



NEWS RELEASE

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Wyeth Receives Positive Opinion from European Regulators for its 13-valent Pneumococcal Candidate Vaccine for Infants and Young Children

September 28, 2009 – Wyeth Pharmaceuticals, a division of Wyeth (NYSE: WYE), announced today that the European Medicines Agency’s (EMA) Committee for Medicinal Products for Human Use (CHMP) has issued a positive opinion for the company’s pneumococcal conjugate vaccine, PCV13 (Prevenar 13*) (Pneumococcal Polysaccharide Conjugate Vaccine [13-valent Adsorbed]). The CHMP recommends approval of PCV13 for active immunization of children aged 6 weeks to 5 years for the prevention of invasive pneumococcal disease, as well as pneumonia and otitis media (middle ear infection) caused by 13 pneumococcal serotypes.¹ The CHMP’s opinion



for PCV13 will now be forwarded to the European Commission and a final decision is expected in the coming months.

“The CHMP’s positive opinion brings us one step closer to providing infants and young children in Europe with the broadest serotype coverage of any pneumococcal conjugate vaccine,” says Emilio Emini, Ph.D., Executive Vice President, Vaccine Research and Development, Wyeth Pharmaceuticals. “PCV13 builds on the scientific foundation of our currently available vaccine³ and, if approved in Europe, will provide coverage for the 13 most prevalent pneumococcal-disease causing serotypes⁴, including serotype 19A, which has emerged as a serious public health threat in Europe and around the world.⁵”

The candidate PCV13 vaccine is designed to provide the broadest serotype coverage of any pneumococcal conjugate vaccine. It contains the seven serotypes (4, 6B, 9V, 14, 18C, 19F and 23F)³ included in Wyeth’s currently available vaccine, plus six additional serotypes (1, 3, 5, 6A, 7F and 19A) that are responsible for the greatest remaining burden of invasive disease.⁵

Both Wyeth’s currently available vaccine and PCV13 use CRM₁₉₇ – an immunological carrier protein with a 20-year history of use in paediatric vaccines.

To date, the company has submitted paediatric license applications for PCV13 in more than 50 countries spanning six continents. PCV13 has been approved in two countries with Chile being the first in July. PCV13 is also being studied in global Phase 3 clinical trials in adults.



Pneumococcal Disease

According to the World Health Organization (WHO), pneumococcal disease is the leading cause of vaccine-preventable death worldwide in children younger than 5 years and is estimated to cause up to 1 million deaths worldwide in children each year.⁷

Pneumococcal disease is complex and describes a group of illnesses, all caused by the bacterium *Streptococcus pneumoniae*.⁸ Pneumococcal disease affects both children and adults,² and includes invasive infections such as bacteremia/sepsis and meningitis, as well as pneumonia and acute otitis media.⁸

Wyeth Pharmaceuticals

Wyeth Pharmaceuticals, a division of Wyeth, has leading products in the areas of women's health care, infectious disease, gastrointestinal health, central nervous system, inflammation, transplantation, haemophilia, oncology, vaccines and nutritional products.

Wyeth is one of the world's largest research-driven pharmaceutical and health care products companies. It is a leader in the discovery, development, manufacturing and marketing of pharmaceuticals, vaccines, biotechnology products, nutritionals and non-prescription medicines that improve the quality of life for people worldwide. The Company's major divisions include Wyeth Pharmaceuticals, Wyeth Consumer Healthcare and Fort Dodge Animal Health.

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The statements in this press release that are not historical facts are forward-looking statements that are subject to risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements. In particular, clinical trial data are subject to differing interpretations, and the views of regulatory agencies, medical and scientific experts and others may differ from ours. There can be no assurance that the European Commission will grant final approval to PCV13 or that PCV13* will be commercially successful or receive regulatory approval in other markets such as the United States. Other risks and uncertainties that could cause actual results to differ materially from those expressed or implied by forward-looking statements include, among others, risks related to our proposed merger with Pfizer, including satisfaction of the conditions of the proposed merger on the proposed timeframe or at all, contractual restrictions on the conduct of our business included in the merger agreement, and the potential for loss of key personnel, disruption in key business activities or any impact on our relationships with third parties as a result of the announcement of the proposed merger; the inherent uncertainty of the timing and success of, and expense associated with, research, development, regulatory approval and commercialisation of our products and pipeline products; government cost-containment initiatives; restrictions on third-party payments for our products; substantial competition in our industry, including from branded and generic products; emerging data on our products and pipeline products; the importance of strong performance from our principal products and our anticipated new product introductions; the highly regulated nature of our business; product liability, intellectual property and other litigation risks and environmental liabilities; the outcome of government investigations; uncertainty regarding our intellectual property rights and those of others; difficulties associated with, and regulatory compliance with respect to, manufacturing of our products; risks associated with our strategic relationships; global economic conditions; interest and currency exchange rate fluctuations and volatility in the credit and financial markets; changes in generally accepted accounting principles; trade buying patterns; the impact of legislation and regulatory compliance; risks and uncertainties associated with global operations and sales; and other risks and uncertainties, including those detailed from time to time in our periodic reports filed with the Securities and Exchange Commission, including our current reports on Form 8-K, quarterly reports on Form 10-Q and annual report on Form 10-K, particularly the discussion under the caption “Item 1A, Risk Factors” in our Annual Report on Form 10-K for the year ended 31 December, 2008, which was filed with the Securities and Exchange Commission on 27 February, 2009. The forward-looking statements in this press release are qualified by these risk factors. We assume no obligation to publicly update any forward-looking statements, whether as a result of new information, future developments or otherwise.*



References

- ¹ Prevenar 13* SmPC 2009. Data on File.
- ² Centers for Disease Control and Prevention. Invasive pneumococcal disease in children 5 years after conjugate vaccine introduction-eight states, 1998-2005. *MMWR*. 2008; 57:144-148.
- ³ PCV13-ISS, 2009 Data on File.
- ⁴ PCV13 Common Technical Document Summaries (CTDS).
- ⁵ Pneumococcal Global Serotype Project. Summary report of stage1/version 1 analysis. Available at:
http://www.preventpneumo.org/pdf/GSP%20Summary%20for%20SAGE%20Nov6-8%202007_Oct%2019-07.pdf. Accessed January 20, 2009.
- ⁶ Data on File
- ⁷ World Health Organization. Pneumococcal conjugate vaccine for childhood immunization, March 2007 – WHO position paper. *Wkly Epidemiol Record*. 2007; 12:93-104.
- ⁸ Centers for Disease Control and Prevention. Pneumococcal Disease. *CDC Pink Book*. 2008; 15:217-230.
- ⁹ Ruckinger S, von Kries R, Siedler A, van der Linden M. Association of serotype of *Streptococcus pneumoniae* with risk of severe and fatal outcome. *Pediatr Infect Dis J*. 2009; 28:118-22.
- ¹⁰ Hausdorff WP. The roles of pneumococcal serotypes 1 and 5 in paediatric invasive disease. *Vaccine*. 2007; 25:2406-12.
- ¹¹ Isaacman D, McIntosh ED, Reinert RR. Burden of invasive pneumococcal disease and serotype distribution among *Streptococcus pneumoniae* isolates in young children in Europe: Impact of the seven-valent pneumococcal conjugate vaccine and considerations for future conjugate vaccines. Draft paper. 2009.
- ¹² Martens P, Westring Worm S, Lundgren B et al. Serotype-specific mortality from invasive *Streptococcus pneumoniae* disease revisited. *BMC Infectious Diseases*. 2004; 4:21:1471-2334.
- ¹³ Hausdorff W, Bryant J, Paradiso P. Which pneumococcal serogroups cause the most invasive disease: Implications for conjugate vaccine formulation and use, part 1. *Clinical Infect Dis*. 2000; 20:100-21.