Pfizer Statement Regarding Prevnar 13® Receiving ACIP Recommendation for Prevention of Pneumococcal Disease in Adults With Immunocompromising Conditions

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(BUSINESS WIRE)--Pfizer Inc (NYSE: PFE) issued the following statement in response to today's Centers for Disease Control and Prevention's (CDC) Advisory Committee on Immunization Practices (ACIP) vote to recommend the use of Pfizer's Prevnar 13® (Pneumococcal 13-valent Conjugate Vaccine [Diphtheria CRM197 Protein]) for adults 19 years of age and older with immunocompromising conditions. The ACIP defines immunocompromised as those people who have functional or anatomic asplenia, HIV infection, cancer, advanced kidney disease, or other immunocompromising conditions.

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Pfizer believes that Prevnar 13 offers a significant health benefit and compelling value proposition for the U.S. health care system. We are committed to continuing discussions with the ACIP with the aim of expanding the recommendations to include all adults 50 years of age and older – a population rapidly increasing in the United States and at risk for developing vaccine-type pneumococcal pneumonia and invasive disease.

In December 2011, Prevnar 13 was approved by the U.S. Food and Drug Administration (FDA) under an accelerated approval pathway for adults 50 years of age and older for active immunization for the prevention of pneumococcal pneumonia and invasive disease caused by the 13 serotypes contained in the vaccine. This indication is based on immune

responses elicited by Prevnar 13. There have been no controlled trials in adults demonstrating a decrease in pneumococcal pneumonia or invasive disease after vaccination with Prevnar 13. Prevnar 13 is not FDA-approved for patients 6 through 49 years of age.

Pfizer is conducting a variety of clinical studies using Prevnar 13 in immunocompromised individuals and expects results at the end of 2012 and into 2013. Data on the safety and effectiveness of Prevnar 13 when administered to immunocompromised individuals are not available. These individuals may have reduced antibody response to active immunization due to impaired immune responsiveness.

Pfizer is conducting the Community-Acquired Pneumonia Immunization Trial in Adults (CAPiTA) and will share results with the ACIP once complete. The ACIP will consider these results and other available evidence before developing a recommendation regarding routine use of Prevnar 13 in adults aged 50 years of age and older. CAPiTA is an efficacy trial involving more than 84,000 subjects 65 years of age and older designed to evaluate whether Prevnar 13 is effective in preventing the first episode of community-acquired pneumonia (CAP) caused by the 13 pneumococcal serotypes contained in the vaccine. Pfizer estimates that the primary outcome measures for this event-driven study will be available in 2013.

Prevnar 13 is available commercially for adults 50 years of age and older in the United States, as well as many other countries around the world. Prevnar 13 was first approved in the United States in February 2010 for the prevention of invasive pneumococcal disease caused by the 13 serotypes included in the vaccine in infants and young children from 6 weeks through 5 years of age.

INDICATIONS FOR PREVNAR 13

Prevnar 13 is a vaccine indicated for adults 50 years of age and older for the prevention of pneumococcal pneumonia and invasive disease caused by 13 Streptococcus pneumoniae strains (1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, and 23F). This indication is based upon immune responses to the vaccine. In children 6 weeks through 5 years of age, Prevnar 13 is indicated for the prevention of invasive disease caused by these same strains, and for the prevention of ear infection caused by 7 of the 13 strains Prevnar 13 is not 100% effective and will only help protect against the 13 strains included in the vaccine Effectiveness when given less than 5 years after a pneumococcal polysaccharide vaccine is not known

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 Children and adults with weakened immune systems (eg, HIV infection, leukemia) may have a reduced immune response In adults, the common side effects were pain, redness, or swelling at the injection site, limitation of arm movement, fatigue, headache, muscle pain, joint pain, decreased appetite, chills, or rash In adults, immune responses to Prevnar 13 were reduced when given with injected seasonal flu vaccine A temporary pause of breathing following vaccination has been observed in some infants born prematurely The most commonly reported serious adverse events in children were bronchiolitis (an infection of the lungs) (0.9%), gastroenteritis (inflammation of the stomach and small intestine) (0.9%), and pneumonia (0.9%) In infants and toddlers, the most common side effects were tenderness, redness or swelling at the injection site, irritability, decreased appetite, decreased or increased sleep, and fever Ask your health care provider about the risks and benefits of Prevnar 13. Only a health care provider can decide if Prevnar 13 is right for you

For the full prescribing information for Prevnar 13, please click here http://www.pfizer.com/products/#prevnar13

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DISCLOSURE NOTICE: The information contained in this statement is as of June 20, 2012. Pfizer assumes no obligation to update forward-looking statements contained in this statement as the result of new information or future events or developments.

This statement contains forward-looking information that involves substantial risks and uncertainties regarding the use of Prevnar 13 for adults 50 years of age and older (the Prevnar 13 Adult indication), including its potential benefits. Such risks and uncertainties include, among other things, the uncertainties inherent in research and development, including uncertainty regarding the results of and the anticipated completion dates of the CAPiTA trial and of ongoing trials of Prevnar 13 in immunocompromised individuals as well as the impact of those trial results on the commercial potential of the Prevnar 13 Adult indication; uncertainty regarding whether and when ACIP will recommend the routine use of Prevnar 13 by all adults 50 years of age and older and the impact of ACIP's decision on the commercial potential of the Prevnar 13 Adult indication; 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, 2011 and in its reports on Form 10-Q and Form 8-K.

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