Pfizer’s Prevnar 13® Shown to be Immunogenic in Older Children and Adolescents

Sunday, March 11, 2012 - 11:37pm

Results from Phase 3 Study Presented at the 8th International Symposium on Pneumococci and Pneumococcal Diseases

"As a global leader in pneumococcal disease prevention, we are excited about the potential to further define the clinical utility of Prevnar 13 with the aim of seeking to broaden prevention efforts to additional age groups,"

--(BUSINESS WIRE)--Pfizer Inc. (NYSE:PFE) announced today that data from a Phase 3 study of Prevnar 13®* (Pneumococcal 13-valent Conjugate Vaccine [Diphtheria CRM197 Protein]) met all study endpoints, showing immunogenicity and establishing a safety profile in children and adolescents aged 5 through 17 years. These data, which are being presented today during the 8th International Symposium on Pneumococci and Pneumococcal Diseases (ISPPD) in Iguacu Falls, Brazil, will support planned regulatory submissions seeking to expand the Prevnar 13 label in the United States, the European Union, and other countries around the world.

Vaccine immunogenicity and safety were evaluated in the Phase 3, open-label trial of 598 healthy children, including children aged 5 to 10 years who had previously been vaccinated for the prevention of invasive pneumococcal disease with Prevnar® (Pneumococcal 7-valent Conjugate Vaccine [Diphtheria CRM197 Protein]), the original version of the vaccine, and vaccine-naïve children and adolescents aged 10 through 17 years.

“As a global leader in pneumococcal disease prevention, we are excited about the potential to further define the clinical utility of Prevnar 13 with the aim of seeking to broaden prevention efforts to additional age groups,” says Emilio Emini, PhD, chief scientific officer, Vaccine Research, Pfizer Inc. “While pneumococcal disease most often strikes younger children, older children and adolescents who have certain medical conditions are also at heightened risk for contracting the disease.”

The primary objective of this study was to assess the pneumococcal immune responses induced by Prevnar 13 when measured one month after vaccination in each of the age groups. The safety objective of the study was to evaluate the safety profile of Prevnar 13 as measured by the incidence rates of local reactions, systemic events, and adverse events. The most common adverse events after vaccination were cough, headache, vomiting, fever, sore throat, influenza and sinusitis.

The data (late-breaker poster #881) will be presented at ISPPD during the daily poster viewing sessions.

About Prevnar 13

Prevnar 13, which is based on the scientific foundation and proven experience of Prevnar, offers the broadest coverage of any pneumococcal conjugate vaccine. Prevnar 13 was first introduced for use in infants and young children in December 2009 in Europe and is now approved for such use in more than 110 countries worldwide. The most widely used pneumococcal conjugate vaccine in the world, Prevnar 13 is part of the routine immunization program in more than 50 countries.

To learn more about Pfizer’s commitment to advancing prevention through vaccination, please visit www.pfizer.com/health/vaccines.

Pneumococcal Disease

Pneumococcal disease (PD) is a group of illnesses caused by the bacterium Streptococcus pneumoniae (S. pneumoniae), also known as pneumococcus. It can affect people of all ages, although young children, older adults, and individuals with certain chronic medical conditions are at heightened risk. PD is associated with significant morbidity and mortality. Non-invasive PD includes non-bacteremic pneumonia, otitis media and sinusitis (upper respiratory tract infection) and invasive manifestations of the disease include bacteremia (bacterial infections of the blood) and meningitis (inflammation of the membrane surrounding the spinal cord and brain).

U.S. Indications for Prevnar 13

Prevnar 13® is a vaccine approved for use in children 6 weeks through 5 years for prevention of invasive disease (caused by the 13 strains of Streptococcus pneumoniae included in the vaccine) and ear infections (caused by 7 of the 13 strains). Based upon immune responses to the vaccine, Prevnar 13® is also approved for adults 50 years and older for the prevention of pneumococcal pneumonia and invasive disease caused by the 13 vaccine 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 for Prevnar 13

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. 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. In adults, immune responses to Prevnar 13 were reduced when given with injected seasonal flu vaccine. 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. 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 your child.

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 March 12, 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 a potential indication for Prevnar 13 for use in older children and adolescents, including its potential benefits. Such risks and uncertainties include, among other things, whether and when supplemental applications may be filed with the FDA, the European Medicines Agency or regulatory authorities in other jurisdictions for a potential indication for Prevnar 13 for use in older children and adolescents; whether and when the FDA, the European Medicines Agency and regulatory authorities in other jurisdictions will approve applications that may be submitted for this potential indication and their decisions regarding labelling 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, 2011 and in its reports on Form 10-Q and Form 8-K.

* Prevnar 13 is referred to as Prevenar 13 in most countries outside the United States.

Pfizer Inc. Media : Victoria Davis, 347-558-3455 Chris Loder, 212-733-7897 or Investors: Suzanne Harnett, 212-733-8009