

Pfizer's Prevnar13 receives FDA approval

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Pfizer has announced that the U.S. Food and Drug Administration (FDA) has granted approval for the expansion of the company's pneumococcal conjugate vaccine, Prevnar 13 (Pneumococcal 13-valent Conjugate Vaccine [Diphtheria CRM197 Protein]), for use in older children and adolescents aged 6 years through 17 years. It states its use for active immunization for the prevention of invasive disease caused by the 13 *Streptococcus pneumoniae* serotypes contained in the vaccine. For this age group, Prevnar 13 is administered as a one-time dose to patients who have never received Prevnar 13. The vaccine was earlier approved for the age group of 6 weeks through 5 years of age.

Prevnar 13 was first introduced for use in infants and young children in December 2009 in Europe and in February 2010 in the U.S. and it is now approved for such use in nearly 120 countries worldwide. It is the most widely used pneumococcal conjugate vaccine in the world, and more than 500 million doses of Prevnar/Prevnar 13 have been distributed worldwide. Currently, Prevnar 13 is included as part of a national or regional immunization program in more than 60 countries, offering coverage against invasive pneumococcal disease to nearly 30 million children per year.

Ms Susan Silbermann, president, vaccines, Pfizer has said, "As a global leader in pneumococcal disease prevention, extending the impact of Prevnar 13 to older children and adolescents aged 6 through 17 years is a reflection of our dedication to improving public health worldwide. We continue to work tirelessly to make this vaccine available to people at risk for invasive pneumococcal disease."

The FDA approval followed submission and review of a Phase 3, open-label trial of Prevnar 13 in 592 older children and adolescents, including those with asthma.² The study met all endpoints, demonstrating immunogenicity and establishing a safety profile in children aged 6 years through 17 years consistent with the safety profile established in previous trials in infants and young children.

Prevnar 13 is also approved for use in adults 50 years of age and older in more than 80 countries and it is the first and only pneumococcal vaccine to be granted World Health Organization prequalification in the adult population.