Pfizer Provides U.S. Regulatory Update On Prevnar 13™ Vaccine

Wednesday, December 30, 2009 - 06:31am

(BUSINESS WIRE)--Pfizer Inc. announced today that the U.S. Food and Drug Administration (FDA) has not yet completed its review of the Biologics License Application (BLA) for Prevnar 13™, (Pneumococcal 13-valent Conjugate Vaccine [Diphtheria CRM197 Protein]), the Company's candidate 13-valent pneumococcal conjugate vaccine. As a result, the review will continue beyond the prescription drug user fee (PDUFA) action date of December 30, 2009. "We remain confident that the data in the BLA support the approval of Prevnar 13," says Emilio Emini, Ph.D., chief scientific officer, Vaccine Research, Pfizer Inc. "We will continue to work closely with the FDA to help expedite the completion of its review of our BLA." In May 2009, Prevnar 13 was designated for priority review, which is given to products that, if approved by the Center for Biologics Evaluation & Research (CBER), would be a significant improvement in the safety or effectiveness of the treatment, diagnosis or prevention of a serious or life-threatening disease. In August 2009, the FDA extended its review by 90 days from the original action date of September 30, 2009, to December 30, 2009, based on the submission of additional manufacturing data requested by the FDA. Pfizer is seeking an indication for Prevnar 13 for active immunization of infants and toddlers for the prevention of invasive disease and otitis media caused by the 13 Streptococcus pneumoniae (S. pneumoniae) serotypes in the vaccine. On November 18, 2009, the FDA's Vaccines and Related Biological Products Advisory Committee voted 10 to 1 that the data presented from the BLA for Prevnar 13 support its safety and efficacy for the prevention of invasive pneumococcal disease in infants and young children. On December 11, 2009, the European Commission granted marketing authorization for Prevenar 13* (Pneumococcal polysaccharide conjugate vaccine [13-valent, adsorbed]) - as it is known outside the United States – for active immunization for the prevention of invasive disease, pneumonia, and acute otitis media caused by 13 S. pneumoniae serotypes in infants and children from 6 weeks to 5 years of

age. To date, Prevnar 13 has been approved for use in infants and young children in 34 countries. Further pediatric regulatory filings for Prevnar 13 are in advanced stages of review in various countries spanning six continents. Prevnar 13 is also being studied in global Phase 3 clinical trials in adults, with regulatory submissions expected in 2010. Prevnar 13 includes the seven serotypes (4, 6B, 9V, 14, 18C, 19F, and 23F) in Prevnar® (Pneumococcal 7-valent Conjugate Vaccine [Diphtheria CRM197 Protein]), plus six additional serotypes (1, 3, 5, 6A, 7F, and 19A). Together, these 13 serotypes are responsible for the majority of remaining invasive pneumococcal disease in infants and young children in the United States. Serotype 19A is now the most common serotype in the United States. The review of Prevnar 13 is based on data from 13 core Phase 3 studies involving more than 7,000 children. Pneumococcal Disease According to a World Health Organization (WHO) 2002 estimate, pneumococcal disease is the leading cause of vaccine-preventable death worldwide in children younger than 5 years. Pneumococcal disease is complex and describes a group of illnesses caused by the bacterium S. pneumoniae. It affects both children and adults and includes invasive infections such as bacteremia/sepsis and meningitis, as well as non-invasive disease including pneumonia and acute otitis media. Indication for Prevnar Prevnar is indicated for active immunization of infants and toddlers against serious invasive disease caused by Streptococcus pneumoniae, including bacteremia (bloodstream infection) and meningitis (infection of the membranes surrounding the brain and spinal cord) caused by the seven serotypes in the vaccine. The seven serotypes (strains) of S. pneumoniae included in the vaccine (4, 6B, 9V, 14, 18C, 19F, and 23F) were the strains that most commonly caused these serious diseases in children prior to the introduction of the vaccine. The routine schedule is 2, 4, 6, and 12 to 15 months of age. Prevnar is also indicated for immunization of infants and toddlers against otitis media (ear infections) caused by the seven serotypes in the vaccine. Protection against ear infections is expected to be less than that for invasive disease. As with any vaccine, Prevnar may not protect all individuals receiving the vaccine from serious invasive disease caused by S. pneumoniae. This vaccine should not be used for treatment of active infection. Important Safety Information for Prevnar In clinical studies, the most frequently reported adverse events included injection site reactions, fever (≥38ºC/100.4ºF), irritability, drowsiness, restless sleep, decreased appetite, vomiting, diarrhea, and rash. Risks are associated with all vaccines, including Prevnar. Hypersensitivity to any vaccine component, including diphtheria toxoid, is a contraindication to its use. Prevnar does not protect 100% of children vaccinated. Immunization with Prevnar does not substitute for routine diphtheria immunization. Pfizer Inc.: Working together for a healthier world™ At Pfizer, we apply science and our global resources to improve health and well-being at every stage of life. We strive to set the standard for quality, safety and value in the discovery, development and manufacturing

of medicines for people and animals. Our diversified global health care portfolio includes human and animal biologic and small molecule medicines and vaccines, as well as nutritional products and many of the world's best-known consumer 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 the world's leading biopharmaceutical company, we also 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, Pfizer has worked to make a difference for all who rely on us. To learn more about our commitments, please visit us at www.pfizer.com. DISCLOSURE NOTICE: The information contained in this release is as of December 30, 2009. 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 infants and young children in the various countries in which the Company's regulatory applications are pending, including the U.S.; the anticipated submission of regulatory applications in various countries in 2010 for a potential indication for Prevnar 13 for use in adults; 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 regulatory applications will be submitted in various countries for a potential indication for Prevnar 13 for use in adults; whether and when the FDA and regulatory authorities in other jurisdictions will approve applications that have been or may be submitted for these potential indications and their decisions regarding labeling and other matters that could affect the availability or commercial potential of these indications; 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, 2008 and in its reports on Form 10-Q and Form 8-K. * Trademark

Pfizer Inc. Media: Gwen Fisher, 484-865-5160 or Investors: Jennifer M. Davis, 212-733-0717