U.S. FDA Approves PREVNAR 20™, Pfizer's Pneumococcal 20-valent Conjugate Vaccine for Adults Ages 18 Years or Older

- *First approval of a conjugate vaccine that helps protect against 20 serotypes responsible for the majority of invasive pneumococcal disease and pneumonia,[1,2,3,4,5,6,7] including seven responsible for 40% of pneumococcal disease cases and deaths in the U.S.*
- *Helps protect against more serotypes of pneumococcal disease than any other conjugate vaccine*
- *Builds on Pfizer's more than 20-year legacy and innovation in developing pneumococcal conjugate vaccines*

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NEW YORK--(BUSINESS WIRE)--Pfizer Inc. (NYSE:PFE) announced today that the U.S. Food and Drug Administration (FDA) has approved PREVNAR 20™ (Pneumococcal 20-valent Conjugate Vaccine) 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. Following today's FDA approval, the U.S. Centers for Disease Control and Prevention's (CDC) Advisory Committee on Immunization Practices (ACIP) is expected to meet in October to discuss and update recommendations on the safe and appropriate use of pneumococcal vaccines in adults.

"Today's approval of PREVNAR 20 marks a significant step forward in our ongoing fight to help address the burden of pneumococcal disease, including pneumonia in adults, and broadens global protection against more disease-causing serotypes than any other pneumococcal conjugate vaccines"

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PREVNAR 20 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 CRM_{197} 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),[8,9,10,11,12] and have been associated with high case-fatality rates,[13,14,15,16] antibiotic resistance,[4,17,18] and/or meningitis.[19,20]

"Today's approval of PREVNAR 20 marks a significant step forward in our ongoing fight to help address the burden of pneumococcal disease, including pneumonia in adults, and broadens global protection against more disease-causing serotypes than any other pneumococcal conjugate vaccines," said Kathrin U. Jansen, Ph.D., Senior Vice President and Head of Vaccine Research & Development, Pfizer. "With a single injection, PREVNAR 20 provides adults with strong and meaningful protection against serotypes responsible for the majority of circulating pneumococcal disease around the world."

In the United States, more than half of all cases of invasive pneumococcal disease (IPD) – which include bacteremia and meningitis – in adults ages 65 or older are due to the 20 serotypes in PREVNAR 20.[21] In the United States, these 20 serotypes are estimated to cause up to 250,000 cases of IPD (including bacteremia and meningitis) and community-acquired pneumonia and more than 10,000 deaths in adults ages 18 or older.[22] Overall, the seven additional serotypes in PREVNAR 20 account for approximately 40 percent of all pneumococcal disease cases and deaths in the U.S.[23]

"Adult vaccinations play a pivotal role in helping protect our health and wellness, especially as we age and our immune systems begin to naturally weaken," said Jane Barratt, Ph.D., Secretary General, International Federation on Ageing (IFA). "We are delighted with today's approval as it addresses a critical need to continually expand coverage to meet the changing burden of disease. We encourage all adults to speak with their healthcare professionals about vaccinations."

The FDA's decision is based on evidence from Pfizer's clinical program in adults, including Phase 1 and 2 trials, and three Phase 3 trials (NCT03760146, NCT03828617, and NCT03835975) describing the safety and evaluating the immunogenicity of the vaccine. More than 6,000 adult subjects 18 years and older participated in the three Phase 3 trials, including adults 65 years of age and older, vaccine-naïve adults, and adults with prior pneumococcal vaccination.[23,24]

"PREVNAR 20 builds on Pfizer's legacy of more than two decades of experience in developing and supplying innovative pneumococcal conjugate vaccines that have had a tangible impact on global disease burden," said Nanette Cocero, Ph.D., Global President of Pfizer Vaccines. "We are thrilled with this approval as it furthers our mission to expand protection against disease-causing bacteria serotypes to help prevent potentially serious respiratory infections like pneumococcal pneumonia throughout the year."

About 20-Valent Pneumococcal Conjugate Vaccine Regulatory Review

On September 20, 2018, Pfizer announced the U.S. Food and Drug Administration (FDA) granted Breakthrough Therapy Designation for PREVNAR 20 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 PREVNAR 20 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.[25]

On February 26, 2021, the European Medicines Agency (EMA) accepted for review Pfizer's Marketing Authorization Application (MAA) for the 20-valent pneumococcal conjugate vaccine candidate, as submitted for the prevention of invasive disease and pneumonia caused by *S. pneumoniae* serotypes in

the vaccine in adults ages 18 years and older. The formal review process by the EMA's Committee for Medicinal Products for Human Use (CHMP) currently is ongoing.

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.

U.S. 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

Please see full prescribing information for PREVNAR 20™,

INDICATIONS FOR PREVNAR 13® IN ADULTS

- Prevnar 13® is a vaccine indicated for active immunization for the prevention of pneumonia and invasive disease caused by *S. pneumoniae* serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, and 23F in adults 18 years of age and older
- Prevnar 13® is not 100% effective and will only help protect against the 13 strains included in the vaccine

U.S. 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
- Adults with weakened immune systems (eg, 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

- 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

Please see full prescribing information for PREVNAR 13®.

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 June 8, 2021. 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 PREVNAR 20™ (Pneumococcal 20-valent Conjugate Vaccine [Diphtheria CRM197 Protein]), including an approval in the U.S. and an MAA filed in the European Union for the prevention of invasive disease and pneumonia caused by the 20 Streptococcus pneumoniae (pneumococcus) serotypes in the vaccine in adults age 18 years or older, 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, uncertainties regarding the commercial success of PREVNAR 20; 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 the prevention of invasive disease and pneumonia in adults age 18 years or older and in any jurisdictions for any other potential indications; whether and when the MAA pending in the EU may be approved and whether and when any such other 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; 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, 2020 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] Centers for Disease Control and Prevention. Active Bacterial Core (ABCs) surveillance. National Center for Immunization and Respiratory Diseases. Atlanta, GA.

[2] Ladhani, SN, Collins S, Djennad A, et al. Rapid increase in non-vaccine serotypes causing invasive pneumococcal disease in England and Wales, 2000–17: a prospective national observational cohort study. Lancet Infect Dis. 2018;18(4):441-451.

[3] Menéndez R, España PP, Pérez-Trallero E, et al. The burden of PCV13 serotypes in hospitalized pneumococcal pneumonia in Spain using a novel urinary antigen detection test. CAPA study. Vaccine. 2017;35(39):5264-5270.

[4] 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.

[5] Pivlishi T. Impact of PCV13 on invasive pneumococcal disease (IPD) burden and the serotype distribution in the U.S. Centers for Disease Control and Prevention. Advisory Committee on Immunization Practices. October 24th, 2018.

[6] European Centre for Disease Prevention and Control. Invasive pneumococcal disease. In: ECDC. Annual epidemiological report for 2016. Stockholm: ECDC; 2018.

[7] Beall B, Chochua S, Gertz RE Jr, et al. A population-based descriptive atlas of invasive pneumococcal strains recovered within the U.S. during 2015-2016. Front Microbiol. 2018;19(9).

[8] 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.

[9] 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.

[10] 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.

[11] 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.

[12] 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.

[13] 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.

[14] 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.
[15] 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.
[16] 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): e 1000081.
[17] 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.
[18] 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.
[19] 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.
[20] Thigpen MC, Whitney CG, Messonnier NE, et al. Bacterial Meningitis in the United States, 1998–2007. NEJM. 2011;364(21):2016-2025.
[21] Grant L, Slack M, Theilacker C, et. al. Coverage of Next Generational Pneumococcal Conjugate Vaccines for Invasive Pneumococcal Disease in Older Adults of High-Income Countries. Abstract No. ISP20-612. Presented at ISPPD-12, Toronto, June 21-25, 2020.
[22] 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
[23] Pfizer Inc. NCT03828617 Study Design. Available at www.clinicaltrials.gov under the identifier NCT03828617.
[24] Pfizer Inc. NCT03835975 Study Design. Available at www.clinicaltrials.gov under the identifier NCT03835975.
[25] U.S. Food and Drug Administration. Breakthrough Therapy https://www.fda.gov/forpatients/approvals/fast/ucm405397.htm
[26] U.S. Food and Drug Administration. Fast Track https://www.fda.gov/ForPatients/Approvals/Fast/ucm405399.htm
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