



Pfizer's Prevenar 13® Receives Approval For Use in Infants and Children in China

Wednesday, November 02, 2016 - 02:45am

Prevenar 13® is Approved to Help Protect Infants and Children Aged Six Weeks to Fifteen Months from Invasive Pneumococcal Disease

Pfizer China announced today that it has received approval from the Chinese Food and Drug Administration (CFDA) to market its pneumococcal 13-valent conjugate vaccine, Prevenar 13®, in China for active immunization for the prevention of invasive diseases (including bacteremic pneumonia, meningitis, septicemia, and bacteremia) caused by *Streptococcus pneumoniae* (*S. Pneumoniae*) serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, and 23F in infants and children aged 6 weeks to 15 months. *S. pneumoniae* is the most common cause of invasive disease as well as pneumonia and upper respiratory tract infections.

Pneumococcal disease is a leading cause of vaccine-preventable deaths globally in children under five years old¹. In China alone, approximately 30 thousand children in this age group die due to pneumococcal diseases every year².

"We applaud the efforts of CFDA and other relevant Chinese government agencies to bring new medicines and vaccines to the Chinese healthcare system," said Dr. Xiaobin Wu, President of Pfizer China. "Pfizer is committed to working closely with the CFDA in these efforts, and also looks forward to partnering with the Chinese government to help improve the lives of patients and people of all ages in China."

In China, the recommended Prevenar 13® immunization series is a primary series administered at 2, 4 and 6 months of age with a fourth (booster) dose administered at approximately 12~15 months of age.

About Streptococcus Pneumoniae

Pneumococcus (also known as Streptococcus pneumoniae) is widely colonized in the human nasopharynx, with a carrier rate of 27% - 85%; infants and young children are the main carrier and transmission group³. Pneumococcus can be spread through respiratory droplets. Vaccination in children is critical as their immune systems are still developing during the first years of life, leaving them more susceptible to infectious diseases⁴. Serious sequelae such as deafness, developmental delay and even death can be associated with invasive pneumococcal disease⁵. Due to the increasingly serious problem of multi-drug resistance to pneumococcus, the clinical treatment of pneumococcus related diseases has also become more difficult⁶.

Pneumococcal disease is a leading cause of vaccine-preventable deaths in children under 5 years old globally and in China⁷. In view of the large public health problem caused by pneumococcal disease, the World Health Organization (WHO) has prioritized vaccination against this disease worldwide⁸.

About Prevenar 13®

Prevenar 13® is the most widely used pneumococcal conjugate vaccine in the world, and is included in the pediatric National Immunization Programs of numerous countries in the Asia Pacific region such as Australia, Hong Kong, Japan, and Taiwan^{9,10}. Prevenar 13® will only protect against Streptococcus pneumoniae serotypes included in the vaccine, and will not protect against serotypes not present in the vaccine or other microorganisms that cause invasive disease, pneumonia, or otitis media.

Pprevnar 13® is the trade name in the United States, Canada, and Taiwan.

U.S. IMPORTANT SAFETY INFORMATION

Pprevnar 13® should not be given to anyone with a history of severe allergic reaction to any component of Pprevnar 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. Only a healthcare provider can decide if Pprevnar 13® is right for an individual.

For the full prescribing information for Prevnar 13®, please click here 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, we have worked to make a difference for all who rely on us. We routinely post information that may be important to investors on our website at www.pfizer.com. In addition, to learn more, please visit us on www.pfizer.com and follow us on Twitter at @Pfizer and @PfizerNews, 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 November 2, 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 about Prevnar 13/Prevenar 13, including its potential benefits, 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 success of Prevnar 13/Prevenar 13; the uncertainties inherent in research and development, including the ability to meet anticipated clinical trial completion dates and regulatory submission dates, as well as the possibility of unfavorable clinical trial results; whether and when any applications that are pending or that may be filed may be approved by regulatory authorities, which will depend on the assessment by such regulatory authorities of the benefit-risk profile suggested by the totality of the efficacy and safety information submitted; decisions by regulatory authorities regarding labeling and other matters that could affect the availability or commercial potential of Prevnar 13/Prevenar 13; and competitive developments.-5-

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 its 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 and www.pfizer.com.

#

1 WHO Centers for Disease Control and Prevention. Pneumococcal disease. In: Atkinson W, Wolfe S, Hamborsky J, eds. Epidemiology and Prevention of Vaccine-Preventable Diseases. 12th ed. Washington, DC: Public Health Foundation; 2011:233-248. Available at: <http://www.cdc.gov/vaccines/pubs/pinkbook/pneumo.html>. Accessed January 28, 2015.

2 O'Brien KL, et al. Burden of disease caused by Streptococcus pneumoniae in children younger than 5 years: global estimates. Lancet. 2009; 374(9693): 893-902.

3 Lynch JP 3rd, et al. Semin Respir Crit Care Med. 2009;30(2): 189-209.

4 Offit P, Quarles J, Gerber M, et al. Addressing Parents' Concerns: Do Multiple Vaccines Overwhelm or Weaken the Infant's Immune System? Pediatrics. 2002;109:124-129.

5 Pneumococcal Disease - Symptoms and Complications, Centers for Disease Control and Prevention. <http://www.cdc.gov/pneumococcal/about/symptoms-complications.html>

6 Chin J. Epidemiol. November 2012, Vol 33, No. 11.

7 Levine OS, Liu G, Garman RL, Dowell SF, Yu S, Yang YH. Haemophilus influenzae type b and Streptococcus pneumoniae as causes of pneumonia among children in Beijing, China. Emerg Infect Dis. 2000. 6(2): 165-70

8 WHO. Meeting of the immunization Strategic Advisory Group of Experts, November 2007 -conclusions and Recommendations. Wkly Epidemiol Rec, 2008;83:1-16.

9 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.

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

Media: Sally Beatty, 347-330-7867 sally.beatty@pfizer.com