European Medicines Agency Approves Pfizer’s 20-Valent Pneumococcal Conjugate Vaccine Against Invasive Pneumococcal Disease and Pneumonia in Adults

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APEXXNAR ® [pneumococcal polysaccharide conjugate vaccine (20-valent, adsorbed)] is the first pneumococcal conjugate vaccine to help protect adults ages 18 years and older against 20 serotypes responsible for the majority of invasive disease and pneumococcal pneumonia

NEW YORK--(BUSINESS WIRE)-- Pfizer Inc. (NYSE:PFE) today announced that the European Medicines Agency (EMA) has approved the company’s 20-valent pneumococcal conjugate vaccine (PCV20), which will be marketed in the European Union (EU) under the brand name APEXXNAR. The vaccine is approved for active immunization for the prevention of invasive disease and pneumonia caused by Streptococcuspneumoniae in individuals 18 years of age and older.

“The EMA’s authorization of APEXXNAR for adults continues Pfizer’s ongoing commitment to help prevent certain potentially-serious infectious respiratory diseases, including invasive pneumococcal disease and pneumonia,” said Nanette Cocero, Ph.D., Global President of Pfizer Vaccines. “APEXXNAR helps protect against the 20 serotypes in the vaccine, and today’s approval offers adults -- through a single dose -- the broadest serotype protection of any available pneumococcal conjugate vaccine in Europe.”

Today’s authorization follows the recent positive opinion from the EMA's Committee for Medicinal Products for Human Use (CHMP) announced on December 17, 2021. The authorization is valid in all 27 EU member states plus Iceland, Lichtenstein, and Norway. The EMA had previously accepted review of Pfizer’s Marketing Authorization Application (MAA) for the 20-valent pneumococcal conjugate vaccine candidate in February 2021.

The EMA authorization for APEXXNAR is based on evidence from a 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. The populations included adults with stable chronic medical conditions, pneumococcal vaccine-naïve adults, and adults with a history of prior pneumococcal vaccination.

About PCV20

PCV20 – known as APEXXNAR in the EU and PREVNAR 20TM in the US -- 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 PREVENAR 13® (Pneumococcal 13-valent Conjugate Vaccine [Diphtheria CRM197 Protein]), known as PREVNAR 13® in the U.S. 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),1,2,3,4,5 and have been associated with high case-fatality rates,6,7,8,9 antibiotic resistance,10,11,12 and/or meningitis.13,14 APEXXNAR contains the broadest serotype coverage of any available conjugate vaccine and helps protect against 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, which is the U.S trade name for PCV20, for the prevention of invasive disease and pneumonia in adults age 18 years or older. Pfizer has recently submitted to the FDA a supplemental Biologics License Application to include data in the PREVNAR 20 prescribing information for adults age 18 years or older regarding coadministration of PREVNAR 20 with a seasonal inactivated influenza vaccine.

Pivotal Phase 3 studies of the 20-valent pneumococcal conjugate vaccine candidate in infants are expected to read out in the second half of 2022 and, if positive, form the basis of potential regulatory submissions to the FDA and EMA later this year.

U.S. 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 This indication for the prevention of pneumonia caused by S. pneumoniae serotypes 8, 10A, 11A, 12F, 15B, 22F, and 33F is approved under accelerated approval based on immune responses as measured by opsonophagocytic activity (OPA) assay. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.

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 any diphtheria toxoid–containing vaccine Some 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, and headache 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™.

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 February 15, 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 APEXXNAR ® [pneumococcal polysaccharide conjugate vaccine (20-valent, adsorbed)] (PCV20), including its potential benefits, an approval in the European Union for active immunization for the prevention of invasive disease and pneumonia caused by Streptococcus pneumoniae in individuals 18 years of age or older, a potential pediatric indication and a supplemental Biologics License Application (sBLA) to include data in the U.S. prescribing information for adults age 18 years or older regarding coadministration of PREVNAR 20 with a seasonal inactivated influenza vaccine, 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 PCV20; 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 PCV20 for the prevention of invasive disease and pneumonia in adults age 18 years or older or for any other potential indications; whether and when the sBLA pending in the U.S. may be approved and whether and when any such other applications that may be pending or filed for PCV20 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 PCV20 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 PCV20; uncertainties regarding the ability to obtain recommendations from vaccine advisory or technical committees and other public health authorities regarding PCV20 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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