PFIZER Statement Regarding FDA Advisory Committee's Recommendation to Extend Use of Prevnar 13® to Adults 50+

November 16, 2011 -- Pfizer Inc. (NYSE: PFE) announced today that the United States Food and Drug Administration's (FDA) Vaccines and Related Biological Products Advisory Committee (VRBPAC) voted 14 to 1 that the clinical data presented are sufficient to support the effectiveness and safety of Prevnar 13® (Pneumococcal 13-valent Conjugate Vaccine [Diphtheria CRM_{197} Protein]) for the prevention of pneumococcal disease, including pneumonia and invasive disease, caused by the serotypes contained in the vaccine in adults 50 years and older.

Pfizer is pleased with the Advisory Committee's vote and we look forward to continuing to work with the FDA on its evaluation of this potential new indication for Prevnar 13. If approved by the FDA, Prevnar 13 will become the first and only pneumococcal conjugate vaccine approved for adults in the United States. Currently, the Company's supplemental biologics license application (sBLA) is under FDA review, with agency action expected in January 2012.

The Committee's favorable recommendation, although not binding, will be considered by the FDA in its final review of the sBLA for the vaccine. If approved, the FDA will determine final prescribing information. The FDA granted Pfizer an "accelerated approval designation" for its sBLA, a decision that reflects the high rate of life-threatening pneumococcal pneumonia in adults 50 years and older and is based on the potential of Prevnar 13 to provide clinical benefit over the currently available nonconjugated pneumococcal polysaccharide vaccine (PPSV).

The Advisory Committee's votes in support of Prevnar 13 were based on a review of immunogenicity data from Phase 3 clinical studies involving more than 6,000 adults 50 years and older.

IMPORTANT SAFETY INFORMATION

- Severe allergic reaction (e.g., anaphylaxis) to any component of Prevnar 13® or any diphtheria toxoid–containing vaccine is a contraindication to the use of Prevnar 13®.
- Prevnar 13® does not provide 100% protection against vaccine serotypes or protect against nonvaccine serotypes.
- The most commonly reported solicited adverse reactions in adult clinical trials with Prevnar 13® were redness, swelling, and pain at the injection site, limitation of arm movement, headache, fatigue, chills, decreased appetite, muscle pain, and joint pain.
- Immunocompromised adults or adults with impaired immune responsiveness due to the use of immunosuppressive therapy may have reduced antibody response to active immunization.

DISCLOSURE NOTICE: The information contained in this statement is as of November 16, 2011. 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 a potential indication for Prevnar 13 for use in adults, including its potential benefits. Such risks and uncertainties include, among other things, the uncertainties inherent in research and development; whether and when the FDA and regulatory authorities in other jurisdictions will approve applications that have been or may be submitted for this potential indication and their decisions regarding labeling and other matters that could affect its availability or commercial potential; 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, 2010 and in its reports on Form 10-Q and Form 8-K.

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