



# Young Children In Developing World Receive Accelerated Access to Pfizer's Prevenar 13 Vaccine

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Nicaragua is First Developing Country to Launch Historic Immunization Program Against a Leading Killer of Young Children

"This innovative new model is poised to drive accelerated access to potentially lifesaving vaccines for millions of children in the world's poorest countries, where PD exacts its greatest toll," (BUSINESS WIRE)--Pfizer Inc. (NYSE: PFE) announced that Prevenar 13\* (Pneumococcal polysaccharide conjugate vaccine [13-valent, adsorbed]) was introduced into the first childhood immunization program for pneumococcal disease (PD) in the developing world under the auspices of the Advance Market Commitment (AMC) when Nicaragua launched its program today. The AMC is an innovative program which involves private-public partnerships to help make newer vaccines available on a sustainable, affordable and accelerated basis to the least developed countries.

"Pfizer remains steadfast in its commitment to accelerate global access to its vaccines and medicines; public-private partnerships such as those that underpin the AMC are a great example of how to make critical progress in that area," says Mark Swindell, president, Pfizer Vaccines. "It truly is historic to see a new vaccine such as Prevenar 13 launched in a developing country within one year of its introduction in the U.S. and Europe, given the previous average 15-year gap between introduction of new vaccines in developed and developing countries."

Prevenar 13 provides coverage against the 13 most prevalent invasive pneumococcal disease-causing strains (1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, and 23F) in infants and young children worldwide. Prevenar 13 is the only pneumococcal conjugate vaccine available under the AMC that is prequalified by the World Health Organization (WHO) for use in children through 5 years of age and to help prevent pneumonia caused by the 13 serotypes contained in the vaccine.

## About the AMC

In March 2010, Pfizer entered into a 10-year agreement to provide Prevenar 13 to infants and young children in the world's poorest countries under the terms of the AMC for pneumococcal disease.

A new approach to public health funding, the AMC, which is administered by the GAVI Alliance, is designed to procure vaccines specifically for least developed countries. In this pilot AMC for PD, the governments of Italy, the United Kingdom, Canada, the Russian Federation and Norway as well as the Bill and Melinda Gates Foundation, the World Bank, and GAVI have committed financing.

In addition, this novel program is a reflection of the dedication and commitment of organizations such as the GAVI Alliance, the World Bank and other public health organizations.

"This innovative new model is poised to drive accelerated access to potentially lifesaving vaccines for millions of children in the world's poorest countries, where PD exacts its greatest toll," adds Mr. Swindell. "It's a great example of how creative partnerships can result in solutions for some of the most pressing public health issues."

## Pneumococcal Disease

PD is complex and describes a group of illnesses, all caused by the bacterium *Streptococcus pneumoniae* (*S. pneumoniae*). It includes invasive infections such as bacteremia and meningitis, as well as non-invasive disease including pneumonia and acute otitis media.

Prevenar 13 is marketed in the United States as Prevnar 13 (Pneumococcal 13-valent Conjugate Vaccine [Diphtheria CRM197 Protein]). In the United States, Prevnar 13 is not indicated for the prevention of pneumonia.

## Indication for Prevnar 13® in the United States

In the United States, Prevnar 13 is a vaccine approved for use in children 6 weeks through 5 years of age (prior to the sixth birthday). Prevnar 13 is indicated for active immunization for the prevention of invasive disease caused by 13 strains of *S. pneumoniae* (1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, and 23F). Prevnar 13 is also indicated for the prevention of otitis media (ear infection) caused by seven strains of *S. pneumoniae* (4, 6B, 9V, 14, 18C, 19F, and 23F). No efficacy data for ear infections are available for strains 1, 3, 5, 6A, 7F, and 19A.

#### World Health Organization Indication for Prevenar 13\*

Earlier this year, the World Health Organization (WHO) prequalified Prevenar 13 for active immunization of infants and children from 6 weeks through five years of age against invasive disease, pneumonia and otitis media caused by the 13 pneumococcal serotypes (1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F and 23F) contained in the vaccine. WHO prequalification allows for the procurement of Prevenar 13 by United Nations agencies. The prequalification is for global use of the vaccine in a single-dose vial.

#### Important Safety Information for Prevnar 13® in the United States

Prevnar 13 should not be given to anyone with a severe allergic reaction to any component of Prevnar 13, Prevnar® (Pneumococcal 7-valent Conjugate Vaccine [Diphtheria CRM197 Protein]), or any diphtheria toxoid-containing vaccine.

Prevnar 13 may not protect all individuals receiving the vaccine.

Protection against ear infections is expected to be less than that for invasive disease.

Children with weakened immune systems may have a reduced immune response to Prevnar 13.

A temporary pause of breathing following vaccination has been observed in some infants born prematurely.

The most commonly reported serious adverse events include bronchiolitis (an infection of the lungs) (0.9%, 1.1%), gastroenteritis (inflammation of the stomach and small intestine) (0.9%, 0.9%), and pneumonia (0.9%, 0.5%) for Prevnar 13 and Prevnar, respectively.

The most common side effects are redness, swelling and tenderness at the injection site, fever, decreased appetite, irritability, increased sleep, and decreased sleep. Any side effects associated with the vaccination should be reported to your child's health care

provider.

Ask your child's health care provider about the risks and benefits of Prevnar 13. Only a health care provider can decide if Prevnar 13 is right for your child.

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At Pfizer, we apply science and our global resources to improve health and well-being at every stage of life. We strive to set the standard for quality, safety and value in the discovery, development and manufacturing of medicines for people and animals. Our diversified global health care portfolio includes human and animal biologic and small molecule medicines and vaccines, as well as nutritional products and many of the world's best-known consumer 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 the world's leading biopharmaceutical company, we also 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 about our commitments, please visit us at [www.pfizer.com](http://www.pfizer.com).

**DISCLOSURE NOTICE:** The information contained in this release is as of December 12, 2010. 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 that involves substantial risks and uncertainties regarding Prevenar 13, including its potential benefits; and the success of the AMC project for vaccines. Such risks and uncertainties include, among other things, the uncertainties inherent in research and development; whether and when regulatory authorities in countries where regulatory applications for Prevenar 13 may be pending or may be submitted will approve such applications and their decisions regarding labeling and other matters that could affect its availability or commercial potential; 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, 2009, and in its reports on Form 10-Q and Form 8-K.

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