Pfizer Receives European Approval For Label Update Regarding The Use Of Prevenar 13 In Certain High-Risk Populations

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Label Now Includes Information on Use of Prevenar 13 in Preterm Infants, Children and Adolescents with Sickle Cell Disease, and Adults with HIV Infection

Pfizer Inc. (NYSE: PFE) announced today that the European Commission approved updates to the Summary of Product Characteristics (SmPC) for the company's pneumococcal conjugate vaccine Prevenar 13[*] (pneumococcal polysaccharide conjugate vaccine [13-valent, adsorbed]), regarding its use in certain populations at high risk of pneumococcal disease. The updated label now includes information describing the use of the vaccine in preterm infants, children and adolescents with sickle cell disease who were previously vaccinated with the 23-valent pneumococcal polysaccharide vaccine, and adults with human immunodeficiency virus (HIV) infection who were previously vaccinated with the 23-valent pneumococcal polysaccharide vaccine.

"People with conditions that compromise the immune system, such as HIV, those with sickle cell disease, and infants born prematurely are all at an increased risk of pneumococcal disease," said Luis Jodar, Ph.D., vice president, Vaccines, Global Medicines Development Group and Scientific Affairs, Pfizer. "The Prevenar 13 label in the European Union now includes important information about appropriate use of the vaccine for the prevention of pneumococcal disease for health care professionals who care for these patients."

The decision to approve the SmPC for Prevenar 13 followed the European Medicines Agency's review of data submitted by Pfizer from several studies assessing

immunogenicity and safety of vaccination with Prevenar 13 in these three risk groups. These data are under review by the U.S. Food and Drug Administration.

Prevenar 13 received an expanded indication in the European Union (EU) in July 2013 to include adults aged 18 to 49 years for active immunization for the prevention of invasive disease caused by vaccine-type Streptococcus pneumoniae (S. pneumoniae). Previously approved in the EU for use in infants, young children and adolescents aged 6 weeks to 17 years, and adults 50 years of age and older, Prevenar 13 is now the only pneumococcal vaccine in the EU that offers protection against invasive pneumococcal disease from infancy through adulthood.

“Pfizer is dedicated to improving public health through vaccination, and to supporting health care professionals in their efforts to reduce the impact of pneumococcal disease among those most at risk,” said Susan Silbermann, president, Vaccines at Pfizer.

Preterm Infants

Preterm infants (gestational age 19 to 36 weeks) have an increased risk for pneumococcal disease compared with infants born full term (gestational age 37 to 42 weeks), according to studies. A Phase 4 study of Prevenar 13 administered at 2, 3, 4 and 12 months to approximately 100 preterm infants (born at 26 to 36 weeks) found a less robust immune response among preterm infants compared to term infants. An acceptable safety profile was demonstrated. Adverse events were generally consistent with those expected in this study population.

Sickle Cell Disease

Individuals with sickle cell disease are 30 to 600 times more likely to contract invasive pneumococcal disease than healthy individuals. A Phase 3, open-label, single-arm study evaluated the safety, tolerability and immunogenicity of two doses of Prevenar 13 given six months apart in 158 children and adolescents aged 6 years to 17 years with sickle cell disease who were previously vaccinated with one or more doses of the 23-valent pneumococcal polysaccharide vaccine. The study showed that Prevenar 13 elicited antibody levels after the first dose that were statistically significantly higher when compared with levels prior to vaccination. Antibody levels after the second dose were comparable to those after the first dose. An acceptable safety profile was demonstrated. Adverse events were generally consistent with those expected in this study population.

HIV Infection

HIV-infected individuals are more vulnerable to invasive pneumococcal disease, with an incidence that has been reported to be 6 to 324 times that of uninfected adults. Studies estimating the risk in the current setting of antiretroviral therapy use suggest the risk remains 20 to 40 times higher in HIV-infected adults than the general population.

A Phase 3, open-label, single-arm study assessed the safety, tolerability and immunogenicity of three doses of Prevenar 13 given six months apart in 331 individuals with HIV infection (with a CD4 count of >200 cells/µL, HIV viral load <50,000 copies/mL) aged 18 years or older who had been previously vaccinated with at least one dose of 23-valent pneumococcal polysaccharide vaccine. The study showed that Prevenar 13 elicited antibody levels after the first dose that were statistically significantly higher when compared with levels prior to vaccination. After the second and third doses of Prevenar 13, immune responses were comparable or higher than those after the first dose. An acceptable safety profile was demonstrated. Adverse events were generally consistent with those expected in this study population.

About Pneumococcal Disease

Pneumococcal disease (PD) is a group of illnesses caused by the bacterium S. pneumoniae, also known as pneumococcus. It includes invasive manifestations such as bacteremia (bacteria in the blood) and meningitis (infection of the tissues surrounding the brain and spinal cord), as well as non-invasive infections such as pneumonia. PD can affect people of all ages, but infants and young children, older adults and individuals with immunocompromising or certain chronic medical conditions are at heightened risk of infection.

About Prevenar 13

Prevenar 13, or Prevnar 13 as it is called in the United States, Canada and Taiwan, 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 120 countries worldwide, including the United States and Japan. It is the most widely used pneumococcal conjugate vaccine (PCV) in the world, and more than 575 million doses of Prevenar/Prevenar 13 have been distributed worldwide. In addition, Prevenar 13 is approved for use in adults 50 years of age and older in more than 90 countries, and is also approved in the United States and European Union (EU) for use in older children and adolescents aged 6 to 17 years. Recently, Prevenar 13 was also approved in the EU for use in adults 18 to 49 years of age, making it the only pneumococcal vaccine in the EU approved to help protect against invasive pneumococcal disease from infancy through adulthood.

Indication for Prevenar 13 in Europe

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 18 years of age and older. For the full prescribing information for Prevenar 13 in the EU, please see the Summary of Product Characteristics.

Indication for Prevnar 13 in the United States · 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 percent 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 infants and toddlers 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 Prevnar 13 in the United States, please click here: http://labeling.pfizer.com/ShowLabeling.aspx?id=501.

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DISCLOSURE NOTICE: The information contained in this release is as of October 17, 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 about Prevnar 13/Prevenar 13 that involves substantial risks and uncertainties. Such risks and uncertainties include, among other things, whether and when the U.S. Food and Drug Administration may approve an update to the U.S. label for Prevnar 13 regarding its use in certain high-risk populations.

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.

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[*] Trademark. Prevnar 13® is the trade name in the United States, Canada, and Taiwan.

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