Pfizer Signs Long-Term Agreement To Supply Prevenar 13* To The World's Poorest Countries

Tuesday, March 23, 2010 - 12:30am

(BUSINESS WIRE)--Pfizer Inc. (NYSE:PFE) today announced it has signed a 10-year Provisional Supply Agreement to supply Prevenar 13* (Pneumococcal Polysaccharide Conjugate Vaccine [13-valent, adsorbed]), the company's 13-valent pneumococcal conjugate vaccine, for infants and young children in the world's poorest countries under the terms of the Advance Market Commitment (AMC) pilot project against pneumococcal disease. The AMC is a novel public-private approach to public health funding designed to create a sustainable marketplace, ensure a stable supply of pneumococcal vaccines and stimulate the development and expansion of manufacturing capacity of vaccines specifically for the world's poorest countries.

"Pfizer is dedicated to broadening access around the world to our medicines, and public-private partnerships such as the one involving the AMC are critical to achieving true inroads on this front," says Jeffrey Kindler, chairman and chief executive officer of Pfizer Inc. "Last year, working with GAVI, we contributed the first pneumococcal conjugate vaccine used in a national immunization program in the developing world, and we are proud to extend our commitment even further to young children in the world's poorest countries by participating in the AMC."

The agreement is the final step in the AMC procurement process which is administered by the United Nations Children's Fund (UNICEF) and supported by GAVI. The agreement is subject to prequalification by the World Health Organization and AMC eligibility designation, which are both expected later this year.

Under the terms of the agreement, the price of the pneumococcal conjugate vaccine under the AMC framework is $7.00 for the first several years. The vaccine price will include a $3.50 subsidy to be paid by the AMC donor fund, and $3.50 to be paid by GAVI

with a co-financing contribution paid by the developing country governments that introduce the vaccine.

Importantly, under the current AMC framework, participating vaccine manufacturers must make a binding commitment to supply vaccine for 10 years at a maximum “tail” price of $3.50 per dose to meet long-term demand and ensure affordability of the vaccine in developing countries even after the donor contributions are exhausted.

“I applaud the groundbreaking milestone achieved today by vaccine manufacturers, developing country governments, donors, the World Bank, and the GAVI Alliance that has made the most advanced pneumococcal conjugate vaccines available to the world's neediest young children at affordable prices and faster than ever before,” says Orin Levine, executive director, International Vaccine Access Center at Johns Hopkins University. ”This year, the Advance Market Commitment will begin helping to save lives and improve the health of infants and young children in Africa.”

Pfizer Increasing Manufacturing Capability to Help Ensure Supply

Prevenar 13 has been approved for use in infants and young children in more than 40 countries. In addition, regulatory filings for Prevenar 13 for pediatric use are in advanced stages of review in various countries. To meet the growing global demand for Prevenar 13, Pfizer is increasing its manufacturing capabilities to help ensure product supply through a combination of capital investment, process improvements and efficiency measures throughout the supply network.

Prevenar 13 includes the seven serotypes (4, 6B, 9V, 14, 18C, 19F, and 23F) in Prevenar* (Pneumococcal Saccharide Conjugated Vaccine, Adsorbed) – the standard in pneumococcal disease prevention in infants and young children – plus six additional serotypes (1, 3, 5, 6A, 7F, and 19A). Together, these serotypes represent the most prevalent invasive disease-causing strains in young children worldwide. Both Prevenar and Prevenar 13 use CRM197 – a carrier protein that has been used in various approved pediatric conjugate vaccines for more than 20 years.

About Advance Market Commitments (AMCs)

A new approach to public health funding, AMCs are designed to procure vaccines specifically for least developed countries. The pilot AMC is for vaccines that prevent pneumococcal disease.

In the AMC pneumococcal disease pilot, the governments of Italy, the United Kingdom, Canada, Russia and Norway as well as the Bill and Melinda Gates Foundation, have committed US$1.5 billion, with GAVI promising to allocate US$1.3 billion through 2015. Companies that wish to participate in the AMC must make legally binding long-term commitments to supply these vaccines at affordable and sustainable prices for certain GAVI-eligible countries after the donor funds are spent.

The GAVI Alliance hopes to assist up to 60 of the world's poorest countries, following required regulatory approvals, to introduce pneumococcal conjugate vaccines that meet a target product profile by 2015. Early estimates suggest this pilot project could prevent more than seven million childhood deaths by 2030. For more formation on AMCs, please go to www.vaccineamc.org.

Pneumococcal Disease

According to a World Health Organization (WHO) 2002 estimate, pneumococcal disease is the leading cause of vaccine-preventable death worldwide in children younger than 5 years. Pneumococcal disease is complex and describes a group of illnesses, all caused by the bacterium S. pneumoniae. It affects both children and adults and includes invasive infections such as bacteremia/sepsis and meningitis, as well as non-invasive disease including pneumonia and acute otitis media.

Indication for Prevenar 13 Outside the United States

Prevenar 13 is indicated for the prevention of invasive disease, pneumonia, and otitis media caused by Streptococcus pneumoniae serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, and 23F in infants and children from 6 weeks to 5 years of age.

Prevenar 13 is marketed in the United States as Prevnar 13TM (Pneumococcal 13-valent Conjugate Vaccine [Diphtheria CRM197 Protein]).

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 Streptococcus 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 7 strains of Streptococcus pneumoniae (4, 6B, 9V, 14, 18C, 19F, and 23 F). No efficacy data for ear infections are available for strains 1, 3, 5, 6A, 7F, and 19A.

IMPORTANT SAFETY INFORMATION FOR PREVNAR 13™

Prevnar 13™ should not be given to anyone with a severe allergic reaction to any component of Prevnar 13, Prevnar® 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 common side effects are redness, swelling and tenderness at the injection site, fever, decreased appetite, irritability, increased sleep, and decreased sleep.

Indication for Prevnar®

Prevnar® is indicated for active immunization of infants and toddlers against serious invasive disease caused by Streptococcus pneumoniae, including bacteremia (bloodstream infection) and meningitis (infection of the membranes surrounding the brain and spinal cord) caused by the seven serotypes in the vaccine. The seven serotypes (strains) of S. pneumoniae included in the vaccine (4, 6B, 9V, 14, 18C, 19F, and 23F) were the strains that most commonly caused these serious diseases in children prior to the introduction of the vaccine. The routine schedule is 2, 4, 6, and 12 to 15 months of age.

Prevnar® is also indicated for immunization of infants and toddlers against otitis media (ear infections) caused by the seven serotypes in the vaccine. Protection against ear infections is expected to be less than that for invasive disease.

As with any vaccine, Prevnar® may not protect all individuals receiving the vaccine from serious invasive disease caused by S. pneumoniae. This vaccine should not be used for treatment of active infection.

IMPORTANT SAFETY INFORMATION FOR PREVNAR®

In clinical studies, the most frequently reported adverse events included injection site reactions, fever (≥38ºC/100.4ºF), irritability, drowsiness, restless sleep, decreased appetite, vomiting, diarrhea, and rash.

Risks are associated with all vaccines, including Prevnar®. Hypersensitivity to any vaccine component, including diphtheria toxoid, is a contraindication to its use. Prevnar® does not protect 100% of children vaccinated. Immunization with Prevnar® does not substitute for routine diphtheria immunization.

Pfizer Inc.: Working together for a healthier world™

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.

DISCLOSURE NOTICE: The information contained in this release is as of March 23, 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 for use

in infants and young children in the various countries in which the Company's regulatory applications are pending; the potential benefits of Prevenar 13; 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 such countries will approve applications that have been or may be submitted for this potential indication and their decisions regarding labeling and other matters that could affect the availability or commercial potential of these indications; 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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