European Medicines Agency Accepts Application Seeking New Indication For Prevenar 13®1 For Prevention Of Pneumococcal Pneumonia In Adults

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Application Includes Data from Pfizer's Community-Acquired Pneumonia Immunization Trial in Adults (CAPiTA)

Pfizer Inc. (NYSE:PFE) announced today that the European Medicines Agency (EMA) has accepted Pfizer's application seeking to expand the indication for Prevenar 13* (pneumococcal polysaccharide conjugate vaccine [13-valent, adsorbed]) in adults to include the prevention of pneumonia caused by the 13 pneumococcal serotypes contained in the vaccine.

"Pneumococcal pneumonia continues to be a serious health problem, causing significant illness and mortality in older adults," said Dr. Emilio A. Emini, senior vice president, Vaccine Research and Development, Pfizer. "The results of the Community-Acquired Pneumonia Trial in Adults study underscore the potential benefits of Prevenar 13 in preventing disease in this age group."

This application is based on the positive results of the landmark Community-Acquired Pneumonia Immunization Trial in Adults (CAPiTA), which demonstrated statistically significant reductions in vaccine-type pneumococcal community-acquired pneumonia (CAP), including non-invasive/non-bacteremic CAP, and invasive pneumococcal disease (IPD) in adults aged 65 and older. Prevenar 13 is currently approved for adults in Europe

for the prevention of invasive pneumococcal disease.

Pfizer also recently submitted a supplemental Biologics License Application to the U.S. Food and Drug Administration (FDA) seeking to add efficacy data regarding the use of Prevnar 13 in older adults to the prescribing information and to meet its commitment under FDA's accelerated approval program. A decision regarding acceptance of this supplement for review by the FDA’s Center for Biologics Evaluation and Research (CBER) is expected by the end of September 2014. Pfizer plans to submit applications in other major markets, including Australia, Canada and Japan, later this year.

About Pneumococcal Disease

Pneumococcal disease refers to a group of illnesses caused by S. pneumoniae bacteria.1 Invasive pneumococcal disease occurs when bacteria enter the bloodstream or another site that is normally sterile.2 Non-invasive pneumococcal pneumonia occurs when the bacteria cause infection in the lungs but are not detected in the blood concurrently.1 In adults, pneumonia is the most common presentation of pneumococcal disease.1 For every one case of invasive pneumococcal pneumonia in adults, it is estimated that at least three cases of non-invasive pneumococcal pneumonia occur.3 While non-invasive forms of pneumococcal disease are typically more common, the invasive types of disease are generally more severe.4

About CAPiTA

As part of its regulatory commitments under the FDA’s accelerated approval program, Pfizer conducted the CAPiTA study (Community-Acquired Pneumonia Immunization Trial in Adults), which was designed to evaluate the efficacy of Prevnar 13 in the prevention of vaccine-type pneumococcal pneumonia. The study showed that Prevenar 13* prevented a first episode of vaccine-type community-acquired pneumonia (CAP) in adults 65 years of age and older, the study’s primary objective. This is one of the largest double-blind, randomized, placebo-controlled vaccine efficacy trials ever conducted in older adults to clearly demonstrate a significant reduction in vaccine-type pneumococcal CAP, and importantly, non-bacteremic/non-invasive vaccine-type pneumococcal CAP. It involved approximately 85,000 subjects aged 65 years and older and was conducted by Julius Clinical, a spin-off of the Julius Center for Health Sciences and Primary Care, a division of the University Medical Center Utrecht in the Netherlands. Fifty-eight sentinel hospitals were used for the surveillance of CAP and IPD. The safety profile of Prevenar 13 observed in the study was consistent with studies previously conducted in adults.

About Prevenar 13

Prevenar 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 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 640 million doses of Prevenar 7-valent/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.

U.S. INDICATIONS FOR PREVNAR 13®

Prevnar 13® is a vaccine approved for adults 50 years of age and older for the prevention of pneumococcal pneumonia and invasive disease caused by 13 Streptococcus pneumoniae strains (1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, and 23F). This indication is based upon immune responses to the vaccine For children 6 weeks through 17 years of age, Prevnar 13® is approved for the prevention of invasive disease caused by the 13 vaccine strains, and for children 6 weeks through 5 years for the prevention of otitis media caused by 7 of the 13 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 (eg, HIV infection, leukemia) may have a reduced immune response 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 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. 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

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

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This release contains forward-looking information regarding Prevnar 13/Prevenar 13, including its potential benefits, and about the CAPiTA trial as well as about an application filed in the EU for a potential new indication for Prevenar 13 in the EU and an application submitted in the U.S. to update the prescribing information for Prevnar 13, that involves substantial risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements. Risks and uncertainties include, among other things, uncertainty concerning the commercial impact of the results of the CAPiTA trial; uncertainty regarding whether and when the CBER will accept and/or approve the application submitted in the U.S.; uncertainty concerning whether and when regulatory authorities in the U.S., the EU and various other jurisdictions will update the label and vaccine technical committees in various jurisdictions will update their recommendations with respect to the use of Prevnar 13/Prevenar 13 in adults based on the results of the CAPiTA trial and other factors; whether and when regulatory submissions may be made in other jurisdictions for Prevenar 13 for the prevention of pneumococcal pneumonia in adults caused by the 13 serotypes in Prevenar 13, and whether and when regulatory authorities in any jurisdictions, including the EU with respect to the application for the potential new indication, will approve any such submissions, as well as their decisions regarding labeling and other matters that could affect the availability and commercial potential of that additional indication for Prevenar 13 in those jurisdictions; 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, 2013 and in our subsequent reports on Form 10-Q, including in the sections thereof captioned “Risk Factors” and “Forward-Looking Information That May Affect Future Results”, as well as in its subsequent reports on Form 8-K, all of which are filed with the SEC and available at www.sec.gov andwww.pfizer.com.

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

1 Centers for Disease Control and Prevention. Pneumococcal disease. In: Atkinson W, Wolfe S, Hamborsky J, eds. Epidemiology and Prevention of Vaccine-Preventable Diseases. 12th ed., second printing. Washington DC: Public Health Foundation, 2012.

2 Musher DM. Streptococcus pneumoniae. In: Mandell GL, Douglas JE, Dolin R, eds. Mandell, Douglas, and Bennett's Principles and Practice of Infectious Diseases. 7th ed. Elsevier: 2010.

3 Said MA, Johnson HL, Nonyane BAS, et al. Estimating the burden of pneumococcal disease among adults: a systematic review and meta-analysis of diagnostic techniques. PLoS ONE. 2013;8(4):e60273.

4 World Health Organization (WHO). Immunization, Vaccines and Biologicals. Pneumoccocal Vaccines. 2003.http://archives.who.int/vaccines/en/pneumococcus.shtml.

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