and 35vPnC 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 25vPnC and 35vPnC; uncertainties regarding the ability to obtain or maintain recommendations from vaccine advisory or technical committees and other public health authorities and uncertainties regarding the commercial impact of any such recommendations; risks and uncertainties related to changes to vaccine or other healthcare policy in the U.S.; challenges related to public vaccine confidence or awareness; risks and uncertainties related to issued or future executive orders or other new, or changes in, laws or regulations; 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, 2025 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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