



**NEWS RELEASE**  
**For Immediate Release**

**Pfizer's Prevenar 13 Receives Approval to Extend Protection against Pneumococcal Disease in Adults**

*Prevenar 13 vaccine now protects adults 50 years and older against Pneumococcal Pneumonia and Invasive Diseases.*

- *Malaysians now have the option of protecting themselves from Pneumococcal Disease with the latest vaccine that uses conjugate technology.*
- *This is the first Pneumococcal Conjugate Vaccine indicated for adults 50 years and older.*
- *Due to the rapidly ageing population in Asia, adults are at increased risk of Pneumococcal Disease.*

**KUALA LUMPUR, 12 November 2012** – Pfizer's Pneumococcal Conjugate Vaccine, Prevenar 13, is now indicated for adults 50 years of age and older for active immunisation for the prevention of pneumonia and invasive disease caused by the *Streptococcus pneumoniae* (*S. Pneumoniae*) bacteria<sup>1</sup>. This approval coincides with U.S. FDA's approval of the new indication for the vaccine in January 2012 that was based on safety and immunogenicity studies involving approximately 6,000 adults 50 years of age and older. Administered as a single dose, it provides long term protection from pneumococcal disease.

The bacterium behind pneumococcal disease, *S. Pneumoniae*, is a leading cause of community-acquired pneumonia, otitis media (inner ear infection), meningitis (inflammation of the brain lining) and bacteremia (blood infection)<sup>2</sup>. It can be life threatening, yet it is significantly under-recognised globally, including Malaysia. Pneumonia is the most common form of pneumococcal disease and is one of the leading causes of morbidity amongst adults in Asia<sup>3</sup>.

According to the latest World Health Organization (WHO) data published in April 2011, influenza and pneumonia deaths in Malaysia reached 9,417 or 9.20% of total

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<sup>1</sup> Product Information, Pneumococcal Polysaccharide Conjugate Vaccine (adsorbed), 13-valent. CDS ver 9.0 dated 22 August 2012, UK SPC dated 27<sup>th</sup> March 2012 and Australian PI dated 28 Oct 2011 (for adult indication only).

<sup>2</sup> Centers for Disease Control and Prevention. Prevention of pneumococcal disease: recommendations of the Advisory Committee on Immunization Practices (ACIP). *MMWR*. 1997;46(RR-8):1-24.

<sup>3</sup> Song J-H et al. Clinical and economic burden of community-acquired pneumonia amongst adults in the Asia Pacific region. *Int J Antimicrob Agents* (2011), doi: 10.1016/j-ijantimicag.2011.02.017

deaths – influenza and pneumonia is the number three killer behind coronary heart disease and stroke. Globally, pneumococcal disease has been recognised as a leading cause of death in adults – in 2002, there were 896,000 deaths in adults worldwide due to pneumococcal disease<sup>4 5</sup>.

The FDA and European Commission have both approved the extended use of pneumococcal conjugate 13-valent vaccine. Prevenar 13 uses conjugate technology which activates several pathways into the immune system, and is believed to induce immune memory which helps the immune system remember the infection and provide sustained protection against it<sup>6</sup>.

More recently, the World Health Organization (WHO) granted an expansion to the prequalification of Prevenar 13 for its new indication for adults. “Prevenar 13 is the first and only pneumococcal conjugate vaccine to be granted WHO prequalification in the adult population,” said Country Manager of Pfizer Malaysia and Brunei, Angel Choi. “This expanded designation will allow for broader global access to the vaccine and bring another prevention option to adults 50 years and older in developing nations.” Age is a primary risk factor for pneumococcal disease and as Malaysia sees an increasing population of elderly people<sup>7</sup>, it is crucial to support the healthy ageing of older adults.

Ms Choi continued to address the disease burden of pneumonia in Asia, “It is a challenge to treat pneumococcal disease in adults in Asia due to the lack of public awareness on how the disease affects the elderly. Pfizer hopes that with the expanded indication, Prevenar 13 can help prevent pneumococcal disease amongst the elderly to reduce the burden of disease.” Asia is and will continue to be home to a dominant share of the world’s population. According to a United Nations report, the proportion of elderly citizens (aged 60 years and below) in Asia will increase from 9.9% in 2010 to 23.6% in 2050<sup>8</sup>, highlighting the importance of preventing pneumonia in the elderly. The number of adults aged 65 years and below is expected to grow by more than 250% in many developing countries, including Philippines, Malaysia, India and Bangladesh<sup>9</sup>.

Pneumococcal disease can affect people of all ages, but children younger than five and adults 65 years of age and older are at an increased risk<sup>10 11</sup>. As people age, the functionality of their immune systems starts to decline<sup>6</sup>. Due to this gradual decline, people face increasing risk of infection as they get older<sup>6</sup>. Caretakers and

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<sup>4</sup> World Health Organisation (WHO). 23 valent pneumococcal polysaccharide vaccine. WHO Position paper. Wkly Epidemiol Rec. 2008,83 (42): 373 – 384.

<sup>5</sup> World Health Organization (WHO). WHO Global Immunization data 2008.

<sup>6</sup> Pfizer Data on File (DOF). Adult Prevenar 13 USPI. 2011.

<sup>7</sup> Weinberger B, Herndler-Brandstetter D, Schwanninger A, et al. Biology of immune responses to vaccines in elderly persons. *Clin Infect Dis*. 2008; 46: 1078-1084

<sup>8</sup> United Nations. World population prospects: the 2008 revision. Highlights. United Nations; 2009. Selected tables. <http://esa.un.org/unpd/wpp2008/pdf/WPP2008 Selected Tables 1.pdf>.

<sup>9</sup> Kinsella K, He W. *US Census Bureau, International Population Reports, P95/09-1, An Aging World 2008*, US Government Printing Office: Washington DC; 2009.

<sup>10</sup> Centres for Disease Control and Prevention. Prevention of Pneumococcal disease: recommendations of the advisory committee on immunization practices (ACIP). *Morb. Mortal Wkly Rep*. 1997;46 (RR-8): 1-24.

<sup>11</sup> World Health Organisation. International Travel and Health. Chapter 6. Vaccine-preventable diseases and vaccines. 2010.

grandparents who spend a lot of time with pre-school children especially are susceptible to getting infected as pneumonia is spread through contact with infected respiratory secretions<sup>12</sup>.

The risk of pneumococcal disease in adults aged 50 and older also increases due to common conditions such as chronic heart, lung (including COPD and asthma), renal or liver disease, cancer, diabetes, or other risk factors such as smoking, alcoholism and living conditions such as long-term care residency<sup>3 6 13</sup>. Additionally Hajj and Umrah pilgrims over the age of 50 are prone to contracting pneumonia during Hajj. Research confirms that pneumonia is the largest cause of hospitalisation of Hajj pilgrims during Hajj season amounting to more than 19.7 percent hospitalisation rate<sup>14</sup>. The risk of pneumococcal disease is also extended to those suffering from respiratory tract infections (LRTIs)<sup>15</sup> – LTRIs are the third leading cause of death in the world<sup>16</sup>.

“Pneumococcal disease is the number one vaccine-preventable cause of death in the world. Advancements in the area of pneumococcal research has upgraded the pneumococcal vaccine to now be available against the 13 most common strains of bacteria which causes 80-92% of invasive pneumococcal disease nationwide. We at Pfizer are very delighted that this protection can now be extended to the elderly, a generation of people that deserve the best care we can offer them.” said Ms Choi.

### **About Prevenar 13 and Conjugate Technology**

It uses a conjugate technology that links pneumococcal polysaccharide sugar chains found on the surface of each bacterial serotype with a carrier protein. Prevenar 13 uses the carrier protein CRM<sub>197</sub>, which has more than 20 years of clinical and commercial use in vaccines. Prevenar 13 is not intended to be used for treatment of active infection.

### **Pneumococcal Disease**

Pneumococcal disease is a group of infections caused by the bacterium *Streptococcus pneumoniae*, also known as pneumococcus. The most common manifestation of PD in adults 50 years of age and older is non-bacteremic pneumococcal pneumonia, a non-invasive form of the disease. PD also causes invasive infections, such as bacteremia and meningitis, in adults.

### **About Pfizer Malaysia**

Pfizer Malaysia is committed towards Working Together for a Healthier World™. We apply our global resources and strive to set the standard for quality, safety and value of medicines to improve the health and well-being of Malaysians at every stage of life. Our diversified health care portfolio includes human biologic, small molecule

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<sup>12</sup> Adapted from “Patient Information: Pneumonia in Adults (Beyond the Basics)”. Available at: <http://www.uptodate.com/contents/pneumonia-in-adults-beyond-the-basics>. Accessed on 3 October 2012.

<sup>13</sup> CDC. Prevention of Pneumococcal Disease: Recommendations of the Advisory Committee on Immunisation Practices (ACIP). <http://www.cdc.gov/mmwr/preview/mmwrhtml/00047135.htm>.

<sup>14</sup> Adapted from “Vaccination during Hajj, Umrah, Pfizer launches awareness campaign on Pneumonia” Available at : <http://www.brecorder.com/business-a-economy/189/1242773/>. Accessed on 3 October 2012.

<sup>15</sup> Hak E et al. Arch Intern Med 2005; 165: 274-80

<sup>16</sup> WHO Global Burden of Disease Report, 2004 update.

[http://who.int/healthinfo/global\\_burden\\_disease/GBD\\_report\\_2004update\\_full.pdf](http://who.int/healthinfo/global_burden_disease/GBD_report_2004update_full.pdf).

medicines and vaccines in Biopharmaceuticals, as well as a wide range of Nutritional products.

We also collaborate closely with public and private health care providers, and communities to support and expand access to reliable, affordable health care in Malaysia. Pfizer Malaysia began operations in 1964, and every day, some 500 colleagues throughout the country work to advance wellness and make a difference for all who rely on us.

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