Pfizer Receives European Approval for New Indication for Prevenar 13 for Prevention of Vaccine-Type Pneumococcal Pneumonia in Adults

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Label Also Updated to Include Data From the Community-Acquired Pneumonia Immunization Trial in Adults (CAPiTA)

Pfizer Inc. (NYSE:PFE) announced today that the European Commission approved an expanded indication for the use of Prevenar 13* (pneumococcal polysaccharide conjugate vaccine [13-valent, adsorbed]) for the prevention of pneumonia caused by the 13 pneumococcal serotypes in the vaccine in adults aged 18 years and older. The Summary of Product Characteristics has also been updated to include efficacy data from Pfizer's landmark Community-Acquired Pneumonia Immunization Trial in Adults (CAPiTA), which demonstrated statistically significant reductions in first episodes of vaccine-type pneumococcal community-acquired pneumonia (CAP), including non-invasive/non-bacteremic CAP, and invasive pneumococcal disease (IPD) in adults aged 65 and older.

"We welcome the approval of this new indication for Prevenar 13 in the EU, which will enable healthcare professionals to help adults reduce their risk of pneumococcal pneumonia caused by the 13 serotypes in the vaccine. This is particularly important for older adults and those with medical conditions that may make them more vulnerable to this serious, debilitating and potentially deadly disease," said Rene Reinert, Vice President, Pfizer Vaccines Medical and Scientific Affairs, Europe. "Pfizer looks forward to working with vaccine technical committees in Europe to discuss this new indication and

the CAPiTA data, as well as potential updates to recommendations for the use of Prevenar 13 in adults.”

Streptococcus pneumoniae, also known as pneumococcus, is the most common bacterial cause of community-acquired pneumonia.1Pneumococcal pneumonia is one of the leading causes of death and hospitalization worldwide.2,3 Pneumococcal pneumonia can be classified as non-invasive, when bacteria cause infection in the lungs but are not detected in the blood concurrently, or invasive, when bacteria also enter the bloodstream (bacteremic pneumonia) or another normally sterile site in the body.4 For every one case of invasive pneumococcal pneumonia in adults, it is estimated that at least three cases of non-invasive pneumococcal pneumonia occur.5 While non-invasive forms of pneumococcal disease are typically more common, the invasive types of disease are generally more severe.6

Pfizer conducted the CAPiTA study (Community-Acquired Pneumonia Immunization Trial in Adults) as part of its regulatory commitments to global regulatory authorities. The results have been submitted to the U.S. Food and Drug Administration and regulatory agencies in other major markets, including Australia and Canada, for inclusion in the product’s labeling.

About CAPiTA (Community-Acquired Pneumonia Immunization Trial in Adults)

This study is one of the largest double-blind, randomized, placebo-controlled vaccine efficacy trials ever conducted in older adults. The study achieved its primary and secondary objectives. It involved approximately 85,000 subjects aged 65 years and older and was conducted by Julius Clinical, an academic research organization affiliated with the University Medical Center Utrecht (UMCU) in the Netherlands. Fifty-nine sentinel hospitals were used for the surveillance of CAP and IPD.

About Prevenar 13

With this approval for Prevenar 13, it is now indicated in the EU for active immunization for the prevention of invasive disease and pneumonia caused by Streptococcus pneumoniae in adults ≥18 years of age and the elderly. 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 750 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, European

Union (EU) and other countries for use in older children and adolescents aged 6 to 17 years.

INDICATIONS FOR PREVNAR 13®

Prevnar 13® is a vaccine approved in the U.S. 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 in the U.S. 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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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 March 3, 2015. 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 regarding Prevnar 13/Prevenar 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, uncertainties concerning the commercial impact of the results of the CAPiTA (Community-Acquired Pneumonia Immunization Trial in Adults) trial and the expanded indication in the EU; uncertainty concerning whether and when regulatory authorities in various other jurisdictions will update the label and whether and when vaccine technical committees in various jurisdictions (other than the U.S. Centers for Disease Control and Prevention’s Advisory Committee on Immunization Practices) 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 additional 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 jurisdictions where such applications are pending or submitted will approve any such submissions, as well as their decisions regarding labeling and other matters that could affect the availability or 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, 2014 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.

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

1 Centers for Disease Control and Prevention. Pneumonia can be prevented - vaccines can help. http://www.cdc.gov/features/pneumonia/. Accessed January 23, 2013.

2 World Health Organization. 23-valent pneumococcal polysaccharide vaccine: WHO position paper. Wkly Epidemiol Rec. 2008 Oct 17;83(42):373-384.

3 Blasi F, Mantero P, Santus P, Tarsia P. Understanding the burden of pneumococcal disease in adults. Clin Microbiol Infect. 2012:18(Suppl. 5):1-8.

4 Centers for Disease Control and Prevention. MMWR Recommendations and Reports. Prevention of pneumococcal disease: Recommendations of the Advisory Committee on Immunization Practices (ACIP). 1997;46(RR-8):1-24.

5 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.

6 World Health Organization. Immunization, vaccines and biologicals. Pneumococcal vaccines. Available at:http://archives.who.int/vaccines/en/pneumococcus.shtml. Accessed October 20, 2014.

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