Pfizer Responds to the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention’s Vote to Revise the Recommendation for Routine Use of Prevnar 13® for the Prevention of Pneumococcal Disease for Adults 65 Years or Older

NEW YORK, N.Y., June 26 – Pfizer Inc. (NYSE: PFE) today responds to the Advisory Committee on Immunization Practices (ACIP) of the Centers for Disease Control and Prevention’s (CDC) vote to revise the pneumococcal vaccination guidelines and recommend Prevnar 13® (Pneumococcal 13-valent Conjugate Vaccine [Diphtheria CRM197 Protein]) for adults aged 65 and older based on the shared clinical decision making of the provider and patient. This vote means the decision to vaccinate should be made at the individual level between health care providers and their patients.

“This revised recommendation reinforces that Prevnar 13® is considered safe and effective by the FDA and ACIP and helps address remaining persistent vaccine type pneumococcal disease in the population of adults age 65 years or older, which causes thousands of pneumococcal pneumonia cases every year in the United States,” said Luis Jodar, Pfizer Vaccines, Chief Medical and Scientific Affairs Officer. “Direct vaccination remains the best available tool to help prevent against pneumococcal disease and the revised recommendation emphasizes the importance of the health care professional and patient relationship in shared decision making regarding vaccination.”

ACIP is a group of medical and public health experts that makes vaccine recommendations to help control disease in the United States. In 2014, the ACIP voted to recommend Prevnar 13® for adults 65 years or older. In 2012, Prevnar 13® was recommended by ACIP for adults 19 years of age and older with immunocompromising conditions (e.g., HIV, chronic renal failure, cancer), functional or anatomic asplenia (e.g., sickle cell disease), cerebral spinal fluid leak, and Cochlear implants.
“Pfizer remains committed to helping protect against the potentially devastating effects of pneumococcal disease and continuing to develop our pneumococcal vaccine pipeline,” added Jodar.

IMPORTANT SAFETY INFORMATION

- Severe allergic reaction (e.g., anaphylaxis) to any component of Prevnar 13® or any diphtheria toxoid-containing vaccine is a contraindication
- Immunocompromised individuals or individuals with impaired immune responsiveness due to the use of immunosuppressive therapy may have reduced antibody 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
- Apnea following intramuscular vaccination has been observed in some infants born prematurely. Vaccination of premature infants should be based on the infant's medical status, and the potential benefits and risks
- In infants and toddlers, the most commonly reported serious adverse events were bronchiolitis (0.9%), gastroenteritis (0.9%), and pneumonia (0.9%)
- In children 6 weeks through 17 years, the most commonly reported solicited adverse reactions were injection site tenderness, redness, or swelling, irritability, decreased appetite, decreased or increased sleep, and fever

INDICATION

Prevnar 13® is a vaccine indicated in children 6 weeks through 17 years (prior to the 18th birthday) for active immunization for the prevention of invasive disease caused by Streptococcus pneumoniae serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, and 23F, and for children 6 weeks through 5 years of age (prior to the 6th birthday) for the prevention of otitis media caused by 7 of the 13 serotypes only (4, 6B, 9V, 14, 18C, 19F, and 23F).

In adults 18 years of age and older, Prevnar 13® is 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.

Limitations of Use and Effectiveness

Prevnar 13® does not protect against disease caused by S. pneumoniae serotypes that are not in the vaccine.

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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. Our global portfolio includes medicines and vaccines as well as many of the world's best-known consumer health care products. 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 150 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 26, 2019. 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 13® (Pneumococcal 13-valent Conjugate Vaccine [Diphtheria CRM197 Protein]) and Pfizer’s pneumococcal vaccine pipeline, including their 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 impact of the ACIP’s vote regarding Prevnar 13®; 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 jurisdictions for our vaccine candidates; 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 our vaccine candidates 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 our products; uncertainties regarding the ability to obtain recommendations from vaccine technical committees and other public health authorities regarding our vaccines and
uncertainties regarding the commercial impact of any such recommendations; 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, 2018 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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