# Prevenar 13®* Receives CHMP Positive Opinion For Prevention Of Vaccine-Type Pneumococcal Pneumonia in Adults

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Pfizer Inc. (NYSE:PFE) announced today that the European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) has adopted a positive opinion recommending that the indication for Prevenar 13* (pneumococcal polysaccharide conjugate vaccine [13-valent, adsorbed]) be expanded to include the prevention of pneumonia caused by the 13 pneumococcal serotypes in the vaccine in adults 18 years and older. Prevenar 13 is currently approved in Europe for the prevention of invasive pneumococcal disease (IPD) in the same population. The CHMP's positive opinion will now be reviewed by the European Commission (EC). The decision on whether to approve Prevenar 13 for this indication will be made by the EC and will be applicable to all European Union member states plus Iceland, Lichtenstein and Norway.

The CHMP opinion was granted following review of the results from the Community-Acquired Pneumonia Immunization Trial in Adults (CAPiTA). Pfizer conducted this study as part of its regulatory commitments to global regulatory authorities, including the European Medicines Agency. The study achieved its primary and secondary objectives. The primary endpoint evaluated the efficacy of Prevenar 13 for the prevention of a first episode of vaccine-type community-acquired pneumonia (CAP) in adults 65 years of age and older. Secondary endpoints were the prevention of a first episode of vaccine-type non-invasive/non-bacteremic CAP, and prevention of a first episode of vaccine-type IPD in adults aged 65 and older.

This study is one of the largest double-blind, randomized, placebo-controlled vaccine efficacy trials ever conducted in older adults. 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-nine sentinel hospitals were used for the surveillance of CAP and IPD.

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, Canada, Australia 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 it 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. Prevenar 13 is 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 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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DISCLOSURE NOTICE: The information contained in this release is as of January 22, 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 and a potential expanded indication in the European Union to include the prevention of pneumonia caused by the 13 pneumococcal serotypes in the vaccine in adults 18 years and older, including their potential benefits, 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, whether and when the European Commission (the “EC”) may approve the potential expanded indication, as well as the EC’s decisions regarding labeling and other matters that could affect the availability or commercial potential of the potential expanded indication; uncertainties concerning the commercial impact of the results of the CAPiTA

(Community-Acquired Pneumonia Immunization Trial in Adults) trial and the potential expanded indication; uncertainty concerning whether and when regulatory authorities in various jurisdictions will update the label and 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, 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.

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