Pfizer Statement Regarding CDC's ACIP Discussion of Prevnar 13® for Use in Adults

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--(BUSINESS WIRE)--Pfizer Inc. (NYSE: PFE) issued the following statement in response to today's discussion by the Centers for Disease Control and Prevention's (CDC) Advisory Committee on Immunization Practices (ACIP) regarding the use of Prevnar 13® (Pneumococcal 13-valent Conjugate Vaccine [Diphtheria CRM197 Protein]) in adults 50 years of age and older.

Pfizer believes Prevnar 13 should be recommended for all adults 50 years of age and older given the current burden of pneumococcal disease in this age group. Along with the ACIP, we are particularly concerned about those adults at heightened risk for pneumococcal disease, especially immunocompromised individuals. However, we also believe that those 65 years of age and older who already have been vaccinated with the pneumococcal polysaccharide vaccine (PPSV) and who have exhausted their options under the existing CDC recommendations are an at risk population.

We are committed to continuing discussions with the CDC about a recommendation concerning the use of Prevnar 13 in adults 50 years of age and older. Pneumococcal disease in adults 50 years of age and older is associated with significant morbidity and mortality. In fact, there are an estimated 25,000 pneumococcal disease-related deaths every year in the United States in that age group. In addition, there are an estimated 440,000 cases of pneumococcal pneumonia in adults 50 years of age and older, accounting for an estimated 200,000 emergency department visits and 300,000 hospitalizations in the United States.

The U.S. Food and Drug Administration (FDA) licensed Prevnar 13 on December 30, 2011, for adults 50 years of age and older for active immunization for the prevention of pneumonia and invasive disease caused by the 13 Streptococcus pneumoniae serotypes

contained in the vaccine. The FDA approved Prevnar 13 under the accelerated approval program, which allows for earlier approval of certain products to help address serious or life-threatening diseases and that have the potential to provide meaningful therapeutic benefit to patients over existing treatments. The approval of this indication was based on immune responses elicited by Prevnar 13, and there have been no controlled trials in adults demonstrating a decrease in pneumococcal pneumonia or invasive pneumococcal disease.

We are confident that Prevnar 13 has the potential to help address the burden of life-threatening pneumococcal pneumonia and invasive disease in adults 50 years of age and older, while offering a compelling value proposition for the United States health care system. In fact, a cost-effectiveness analysis that was published this week in the Journal of the American Medical Association (JAMA), which was co-authored by the CDC and the University of Pittsburgh School of Medicine, favors vaccinating adults aged 50 and over with Prevnar 13 and indicates that routine use at ages 50 and 65 might reduce the burden of pneumococcal disease in an “economically reasonable fashion.” Therefore, we intend to proceed with the launch of Prevnar 13 to health care providers in the United States in the coming weeks, as planned.

Pfizer is currently conducting the Community-Acquired Pneumonia Immunization Trial in Adults (CAPiTA) to fulfill requirements under the accelerated approval program. The Committee indicated today it needs the results of this trial before voting on a broad recommendation for all adults 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 this event-driven study will be complete in 2013.

While the rate of uptake for the use of Prevnar 13 by adults 50 years of age and older will be impacted by the outcome of today’s ACIP meeting, Pfizer is not changing its 2012 financial guidance.

INDICATIONS FOR PREVNAR 13®

In adults 50 years of age and older, Prevnar 13® is a vaccine indicated for:

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

active immunization for the prevention of invasive disease caused by 13 strains of Streptococcus pneumoniae (1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, and 23F) active immunization for the prevention of otitis media (ear infection) caused by 7 strains of Streptococcus pneumoniae (4, 6B, 9V, 14, 18C, 19F, and 23F). No efficacy data for ear infections are available for other strains included in the vaccine (1, 3, 5, 6A, 7F, and 19A) Limitations of Use and Effectiveness

Prevnar 13® will not protect against disease caused by strains of Streptococcus pneumoniae not contained in the vaccine The effectiveness of Prevnar 13® when given less than 5 years after the 23-valent 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 (e.g., HIV infection, leukemia) may have a reduced immune response to Prevnar 13® In adults, immune responses to Prevnar 13® were reduced when given with injected seasonal flu vaccine In adults aged 50 years and older, the common side effects were pain at the injection site, fatigue, headache, muscle pain, joint pain, decreased appetite, injection site redness, injection site swelling, limitation of arm movement, chills, or rash A temporary pause of breathing following vaccination has been observed in some infants born prematurely The most commonly reported serious adverse events in children include bronchiolitis (an infection of the lungs) (0.9%, 1.1%), gastroenteritis (inflammation of the stomach and small intestine) (0.9%, 0.9%), and pneumonia (0.9%, 0.5%) for Prevnar 13® and Prevnar® (Pneumococcal 7-valent Conjugate Vaccine [Diphtheria CRM197 Protein]), respectively In infants and toddlers, the most common side effects were irritability, injection site tenderness, decreased appetite, decreased sleep, increased sleep, fever, injection site redness, and injection site swelling Any side effects associated with the vaccination should be reported to your child’s or your health care provider 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 or your child
For the full prescribing information for Prevnar 13, please click here
http://www.pfizer.com/products/#prevnar13

DISCLOSURE NOTICE: The information contained in this release is as of February 22, 2012. 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 that involves substantial risks and uncertainties regarding the commercial potential and cost-effectiveness of the use of Prevnar 13 in adults 50 years of age and older (the Prevnar 13 Adult Indication), the CAPiTA trial and the Company's financial performance in 2012. Such risks and uncertainties include, among other things, the uncertainties inherent in research and development, including uncertainty regarding when the CAPiTA trial will complete and regarding the results of the CAPiTA trial and their impact on the commercial potential for the

Prevnar 13 Adult Indication; uncertainty regarding the guidance to be provided by the ACIP regarding the Prevnar 13 Adult Indication and its impact on the commercial potential for that indication; and the uncertainties and variables inherent in business operating and financial performance, including, among other things, competitive developments, general economic, political, business, industry, regulatory and market conditions, and the other risks and uncertainties set forth in Pfizer's Annual Report on Form 10-K for the fiscal year ended December 31, 2010 and in its reports on Form 10-Q and Form 8-K.

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