# Pfizer Signs New Agreement With UNICEF To Supply A Total Of Up To 740 Million Doses Of Prevenar 13\* For The World's Poorest Countries Through 2025

Monday, July 29, 2013 - 02:00am

"Pfizer is dedicated to broadening vaccine access and helping to improve health outcomes around the world, and we're proud to make Prevenar 13 available through the AMC program"

NEW YORK--(BUSINESS WIRE)--Pfizer Inc. (NYSE:PFE) welcomes today's announcement from the GAVI Alliance regarding the signing of a new supply agreement for Pfizer to provide additional doses of Prevenar 13\* (Pneumococcal Polysaccharide Conjugate Vaccine [13-valent, adsorbed]), the company's 13-valent pneumococcal conjugate vaccine, for use in infants and young children to help protect against pneumococcal disease <sup>1</sup> in the world's poorest countries under the terms of the Advance Market Commitment (AMC). Pneumococcal disease is one of the leading causes of vaccine-preventable deaths worldwide in children younger than 5 years of age. <sup>2</sup> Prevenar 13 is a vaccine that helps protect against the 13 strains of pneumococcal disease that are included in the vaccine. In the United States, it is known as Prevnar 13 and is used for the prevention of invasive pneumococcal disease in infants and young children.

The AMC is an innovative public health financing mechanism designed to accelerate global rollout of vaccines in the world's poorest countries and is administered by the GAVI Alliance, a global health partnership committed to saving children's lives by increasing access to immunization. Under the terms of the new supply agreement, Pfizer has committed to supply the United Nations Children's Fund (UNICEF) with up to 260 million doses of Prevenar 13, at a reduced tail price, over the course of the agreement period (through 2025). This is in addition to 480 million doses of the vaccine already committed through the first two Supply Agreements. The tail price is the reduced price per dose set by the manufacturer and paid by GAVI; the remaining amount is paid by the AMC.

Pfizer will offer Prevenar 13 through the AMC at the reduced price of \$3.40 per dose for the remainder of this year, at which time the price will further decrease to \$3.30 per dose for the remainder of the agreement. This pricing will apply to doses purchased under all AMC Supply Agreements.

"Pfizer is dedicated to broadening vaccine access and helping to improve health outcomes around the world, and we're proud to make Prevenar 13 available through the AMC program," said Susan Silbermann, president, vaccines at Pfizer. "Strong vaccination programs are a cornerstone of economic development – a simple intervention that has dramatic short and long term impact on health. Since first offering Prevenar 13 through the

AMC in 2010, we have continued to support this revolutionary public health program that helps those most in need of potentially lifesaving vaccinations."

Pfizer entered into the first Supply Agreement to participate in the AMC in March 2010, and then expanded its commitment through a second Supply Agreement in 2011, pledging to supply Prevenar 13 through 2023. Since Pfizer's original agreement with the AMC in 2010, more than 20 countries have introduced Prevenar 13 into their immunization programs,<sup>3</sup> and pneumococcal vaccines are expected to reach more than 50 GAVI-supported countries by 2015.<sup>3</sup> 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. Prevenar 13 is also approved for use in children six weeks to 17 years old and adults 18 and older in Europe and certain other countries. In the United States, Prevnar 13 (Pneumococcal 13-valent Conjugate Vaccine [Diphtheria CRM197 Protein]) is not indicated for the prevention of pneumococcal pneumonia in the pediatric population and is not approved for adults 18 through 49 years of age.<sup>5</sup>

Prevenar 13 is the most widely used pneumococcal conjugate vaccine in the world, and more than 500 million doses of Prevenar/Prevenar 13 have been distributed worldwide. Prevenar 13 offers the broadest serotype coverage of any currently available pneumococcal conjugate vaccine for prevention of pneumococcal disease. 1,5

### **About Advance Market Commitments (AMCs)**

The AMC is a public-private health funding mechanism administered by the GAVI Alliance that is designed to create a sustainable marketplace, ensure an affordable and stable supply of newer vaccines at a steeply discounted price and stimulate the development and expansion of manufacturing capacity for vaccines specifically for the world's poorest countries.

Donors commit funds to guarantee the price of vaccines once they have been developed. These financial commitments provide vaccine manufacturers with the incentive they need to invest in vaccine research and development, and to expand manufacturing capacity. In exchange, companies sign a legally-binding commitment to provide the vaccines at a price affordable to developing countries in the long term. For more formation on AMCs, please go to www.vaccineamc.org.

### **Pneumococcal Disease**

Pneumococcal disease is a group of illnesses caused by the bacterium *Streptococcus pneumoniae* (*S. pneumoniae*), also known as pneumococcus. It can affect people of all ages, although older adults, young children and individuals with certain chronic medical conditions are at heightened risk. The World Health Organization estimates that more than 1.6 million people —including more than 800,000 children younger than 5 years of age —die every year from pneumococcal infections. Nearly all these deaths occur in the world's poorest countries. Pneumococcal disease includes invasive infections such as bacteremia (bacteria in the blood) and meningitis (infection of the tissues surrounding the brain and spinal cord), as well as noninvasive disease such as pneumonia and acute otitis media (middle ear infection).

### **U.S. Indication for Prevnar 13**

• Prevnar 13 is a vaccine approved for children 6 weeks through 17 years of age for the prevention of invasive disease caused by 13 *S. 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)

- Based upon immune responses to the vaccine, Prevnar 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
- 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 (e.g., 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. Most commonly reported side effects in children 5 years through 17 years also included hives
- 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
- 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 or your child

For the full prescribing information for Prevnar 13, please click here <a href="http://www.pfizer.com/products/#prevnar13">http://www.pfizer.com/products/#prevnar13</a>

# Pfizer Inc: Working together for a healthier world $^{\text{TM}}$

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. To learn more, please visit us at www.pfizer.com.

\*Trademark. Prevenar 13 is referred to as Prevnar 13 in the United States, Canada and Taiwan.

## **References:**

1. Prevenar 13 Global Summary of Product Characteristics (SmPC). <a href="http://www.ema.europa.eu/docs/en\_GB/document\_library/EPAR\_--">http://www.ema.europa.eu/docs/en\_GB/document\_library/EPAR\_--</a>\_Product\_Information/human/001104/WC500057247.pdf.

- 2. World Health Organization (WHO). 23-valent pneumococcal polysaccharide vaccine. WHO Position Paper. Wkly Epidemiol Rec. 2008;83(42):373-384.
- 3. GAVI Alliance. 2013 Pneumococcal AMC Annual Report. http://www.gavialliance.org/library/documents/amc/2013-pneumococcal-amc-annual-report/
- 4. Pfizer Data on File (DOF).
- 5. Prevnar 13 USPI. 2013. http://www.pfizer.com/products/#prevnar13.
- 6. Centers for Disease Control and Prevention. Prevention of Pneumococcal Disease: Recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR Recommendations and Reports. 1997;46(RR-8):1-24.
- 7. World Health Organization (WHO). Pneumococcal Vaccines. 2003. Available at <a href="http://www.who.int/vaccines/en/pneumococcus.shtml">http://www.who.int/vaccines/en/pneumococcus.shtml</a>. Accessed February 9, 2011.
- 8. National Institute of Allergy and Infectious Diseases (NIAID). Pneumococcal Disease. 2009. Available at <a href="http://www.niaid.nih.gov/topics/pneumococal/Pages/Pneumococcal/Pneumococcal/Pneumoco

Pfizer Inc. Media: Kim Bencker, 610-329-1340 (m) Kim.Bencker@pfizer.com or Investor: Suzanne Harnett, 212-733-8009 (o) Suzanne.Harnett@pfizer.com