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Advisory Committee on Immunization Practices Recommends PREVNAR 20® (20-Valent Pneumococcal Conjugate Vaccine) for Adults Aged 50 and Older

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- *Millions of newly eligible U.S. adults aged 50 to 64 now recommended to receive vaccination against invasive pneumococcal disease (IPD) and pneumococcal pneumonia* [1]

NEW YORK--(BUSINESS WIRE)-- Pfizer Inc. (NYSE: PFE) announced today that the U.S. Centers for Disease Control and Prevention's (CDC) Advisory Committee on Immunization Practice (ACIP) voted to expand its recommendation for the use of certain pneumococcal vaccines, including PREVNAR 20 ® (20-valent Pneumococcal Conjugate Vaccine) for all adults aged 50 and older. This recommendation is pending final approval by the director of the CDC and the Department of Health and Human Services. With respect to PREVNAR 20, ACIP recommended:

- Vaccination is recommended for all adults aged ?50 years and for adults aged 19–49 years with certain underlying conditions or risk factors who have not received a PCV or whose vaccination history is unknown.

"ACIP's vote to expand adult pneumococcal vaccination to now include all adults aged 50 and older marks an important milestone in Pfizer's long-standing commitment to reducing the burden of this life-threatening disease," said Luis Jodar, PhD, Senior Vice President, Vaccines and Anti-Infectives Chief Medical Affairs Officers, Pfizer. "PREVNAR 20 offers protection against the serotypes responsible for the majority of invasive pneumococcal disease cases in this age group. Expanding its use also provides an opportunity to limit the re-emergence of disease-causing strains like serotype 4, which has recently affected certain U.S. adult populations and is covered by the vaccine."

In the U.S., the 20 serotypes contained in PREVNAR 20 are estimated to cause over 2,000 deaths and more than 65,000 cases of invasive pneumococcal disease (IPD), including bacteremia and meningitis, and community-acquired pneumonia annually in adults aged 50 to 64. [2] Between 2018 and 2022, more than half of IPD cases in people aged 50 to 64 were caused by these 20 serotypes. [3] Vaccination with PREVNAR 20 helps prevent serotype 4 disease, which incidence has been rising in certain populations in the western U.S. [4]

About PREVNAR 20 ®
PREVNAR 20 ® is Pfizer's next-generation pneumococcal conjugate vaccine that includes capsular polysaccharide conjugates for the 13 serotypes (1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, and 23F) already included in Prevnar 13 ® (Pneumococcal 13-valent Conjugate Vaccine [Diphtheria CRM197 Protein]). The vaccine also contains capsular polysaccharide conjugates for seven additional serotypes (8, 10A, 11A, 12F, 15B, 22F and 33F) that cause invasive pneumococcal disease (IPD), [5,6,7,8,9] and have been associated with high case-

fatality rates, [10,11,12,13] antibiotic resistance, [14,15,16] and/or meningitis. [17,18] PREVNAR 20 helps protect against disease caused by the 20 *Streptococcus pneumoniae* serotypes in the vaccine.

On June 8, 2021, Pfizer announced the U.S. Food and Drug Administration (FDA) approved PREVNAR 20 for the prevention of invasive pneumococcal disease and pneumococcal pneumonia in adults aged 18 years or older. On September 30, 2022, the FDA approved the addition of information in the PREVNAR 20 prescribing information regarding coadministration with an influenza vaccine, adjuvanted (Fluad Quadrivalent [19]), in adults aged 65 years or older.

INDICATIONS FOR PREVNAR 20
PREVNAR 20 ® is a vaccine indicated 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 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 of PREVNAR 20 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 FOR PREVNAR 20

- 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-containing vaccine.
- 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 the vaccine has been observed in some infants who were born prematurely. For premature infants, talk to your doctor 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 and 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 and muscle pain, decreased appetite, injection site swelling and 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 doctor about the risks and benefits of PREVNAR 20. Only a doctor can decide if PREVNAR 20 is right for you or your child.

View the 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 October 23, 2024. Pfizer assumes no obligation to update forward-looking statements contained in this release as the result of new information or future events or developments.

T his release contains forward-looking information about PREVNAR 20 ® (20-valent Pneumococcal Conjugate Vaccine), including its potential benefits and a vote by ACIP to expand its recommendation for the use of certain pneumococcal vaccines, including PREVNAR 20 for all adults aged 50 and older and for adults aged 19–49 years with certain underlying conditions or risk factors who have not received a PCV or whose vaccination history is unknown, 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, uncertainties regarding the commercial success of PREVNAR 20 and uncertainties regarding the commercial impact of ACIP's recommendation; 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 other jurisdictions for PREVNAR 20 for any potential indications; whether and when any such applications that may be pending or filed 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 PREVNAR 20 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 PREVNAR 20; uncertainties regarding the ability to obtain recommendations from vaccine advisory or technical committees and other public health authorities regarding PREVNAR 20 and uncertainties regarding the commercial impact of any such recommendations; uncertainties regarding the impact of COVID-19 on our 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, 2023, 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] U.S. Census Bureau. Population by age. https://data.census.gov/table?q=Population%20by%20age. Accessed October 2024.
[2] Perdrizet J, Chilson E, Wasserman M, et al. Current and future pneumococcal conjugate vaccine serotype-specific burden in the United States adult population. Abstract No. ISP20-287 Presented at ISPPD-12, Toronto,

June 21-25, 2020. Available at: https://cslide.ctimeetingtech.com/isppd20/attendee/confcal/presentation/list?q=Perdrizet.
[3] U.S. Centers for Disease Control and Prevention. Summary of Work Group Interpretations of EtR and Policy Option on PCV21 Use in Adults. https://www.cdc.gov/acip/downloads/slides-2024-06-26-28/04-Pneumococcal-Kobayashi-508.pdf. Presented June 27, 2024. Accessed October 11, 2024.
[4] U.S. Centers for Disease Control and Prevention. Summary of Risk-based Pneumococcal Vaccination Recommendations. https://www.cdc.gov/pneumococcal/hcp/vaccine-recommendations/risk-indications.html. Updated October 10, 2024. Accessed October 11, 2024.
[5] Baisells E, Guillot L, Nair H, et al. Serotype distribution of Streptococcus pneumoniae causing invasive disease in children in the post-PCV era: A systematic review and meta-analysis. PlosOne. 2017;12(5): e0177113.
[6] Hausdorff W & Hanage W. Interim results of an ecological experiment – conjugate vaccination against the pneumococcus and serotype replacement. Hum Vaccin Immunother. 2016;12(2):358-374.
[7] Cohen R, Cohen J, Chalumeau M, et al. Impact of pneumococcal conjugate vaccines for children in high- and non-high income countries. Expert Rev Vaccines. 2017;16(6):625-640.
[8] Moore M, Link-Gelles R, Schaffner W, et al. Effect of use of 13-valent pneumococcal conjugate vaccine in children on invasive pneumococcal disease in children and adults in the USA: analysis of multisite, population-based surveillance. Lancet Infect Dis. 2015;15(3):301-309.
[9] Metcalf B, Gertz RE, Gladstone RA, et al. Strain features and distributions in pneumococci from children with invasive disease before and after 13-valent conjugate vaccine implementation in the USA. Clin Microbiol Infect. 2016;22(1):60.e9-60.e29.
[10] Oligbu G, Collins S, Sheppard CL, et al. Childhood deaths attributable to invasive pneumococcal disease in England and Wales, 2006–2014. Clin Infect Dis. 2017;65(2):308-314.
[11] van Hoek, Andrews N, Waight PA, et al. Effect of serotype on focus and mortality of invasive pneumococcal disease: Coverage of different vaccines and insight into non-vaccine serotypes. PlosOne. 2012;7(7):e39150.
[12] Stanek R, Norton N, Mufson M. A 32-years study of the impact of pneumococcal vaccines on invasive Streptococcus pneumoniae disease. Am J Med Sci. 2016;352(6):563-573.
[13] Harboe ZB, Thomsen RW, Riis A, et al. Pneumococcal serotypes and mortality following invasive pneumococcal disease: A population-based cohort study. PlosOne. 2009;6(5):e1000081.
[14] Azzari C, Cortimiglia M, Nieddu F, et al. Pneumococcal serotype distribution in adults with invasive disease and in carrier children in Italy: Should we expect herd protection of adults through infants' vaccination? Hum Vaccin Immunother. 2016;12(2):344-350.
[15] Tomczyk S, Lynfield R, Schaffner W, et al. Prevention of antibiotic-nonsusceptible invasive pneumococcal disease with the 13-valent pneumococcal conjugate vaccine. Clin Infect Dis. 2016;62(9):1119-1125.
[16] Mendes RE, Hollingsworth RC, Costello A, et al. Noninvasive Streptococcus pneumoniae serotypes recovered from hospitalized adult patients in the United States in 2009 to 2012. Antimicrob Agents Chemother. 2015;59(9):5595-5601.
[17] Olarte L, Barson WJ, Lin PL, et al. Impact of the 13-valent pneumococcal conjugate vaccine on pneumococcal meningitis in US children. Clin Infect Dis. 2015;61(5):767-775.
[18] Thigpen MC, Whitney CG, Messonnier NE, et al. Bacterial meningitis in the United States, 1998–2007. NEJM. 2011;364(21):2016-2025.
[19] Fluad Quadrivalent is not a Pfizer product

Category: Vaccines

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