



Pfizer Receives European Approval for New Multi-Dose Vial Presentation of Prevenar 13®

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Four-Dose Vial Will Help Address Infrastructure Challenges in Developing Countries

NEW YORK--Pfizer Inc. (NYSE:PFE) announced today that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) approved a new four-dose, multi-dose vial (MDV) presentation of Prevenar 13®* (pneumococcal polysaccharide conjugate vaccine [13 – valent, adsorbed]). This new MDV presentation was developed to help maximize efficiency for health care workers by helping to significantly reduce storage requirements and shipping costs in communities with health systems that are still developing.

The MDV presentation of Prevenar 13® offers significant benefits to developing countries, including a 75 percent reduction in:

Temperature-controlled supply chain requirements, United Nations Children’s Fund (UNICEF) shipping costs, and Storage requirements at the national, regional, district, and community levels.

“Prevenar 13® is the first approved pneumococcal conjugate vaccine available in a preserved multi-dose vial presentation,” said Luis Jodar, Ph.D., global vice president, Vaccines, Pfizer Global Medicines Development Group and Medical/Scientific Affairs.

“With this new presentation, a box that once carried enough vaccine to help protect 50 infants and children will potentially vaccinate 200, helping to ensure Prevenar 13® is accessible in the most remote regions of the world where the greatest burden of invasive pneumococcal disease lies.”

Pfizer plans to submit its Prevenar 13® MDV presentation to the World Health Organization (WHO) for prequalification, which, if and when approved, will allow for the

global use of this new presentation of Prevenar 13® by United Nations agencies and countries worldwide that require WHO prequalification. If and when prequalified, the MDV presentation is expected to be introduced under the Advance Market Commitment program in early 2017, for shipment to countries covered by Gavi, the Vaccine Alliance (Gavi). This presentation will be available at a lower price of \$3.10 per dose.

“Prevenar 13® formulated in multi-dose vials was studied in collaboration with the Medical Research Council Unit, The Gambia,” said William Gruber, M.D., Senior Vice President Vaccine Clinical Research and Development. “This multi-dose presentation of Prevenar 13® demonstrated a favorable safety profile and immune responses to help protect children from invasive pneumococcal disease due to serotypes contained in the vaccine.¹”

Pfizer Vaccines in the Developing World

Accelerating the availability of potentially life-saving vaccines around the world is a key component of Pfizer’s commitment to making true inroads toward global health care access. Through its participation in international public-private programs, Pfizer provided its 13-valent pneumococcal conjugate vaccine, Prevenar 13®, to infants and young children in the developing world to help protect against invasive pneumococcal disease. Since 2010, more than 40 low- and lower middle-income countries have launched pneumococcal immunization programs with Prevenar 13®, via the Advance Market Commitment, an innovative program by Gavi, the Vaccine Alliance.² With continued investment in research and development, Pfizer has helped meet the challenges of the developing world by providing innovative manufacturing, storage, inventory management, and supply chain solutions. Pfizer also continues to develop and deliver educational materials to aid health care workers in the field and conducts surveillance studies to understand the impact of pneumococcal immunization programs on reducing the burden of disease. For more information on Pfizer Vaccines in the Developing World, go to http://www.pfizer.com/health/vaccines/developing_world.

About Prevenar 13®

Prevenar 13® (pneumococcal polysaccharide conjugate vaccine [13 – valent, adsorbed]) was first approved for use in the European Union (EU) in December 2009 for use in infants and young children to help protect against invasive pneumococcal disease. Prevenar 13® is now approved for such use in more than 150 countries worldwide, including the United States, Canada, Australia and Japan. Prevenar 13® is the most widely used pneumococcal conjugate vaccine in the world, and is included in the

pediatric National Immunization Programs in 102 countries. In addition, Prevenar 13® is approved for use in adults 50 years of age and older in more than 100 countries. It is also approved in the United States, EU and other countries for use in older children and adolescents aged 6 to 17 years. Prevenar 13® is approved in the EU for use in adults 18 to 49 years of age.

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

INDICATIONS FOR PREVNAR 13®

Pevnar 13® is a vaccine approved for children 6 weeks through 17 years of age for the prevention of invasive disease caused by 13 *Streptococcus 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) Pevnar 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 Pevnar 13® is not 100% effective and will only help protect against the 13 strains included in the vaccine

IMPORTANT SAFETY INFORMATION

Pevnar 13® should not be given to anyone with a history of severe allergic reaction to any component of Pevnar 13® or any diphtheria toxoid-containing vaccine Children and adults with weakened immune systems (eg, 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 In adults, immune responses to Pevnar 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 Pevnar 13®. Only a health care provider can decide if Pevnar 13® is right for you or your child

For the full prescribing information for Pevnar 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. For more information, please visit us at www.pfizer.com. In addition, to learn more, follow us on Twitter at @Pfizer and @Pfizer_News, LinkedIn, YouTube and like us on Facebook at [Facebook.com/Pfizer](https://www.facebook.com/Pfizer).

DISCLOSURE NOTICE: The information contained in this release is as of April 6, 2016. 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 new four-dose, multi-dose vial (MDV) presentation of Prevenar 13® in the EU; uncertainty concerning whether and when regulatory authorities in various other jurisdictions will approve the MDV presentation of Prevnar 13®/Prevenar 13® and other factors; whether and when regulatory submissions may be made in additional jurisdictions for the Prevnar 13®/Prevenar 13® MDV presentation, 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 the Prevnar 13®/Prevenar 13® MDV presentation 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, 2015 and in our subsequent reports on Form 10-Q, including in the sections thereof captioned "Risk Factors" and "Forward-Looking Information and Factors 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 and www.pfizer.com.

1 Data on file. Pfizer Inc, New York, NY. [Clinical Study Report Protocol B4671001]

2 Gavi, the Vaccine Alliance. Advance Market Commitment for Pneumococcal Vaccines: Annual Report. April 1, 2014-March 31, 2015. <http://www.gavi.org/library/documents/amc/2015-pneumococcal-amc-annual-report/>. Accessed March 2, 2016.

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