Pfizer Provides U.S. Regulatory Update on Prevnar 13® for Use in Adults 50 Years and Older

Friday, July 29, 2011 - 04:49am

FDA Extends Review Time of Supplemental Application by 90 Days

"We are working closely with the FDA on its review,"

(BUSINESS WIRE)--Pfizer Inc (NYSE:PFE) today announced that the U.S. Food and Drug Administration (FDA) has issued a 90-day extension to the action date for the Company's supplemental Biologics License Application (sBLA) for use of Prevnar 13®, (Pneumococcal 13-valent Conjugate Vaccine [Diphtheria CRM197 Protein]) in adults aged 50 and older. This extends the review period to January 2012. The extension is due to additional data that Pfizer elected to submit from two studies that were part of the original sBLA. These data, which are derived from an additional immune response assay method, were submitted to support the FDA in its evaluation of the concomitant use of Prevnar 13 and trivalent inactivated influenza vaccine (TIV). The FDA considered this data submission to be a major amendment to the filing.

Prevnar 13 is under review for active immunization of adults 50 years of age and older for the prevention of pneumococcal disease (including pneumonia and invasive disease) caused by the 13 Streptococcus pneumoniae (S. pneumoniae) serotypes in the vaccine.

"We are working closely with the FDA on its review," says Emilio Emini, PhD, chief scientific officer, Vaccine Research, Pfizer. "We remain confident that our application supports the approval of Prevnar 13 in adults aged 50 and older."

Prevnar 13 was approved for use in infants and young children in Europe in December 2009 and in the U.S. in February 2010. It is currently approved for that use in more than 100 countries.

Pfizer's application to the FDA is based on six Phase 3 studies involving approximately 6,000 subjects. To date, the Company has submitted regulatory applications for use of Prevnar 13 in adults aged 50 and older in more than 40 countries. Earlier this year, Prevenar 13*, as it is known in most countries outside the U.S., was approved in Colombia, the Philippines and Thailand for use in adults aged 50 and older.

Pneumococcal Disease

Pneumococcal disease (PD) is a group of illnesses caused by the bacterium S. pneumoniae, also known as pneumococcus. PD includes invasive infections such as meningitis and bacteremic-pneumonia, as well as non-invasive infections, such as non-bacteremic pneumonia. PD is a major cause of morbidity and mortality in adults worldwide.

In the U.S., pneumococcal pneumonia is the most common community-acquired bacterial pneumonia. Up to 5.6 million community acquired pneumonia (CAP) cases per year are reported in the U.S., of which 1.1 million, or 20 percent, require hospitalization.

Indication for Prevnar 13 for Pediatric Use in the United States

In the United States, Prevnar 13 is a vaccine approved for use in children 6 weeks through 5 years of age (prior to the sixth birthday). Prevnar 13 is indicated for active immunization for the prevention of invasive disease caused by 13 serotypes of S. pneumoniae (1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, and 23F). Prevnar 13 is also indicated for the prevention of otitis media (ear infection) caused by seven serotypes of S. pneumoniae (4, 6B, 9V, 14, 18C, 19F, and 23F). No efficacy data for ear infections are available for serotypes 1, 3, 5, 6A, 7F, and 19A.

Prevnar 13 is not indicated for the prevention of pneumonia in the United States.

Important Safety Information for Prevnar 13 for Pediatric Use in the United States

Prevnar 13 should not be given to anyone with a severe allergic reaction to any component of Prevnar 13, Prevnar, or any diphtheria toxoid–containing vaccine.

Prevnar 13 may not protect all individuals receiving the vaccine. Protection against ear infections is expected to be less than that for invasive disease.

Children with weakened immune systems may have a reduced immune response to Prevnar 13.

A temporary pause of breathing following vaccination has been observed in some infants born prematurely.

The most commonly reported serious adverse events 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, respectively.

The most common side effects are redness, swelling and tenderness at the injection site, fever, decreased appetite, irritability, increased sleep, and decreased sleep. Any side effects associated with the vaccination should be reported to your child's health care provider.

Ask your child's health care provider about the risks and benefits of Prevnar 13. Only a health care provider can decide if Prevnar 13 is right for your child.

For full product and prescribing information for Prevnar 13 in the U.S., please click here.

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DISCLOSURE NOTICE: The information contained in this release is as of July 29, 2011. 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 a potential indication for Prevnar 13 for use in adults in various markets, including the U.S., and the potential benefits of Prevnar 13. 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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