Pfizer Presents Phase 3 Safety And Immunogenicity Data On Prevenar 13 In Adults Aged 18 To 49 Years

Saturday, April 27, 2013 - 06:00pm

"We continue to further investigate the use of Prevenar 13 with the aim of broadening prevention efforts to additional populations."

(BUSINESS WIRE)--Pfizer Inc. (NYSE:PFE) presented today the results from a Phase 3 study investigating immunogenicity, tolerability and safety of Prevenar 13* (Pneumococcal polysaccharide conjugate vaccine [13-valent, adsorbed]) in adults 18 to 49 years of age. The study met all primary and secondary objectives and provides the clinical foundation for the Company’s regulatory submission in the European Union (EU) and planned regulatory submissions in the United States (U.S.) and other countries around the world to seek expansion of the use of Prevenar 13 to include adults 18 to 49 years of age. These results were presented at the 23rd European Congress of Clinical Microbiology and Infectious Diseases (ECCMID) in Berlin, Germany.

Data from this study showed that Prevenar 13 was at least as immunogenic in adults 18 to 49 years of age as it is in adults 60 to 64 years of age, as measured one month after vaccination; for adults 18 to 49 years of age, functional antibody responses to all 13 serotypes included in the vaccine were non-inferior to responses in adults 60 to 64 years of age. In the study, Prevenar 13 showed a favorable safety profile and was generally well tolerated. Pain at the injection site was the most frequently observed local reaction. Muscle pain, headache and fatigue were the most common systemic events.

“This important analysis shows the immunogenicity and safety profile following vaccination with Prevenar 13 in adults aged 18 to 49 years. This vaccine has the potential to help prevent pneumococcal disease caused by the Streptococcus pneumoniae

serotypes contained in the vaccine," said lead investigator Dr. Kristina Bryant, associate professor of Pediatrics at the University of Louisville.

Currently, Prevenar 13, or Prevnar 13 as it is called in the U.S., Canada and Taiwan, is approved in more than 120 countries worldwide for use in infants and young children and in more than 80 countries for use in adults 50 years of age and older.

"Pfizer is committed to developing vaccines with the goal of preventing serious disease through every stage of life," said Dr. William Gruber, senior vice president, Pfizer Vaccine Clinical Research and Development. "We continue to further investigate the use of Prevenar 13 with the aim of broadening prevention efforts to additional populations."

This study, titled "Immunogenicity and safety of a 13-valent pneumococcal conjugate vaccine in adults 18-49 years, naïve to 23-valent pneumococcal polysaccharide vaccine," was presented as an ePoster during the session "Streptococcus pneumoniae: Serotypes and Vaccination," at ECCMID 2013 on April 28 at 1:30 p.m. CEST.

Pneumococcal Disease (PD)

Pneumococcal Disease 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).

E.U. Indication for Prevenar 13

Prevenar 13 is approved in the EU for the prevention of invasive disease, pneumonia and acute otitis media caused by S. pneumoniae serotypes (1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, and 23F) in children and adolescents aged 6 weeks to 17 years. It is also approved in the EU for the prevention of invasive disease caused by 13 S. pneumoniae serotypes (single dose) in adults 50 years and older.

U.S. Indication for Prevnar 13

Prevnar 13 is a vaccine approved for children 6 weeks through 17 years of age 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), and for 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 children 6 weeks through 17 years, the most common side effects were tenderness, redness, or swelling at the injection site, irritability, decreased appetite, decreased or increased sleep, and fever. Most commonly reported side effects in children 5 years through 17 years also included hives 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 you or your child
For the full prescribing information for Prevenar 13, please click here http://www.pfizer.com/products/#prevnar13.

Pfizer Inc: Working together for a healthier world™

At Pfizer, we apply science and our global resources to bring therapies to people that extend and significantly improve their lives. We strive to set the standard for quality, safety and value in the discovery, development and manufacture of health care products. Our global portfolio includes medicines and vaccines as well as many of the world's best-known consumer health care 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 one of the world's premier innovative biopharmaceutical companies, we 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, please visit us at

www.pfizer.com.

DISCLOSURE NOTICE: The information contained in this release is as of April 28, 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 a regulatory submission in the European Union (EU) and planned regulatory submissions in other countries to include data on adults 18 to 49 years of age in the Prevnar 13/Prevenar 13 label, including its potential benefits. Such risks and uncertainties include, among other things, the uncertainties inherent in research and development; whether and when regulatory submissions may be made in jurisdictions other than the EU for this potential label update for Prevnar 13/Prevenar 13; decisions by 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/Prevenar 13 as well as their other decisions regarding labeling and other matters that could affect the availability and commercial potential of Prevnar 13/Prevenar 13 for adults 18 to 49 years of age; and competitive developments.

A further description of risks and uncertainties can be found in Pfizer’s Annual Report on Form 10-K/A for the fiscal year ended December 31, 2012 and in its reports on Form 10-Q and Form 8-K.

*Trademark. Prevenar 13 is referred to as Prevnar 13 in the United States.

Pfizer Inc. Media: Victoria Davis, +1 484-865-5194(o) or Investors: Suzanne Harnett, +1 212-733-8009(o)