



## NEWS RELEASE

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### **Wyeth Submits European Marketing Authorization Application for its 13-Valent Vaccine for the Prevention of Pneumococcal Disease in Infants and Young Children**

*Approval sought for investigational vaccine for protection against the 13 most prevalent serotypes associated with serious pneumococcal disease*

**Collegeville, Pa., December 3, 2008** – Wyeth Pharmaceuticals, a division of Wyeth (NYSE:WYE), announced today that it has submitted a marketing authorization application (MAA) to the European Medicines Agency (EMA) for approval to market its investigational 13-valent pneumococcal conjugate vaccine (PCV13) for infants and young children. Wyeth is seeking an indication for the prevention of pneumococcal disease (PD) caused by the 13 serotypes included in the investigational vaccine in infants and children from two months to five years of age. The review of the MAA will be coordinated by the EMA for all 27 countries in the European Union, as well as Norway, Iceland and Liechtenstein.

PCV13 includes the 13 most prevalent pneumococcal serotypes associated with serious PD. Seven of these (4, 6B, 9V, 14, 18C, 19F and 23F) are included in Prevenar™ (Pneumococcal saccharide conjugated vaccine, adsorbed) – the current global standard in PD prevention in infants and young children. The six additional serotypes (1, 3, 5, 6A, 7F and 19A) are associated with the greatest burden of remaining invasive disease. Both Prevenar (also known as PCV7) and PCV13 use CRM<sub>197</sub> – an immunological carrier protein with a 20-year history of use in pediatric vaccines.

“Today’s submission is an important milestone for Wyeth and underscores the company’s commitment to help protect current and future generations from serious pneumococcal disease,” says Emilio Emini, Ph.D., Executive Vice President, Vaccine Research and Development, Wyeth Pharmaceuticals. “Since its introduction, Prevenar has had a substantial impact on public health, dramatically reducing the rate of invasive pneumococcal disease where it is routinely used. Our

investigational 13-valent pneumococcal conjugate vaccine is designed to broaden protection, with the potential to cover up to 92 percent of invasive pneumococcal disease in infants and young children worldwide.”

The PCV13 submission to EU regulators includes data from 12 Phase 3 studies, involving more than 7,000 infants and young children. Data from these studies have demonstrated that, for the pneumococcal serotypes common to both vaccines, the immunogenicity of PCV13 is comparable to that of Prevenar™ using a pre-determined set of immunological criteria. In addition, PCV13 elicits antibacterial functional antibodies to the six additional serotypes. These observations indicate that PCV13 may be as effective as Prevenar in helping to prevent invasive pneumococcal disease (IPD) due to the seven shared serotypes in the vaccines and may also be effective in helping to prevent IPD due to the six additional serotypes. The results also showed that the safety and tolerability of PCV13 and Prevenar are comparable, and that PCV13 can be administered with other commonly used pediatric vaccines.

Earlier this year, the U.S. Food and Drug Administration (FDA) granted Fast Track designation to PCV13 for infants and toddlers. Fast Track designation is designed to facilitate review of products for serious or life-threatening conditions for which there is an unmet medical need. The Company expects to complete its U.S. filing for pediatric use of the vaccine in the first quarter of 2009, while initiating other pediatric filings in the near term. PCV13 is also being studied in global Phase 3 clinical trials in adults, with regulatory filings expected in 2010.

### **Pneumococcal Disease**

Pneumococcal disease affects both children and adults, and is a leading cause of illness and death worldwide. Pneumococcal disease describes a group of illnesses, all caused by the bacterium *Streptococcus pneumoniae*, that include invasive infections such as bacteremia/sepsis and meningitis, as well as pneumonia and otitis media. Most recently, the pneumococcal serotype 19A, which is included in the candidate vaccine, has been increasing in prevalence in many regions of the world and is frequently resistant to antibiotics.

Due to the significant burden of pneumococcal disease and demonstrated vaccine efficacy, the World Health Organization (WHO) recommends the priority inclusion of PCV7 in national childhood immunization programs worldwide.

### **Important Safety Information for Prevenar™ (PCV7)**

In clinical studies (n=18,168) in children, the most frequently reported adverse events included injection site reactions, fever ( $\geq 38^{\circ}\text{C}/100.4^{\circ}\text{F}$ ), irritability, drowsiness, restless sleep, decreased appetite, vomiting, diarrhea, and rash. Risks are associated with all vaccines, including Prevenar™. Hypersensitivity to any vaccine component, including diphtheria toxoid, is a contraindication to its use. Prevenar does not provide 100% protection against vaccine serotypes or protect

against nonvaccine serotypes. The frequency of pneumococcal serotypes and serogroups can vary from country to country, which could influence the effectiveness of the vaccine in any given country.

### **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, hemophilia, 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.

*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. The Phase 3 clinical trial data publicly presented to date reflect only four of the core Phase 3 studies of PCV13 in the pediatric population and, accordingly, do not represent the totality of data and other information that may affect regulatory review and commercialization of PCV13. There can be no assurance that our regulatory submissions for PCV13 will be accepted for review by regulatory agencies or that PCV13 will ever receive regulatory approval or be successfully developed and commercialized. Other risks and uncertainties that could cause actual results to differ materially from those expressed or implied by forward-looking statements include, without limitation, the inherent uncertainty of the timing and success of, and expense associated with, research, development, regulatory approval and commercialization 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; 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; economic conditions including interest and currency exchange rate fluctuations; 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 December 31, 2007, which was filed with the Securities and Exchange Commission on February 29, 2008. 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.*

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