Pfizer Presents Phase 3 Safety And Immunogenicity Data On Prevnar 13® In Adults With HIV

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(BUSINESS WIRE)--Pfizer Inc. (NYSE:PFE) presented today the results from a Phase 3 study demonstrating the immunogenicity, tolerability and safety of Prevnar 13® (Pneumococcal 13-valent Conjugate Vaccine [Diphtheria CRM197 Protein])in adults infected with human immunodeficiency virus (HIV). The results were presented at the 20th Conference on Retroviruses and Opportunistic Infections (CROI) in Atlanta, Ga.

These data support planned regulatory submissions seeking to include data on HIV-infected immunocompromised adults in the Prevnar 13 label in the United States, the European Union, and other countries around the world.

In this study, HIV-infected individuals aged 18 years and older who had been previously vaccinated with at least one dose of the conventional pneumococcal polysaccharide vaccine (PPSV) received three doses of Prevnar 13 given six months apart. An immune response to the serotypes in the vaccine was observed after the first dose of Prevnar 13, and each of the two subsequent doses. The clinical relevance of the level of response is not known. The most common local reaction at the injection site was pain and the most common adverse event after vaccination was headache. Adverse events were generally consistent with those expected in this study population.

“Modern advances in medicine have significantly improved HIV case management, but the threat of infectious diseases to those with weakened immune systems is still prevalent,” said Dr. Raul Isturiz, Pfizer Medicine Development Group and Scientific Affairs, Vaccines. “In fact, people living with HIV are more susceptible to the potentially devastating effects of pneumococcal diseases.”

For adults with HIV, the incidence of invasive pneumococcal disease is significantly higher and the potential of recurrent disease, most of which represents re-infection, is more likely to occur in these individuals.

“These data add to the compelling body of research for Prevnar 13,” said Dr. William Gruber, senior vice president, Pfizer Vaccine Clinical Research and Development. “Pfizer is committed to providing information about this important vaccine across all age groups, especially those with conditions that put them at higher risk of pneumococcal infections, such as those with HIV infection.”

About the Study

Vaccine safety, tolerability and immunogenicity were evaluated in the Phase 3, open-label, single-arm trial of 331 adults with HIV aged 18 years or older. All participants had CD4 cell counts of 200 cells/mm3 or higher and had previously received one or more doses of PPSV. Subjects were stratified equally into two groups, those previously vaccinated with one dose of PPSV and those previously vaccinated with two or more doses of PPSV. Participants received three doses of Prevnar 13 at six months intervals. Local and systemic reactions and adverse events were collected.

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 older adults, young children and individuals with certain chronic medical conditions are at heightened risk. PD is associated with significant morbidity and mortality. Invasive manifestations of the disease include bacteremia (bacteria in the blood) and meningitis (infection of the tissues surrounding the brain and spinal cord).

U.S. Indication for Prevnar 13

Prevnar 13 is a vaccine approved for the prevention of invasive disease caused by 13 S. pneumoniae strains (1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, and 23F) in children 6 weeks through 17 years of age, and in children 6 weeks through 5 years for the prevention of otitis media caused by 7 of the 13 strains (4, 6B, 9V, 14, 18C, 19F, and 23F)

Based upon immune responses to the vaccine, Prevnar 13 is also approved for adults 50 years of age 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

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
For the full prescribing information for Prevnar 13, please click here http://www.pfizer.com/products/#prevnar13

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DISCLOSURE NOTICE: The information contained in this release is as of March 4, 2013. 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 planned regulatory submissions to include data on HIV-infected immunocompromised adults in the Prevnar 13 label, including its potential benefits. Such risks and uncertainties include, among other things, the uncertainties inherent in research and development; whether and when submissions may be made to regulatory authorities for this potential label update for Prevnar 13; decisions by the U.S. Food and Drug Administration, the European Medicines Agency and regulatory authorities in other jurisdictions in which submissions may be made regarding whether and when to approve this potential label update for Prevnar 13 as well as their other decisions regarding labeling and other matters that could affect its availability and 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, 2012 and in its reports on Form 10-Q and Form 8-K.

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

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