NEWS RELEASE

European Commission Approves Pfizer’s PREVENAR 20® to Help Protect Infants and Children Against Pneumococcal Disease

3/13/2024

- PREVENAR 20® (20-valent Pneumococcal Conjugate Vaccine) offers the broadest serotype coverage of any pediatric pneumococcal conjugate vaccine to help protect infants and children from the 20 serotypes responsible for the majority of currently circulating pneumococcal disease in the EU and globally 1,2,3,4,5,6,7,8

NEW YORK--(BUSINESS WIRE)-- Pfizer Inc. (NYSE: PFE) today announced that the European Commission (EC) has granted marketing authorization for the company’s 20-valent pneumococcal conjugate vaccine, marketed in the European Union under the brand name PREVENAR 20®, for active immunization for the prevention of invasive disease, pneumonia and acute otitis media caused by Streptococcus pneumoniae in infants, children and adolescents from 6 weeks to less than 18 years of age.

“The EC’s authorization of PREVENAR 20 for infants and children represents a significant opportunity to improve public health by helping to protect against the 20 serotypes responsible for the majority of currently circulating pneumococcal disease in the EU,” said Alexandre de Germay, Chief International Commercial Officer, Executive Vice President, Pfizer. “PREVENAR 20 builds on Pfizer’s decades-long commitment to develop vaccines to help prevent potentially life-threatening infections, and we are proud to now provide the broadest serotype coverage of any pneumococcal conjugate vaccine for children in Europe.”

Today’s authorization follows the **recent positive opinion** from the European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP). The authorization is valid in all 27 EU member states plus Iceland, Lichtenstein and Norway. It also follows the approval of PREVNAR 20 for infants and children by the U.S. Food and Drug Administration (FDA) in April 2023, and approvals in several other countries including Canada, Australia and

Brazil. Regulatory applications for PREVENAR 20 for the pediatric indication have been submitted to additional countries around the world.

The EC authorization of PREVENAR 20 is based on evidence from the Phase 3 clinical trial program comprised of four core pediatric studies (NCT04546425, NCT04382326, NCT04379713, NCT04642079), which helped to expand the data on the safety, tolerability, and immunogenicity of the vaccine. These studies collectively enrolled more than 4,700 infants and 800 toddlers and children of all ages.

About PREVENAR 20®

Pfizer's PREVENAR 20® 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 PREVENAR 20 – 8, 10A, 11A, 12F, 15B, 22F, and 33F – are global causes of invasive pneumococcal disease (IPD), and are associated with high case-fatality rates, antibiotic resistance, and/or meningitis.9 Together, the 20 serotypes included in PREVENAR 20 are responsible for the majority of currently circulating pneumococcal disease in the EU and globally.1,2,3,4,5,6,7,8

In February 2022, the European Commission Decision was adopted for APEXXNAR® (20-valent Pneumococcal Conjugate Vaccine) for the prevention of invasive disease and pneumonia caused by the 20 S. pneumoniae (pneumococcus) serotypes in the vaccine in adults ages 18 years and older. Pfizer is changing the tradename of APEXXNAR to PREVENAR 20 following the expansion of its indication to include individuals from 6 weeks of age and older.

In April 2023, the United States Food and Drug Administration (FDA) approved PREVNAR 20® (20v PnC) for the prevention of invasive pneumococcal disease (IPD) caused by the 20 S. pneumoniae (pneumococcal) serotypes contained in the vaccine in infants and children six weeks through 17 years of age, and for the prevention of otitis media in infants six weeks through five years of age caused by the original seven serotypes contained in PREVNAR®.

EU INDICATION FOR PREVENAR 20®

- Active immunization for the prevention of invasive disease, pneumonia and acute otitis media caused by Streptococcus pneumoniae in infants, children and adolescents from 6 weeks to less than 18 years of age.
- Active immunization for the prevention of invasive disease and pneumonia caused by Streptococcus pneumoniae in individuals 18 years of age and older.

US INDICATIONS FOR PREVNAR 20®

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 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.

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 your child.

View the full Prescribing Information.

EU INDICATION FOR APEXXNAR ®

- Active immunization 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 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 March 13, 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.

This release contains forward-looking information about Prevnar 20/Prevenar 20, including its potential benefits, a marketing authorization granted by the European Commission for active immunization for the prevention of invasive disease, pneumonia and acute otitis media caused by Streptococcus pneumoniae in infants, children and adolescents from 6 weeks to less than 18 years of age and applications pending in other jurisdictions , 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/Prevenar 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 particular jurisdictions for Prevnar 20/Prevenar 20 for any potential indications; whether and when any applications that may be pending or filed for Prevnar 20/Prevenar 20 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/Prevenar 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/Prevenar 20; uncertainties regarding the ability to obtain recommendations from vaccine advisory or technical committees and other public health authorities regarding Prevnar 20/Prevenar 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** .

1 Active Bacterial Core (ABCs) surveillance. National Center for Immunization and Respiratory Diseases. Atlanta, GA. CDC. Published March 2020. Updated May 22, 2020. Accessed February 6, 2024. Available at: **https://www.cdc.gov/abcs/reports-findings/survreports/spneu18.pdf**.

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 [published correction appears in Lancet Infect Dis. 2018 Feb 6;:]. Lancet Infect Dis. 2018;18(4):441-451. doi:10.1016/S1473-3099(18)30052-5

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. doi:10.1016/j.vaccine.2017.08.007

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. doi:10.1080/21645515.2015.1102811

5 Pivlishi T. Impact of PCV13 on invasive pneumococcal disease (IPD) burden and the serotype distribution in the U.S. CDC. ACIP. Published October 24, 2018. Accessed February 6, 2024. Available at: **https://stacks.cdc.gov/view/cdc/61449**.

6 Invasive pneumococcal disease. In: ECDC. Annual epidemiological report for 2016. ECDC. Published August 8, 2018. Accessed February 6, 2024. Available at: **https://www.ecdc.europa.eu/sites/default/files/documents/AER_for_2016-invasive-pneumococcal-disease_0.pdf**.

7 Beall B, Chochua S, Gertz RE Jr, et al. A population-based descriptive atlas of invasive pneumococcal strains recovered within the US during 2015-2016. Published November 2018. Accessed February 6, 2024. Available at: **https://pubmed.ncbi.nlm.nih.gov/30524382/**.

8 Grant L, Suaya J, Pugh S, et. al. Coverage of the 20-Valent Conjugate Vaccine Against Invasive Pneumococcal Disease By Age Group in the United States, 2017. Abstract No. ISP20-237.

9 Senders, S., et al. (2021, October 1). Safety and immunogenicity of a 20-valent pneumococcal conjugate vaccine in healthy infants in the United States. The Pediatric Infectious Disease Journal. Published September 13, 2021. Accessed February 6, 2024. Available at: **https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8443440/**.

Category: Vaccines

Media Contact:

EUPress@Pfizer.com

+44 (0)1737 332 335

Investor Contact:

IR@Pfizer.com

+1 (212) 733-4848

Source: Pfizer Inc.