



# Pfizer Receives World Health Organization Prequalification for Multi-Dose Vial Presentation of Prevenar 13®

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Designation Will Enable Increased Access to Vaccine in World's Poorest Countries

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Pfizer Inc. (NYSE: PFE) announced today that the World Health Organization (WHO) has prequalified its four-dose, multi-dose vial (MDV) presentation of Prevenar 13®\* (pneumococcal polysaccharide conjugate vaccine [13 - valent, adsorbed]). WHO prequalification allows for the global use of Prevenar 13® MDV by United Nations agencies and countries worldwide that require WHO prequalification.

"It is unconscionable that children in developing countries are still falling ill, or dying, by the hundreds of thousands every year from preventable diseases like invasive pneumococcal disease and meningitis," said Orin Levine, director of the vaccine delivery team at the Bill & Melinda Gates Foundation. "We need a range of tools to save children's lives and welcome advances like this one that help improve our ability to prevent life-threatening invasive pneumococcal disease."

"We are pleased that the WHO has prequalified the MDV presentation of Prevenar 13®, another crucial step in providing broader global access to this important vaccine for those who need it," said Susan Silbermann, President and General Manager, Pfizer Vaccines. "Pfizer is committed to continued innovation aimed at meeting the challenges of the developing world and helping to prevent invasive pneumococcal disease by providing a

path for children in resource-limited countries to access a reliable supply of Prevenar 13®.”

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.

The Prevenar 13® MDV presentation includes the preservative 2-Phenoxyethanol, which enables use of the vaccine over a 28-day period following its first use, provided it is stored at 2-8 degrees Celsius. This presentation has been approved in the European Union following the positive opinion from the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) in April 2016.

“It is encouraging to see vaccine manufacturers committed to addressing the unique conditions and challenges experienced by those of us working in communities whose health systems are still developing,” said Dawda Sowe, Program Manager, Expanded Program on Immunization, The Gambia. “The MDV presentation is expected to aid in increasing availability of Prevenar 13®, thereby allowing us to help protect more infants and children against invasive pneumococcal disease.”

The prequalified MDV presentation is expected to be introduced under the Advance Market Commitment (AMC) program in early 2017, for shipment to countries supported by Gavi, the Vaccine Alliance (Gavi). In January 2015, during Gavi’s pledging conference, Pfizer began to prepare for the potential introduction of Prevenar 13® in the MDV presentation by announcing a 20 cent reduction in cost, from \$3.30 per-dose to \$3.10 per-dose, in its MDV per-dose price for Gavi-eligible countries. Once the MDV presentation is introduced under the AMC, this pricing is expected to be available to all Gavi-eligible countries. In addition, expanded availability will enable Gavi-graduated countries to access the same pricing until 2025.

## 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 healthcare access. Through its participation in international public-private programs, Pfizer provides 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.<sup>1</sup> 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 healthcare workers in the field and supports 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](http://www.pfizer.com/health/vaccines/developing_world).

### About Prevenar 13®

Prevenar 13®\*(pneumococcal polysaccharide conjugate vaccine [13 - valent, adsorbed]) was first approved 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 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.<sup>2,3</sup> It is approved in the United States, EU and other countries for use in infants, older children and adolescents aged 6 to 17 years.

In addition, Prevenar 13® is approved for use in adults 50 years of age and older in more than 100 countries. Prevenar 13® is now approved in the U.S., the EU and 44 other countries for use in adults 18 to 49 years of age.

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

### U.S. INDICATIONS FOR PREVNAR 13®

Prevnar 13® is a vaccine approved for adults 18 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) In children 6 weeks through 17 years of age (prior to the 18th birthday), Prevnar 13® is indicated for the prevention of invasive disease caused by *S pneumoniae* serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, and 23F In children 6 weeks through 5 years of age (prior to the 6th birthday), Prevnar 13® is indicated for the prevention of otitis media caused by *S pneumoniae* serotypes 4, 6B, 9V, 14, 18C, 19F, and 23F Prevnar 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. 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, vomiting, 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 healthcare provider about the risks and benefits of Pevnar 13®. Only a healthcare 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/product-detail/prevnar\\_13](http://www.pfizer.com/products/product-detail/prevnar_13).

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](http://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 July 19, 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®, including its potential benefits and the expected timing of the introduction of the four-dose, multi-dose vial (MDV) presentation under the Advance Market Commitment, 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 regarding the commercial impact of the MDV presentation of Prevenar 13®; uncertainty regarding whether the anticipated benefits of the WHO prequalification will be realized; 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 U.S. Securities and Exchange Commission and available at [www.sec.gov](http://www.sec.gov) and [www.pfizer.com](http://www.pfizer.com).

1 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.

2 Data on file. Pfizer Inc, New York, NY. [Total Prevenar 13V Doses Through May 2016]

3 GlaxoSmithKline. GSK's Synflorix™ receives CHMP positive opinion for major label extension. July 27, 2015. <http://www.gsk.com/en-gb/media/press-releases/2015/gsk-s-synflorix-receives-chmp-positive-opinion-for-major-label-extension/>. Accessed July 7, 2016.

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