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## **FDA APPROVES BOOSTRIX® A NEW U.S. VACCINE FOR ADOLESCENTS AGAINST PERTUSSIS**

### *Pertussis (Whooping Cough), A Highly Contagious Disease On The Rise in U.S. Teens*

PHILADELPHIA, PA, May 3, 2005 – GlaxoSmithKline (NYSE: GSK) today announced that its booster vaccine, Boostrix® [Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine, Adsorbed (Tdap)] received approval from the United States (U.S.) Food and Drug Administration (FDA). *Boostrix* is indicated to be given as a single dose to individuals aged 10 to 18 years thereby adding a pertussis component to the routine tetanus/diphtheria booster currently administered to teens. Previously, there was no pertussis vaccine approved for use in the United States in children seven years of age or older. Immunity from childhood vaccination generally begins to wear off after five to 10 years, leaving many adolescents susceptible to this highly contagious disease.

“The introduction of *Boostrix* marks a milestone in the fight against pertussis in the United States, particularly among adolescents who are an important reservoir for the disease and often the source of infection for infants,” said Gary Marshall, M.D., professor of Pediatrics, University of Louisville School of Medicine, Louisville, Kentucky. “Adding pertussis to the current tetanus and diphtheria booster shot for teens is a logical strategy to prevent this disease in adolescents – without additional injections.”

Reported cases of pertussis have risen nearly 20-fold since 1976. According to the Centers for Disease Control and Prevention (CDC), there were almost 20,000 cases in 2004 – the highest number of reported cases in more than 40 years.

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In addition, experts believe the disease is underreported and estimate that the true incidence of the disease in the United States may be greater than one million cases per year. Adolescents aged 10 – 19 are being hit particularly hard, with almost 40 percent of cases reported to the CDC in 2004 occurring in this age group. Alarming, there was a 743 percent increase in reported adolescent pertussis cases in the last decade. Teens, in whom classic signs and symptoms of pertussis are often absent, may go undiagnosed and be the source of infection for susceptible family members.

"GlaxoSmithKline is proud to introduce *Boostrix* in the United States," said Barbara Howe, M.D., vice president, Clinical Research and Development and Medical Affairs, Vaccines North America, GlaxoSmithKline. "*Boostrix* is approved in many other countries, and we believe that this vaccine, which adds a pertussis component to the routine tetanus/diphtheria booster currently recommended for adolescents, will be an important tool in preventing pertussis among teens – a population in which there is a significant disease burden."

#### **Boostrix [Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine, Adsorbed (Tdap)] Clinical Trials**

In making its decision, the FDA reviewed several clinical trials which included safety and immunogenicity data from one pivotal trial, which studied *Boostrix* in approximately 3,000 adolescents in the United States, aged 10 to 18. The Phase III clinical trial showed *Boostrix* to be comparable to a U.S.-licensed Td vaccine [Tetanus and Diphtheria Toxoids for Adult Use] with regard to overall safety and immunogenicity. In addition, the use of *Boostrix* induced anti-pertussis antibody levels which were non inferior to those observed in infants following a primary immunization series with a DTaP vaccine (Infanrix<sup>®</sup>) [Diphtheria and Tetanus Toxoids and Acellular Pertussis Vaccine Adsorbed] in whom efficacy against pertussis disease was demonstrated in a previous study. As compared to *Infanrix*, the ratio of geometric mean antibody levels to pertussis antigens following the use of *Boostrix* ranged from 1.9 to 7.3.

In this observer-blinded, randomized, controlled, multi-center clinical trial, 4,114 healthy 10-18 year-olds were vaccinated with one dose of *Boostrix* or a U.S.-licensed Td vaccine. Each subject had completed his or her routine childhood vaccinations against diphtheria, tetanus and pertussis according to the U.S. recommended schedule. According to study results:

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- In both treatment groups,  $\geq 99.9$  percent of subjects had anti-diphtheria and anti-tetanus concentrations  $\geq 0.1$  IU/ml, indicating seroprotection against diphtheria and tetanus
- In the *Boostrix* treatment group, the levels of anti-pertussis antibodies, anti-PT, anti-FHA and anti-PRN were found to be non inferior to pertussis antibody concentrations observed in infants, following primary immunization with a DTaP vaccine (Infanrix<sup>®</sup>), in whom efficacy against pertussis disease was previously demonstrated
- The overall safety profile was comparable between the *Boostrix* and Td groups

### **About Pertussis**

Pertussis, commonly known as “whooping cough,” is a highly contagious bacterial infection of the respiratory system that causes spasms of severe coughing. Up to 90 percent of non-vaccinated susceptible household members may develop the disease when exposed to people infected with pertussis.

It is spread through airborne droplets of an infected person’s cough or sneeze. The first symptoms of pertussis are similar to the “common cold” with a mild fever, runny nose and a cough. Symptoms generally progress to more severe coughing episodes, often with a high-pitched “whoop,” followed by vomiting. Adolescents generally exhibit different symptoms of the disease, often without the classic “whoop,” making it difficult to diagnose. However, for these older pertussis sufferers, severe coughing episodes can lead to vomiting, a hernia, or even a broken rib. These severe coughing episodes can last more than 100 days. While pertussis is threatening to all, this highly contagious disease can be deadly in infants who are too young to be fully immunized.

Although the disease is usually less severe in adolescents, morbidity can be considerable. In interviews with 314 adolescents with confirmed pertussis, a total of 83 percent of the adolescents missed a mean of 5.5 days from school, and 38 percent of the adolescents were still coughing at the time of the interview, which occurred an average of 106 days after cough onset.

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In addition to the public health threat pertussis poses, the disease also has economic repercussions. A cost-benefit analysis for the use of a pertussis booster vaccine in adolescents projected that vaccination of people in the U.S. ages 10-19 during a 10-year period would prevent up to 1.8 million cases of pertussis and save as much as \$1.6 billion in direct and indirect costs.

### **About Diphtheria and Tetanus**

Diphtheria is a serious disease that results in the death of approximately five to 10 percent of infected persons, with higher death rates (up to 20 percent) in persons younger than five and older than 40 years of age. Symptoms may include malaise, sore throat and low-grade fever. As the disease progresses, a membrane can form over the airway and result in respiratory obstruction which can lead to death. Other complications may include heart failure and paralysis. Most cases of diphtheria occur among unvaccinated or inadequately vaccinated persons.

Tetanus (lockjaw) is a severe, often fatal disease. The bacteria that cause tetanus are widely found in soil and the manure of many animals. Almost all reported cases of tetanus are in persons who have either never been vaccinated, or who completed a primary series, but have not had a booster in the preceding 10 years. Infants of unvaccinated mothers are at risk for neonatal tetanus. Early symptoms are lockjaw, stiffness in the neck and abdomen, and difficulty swallowing. Later symptoms may include fever, elevated blood pressure and severe muscle spasms.

### **About Boostrix®**

*Boostrix* is indicated as a booster vaccination for the prevention of tetanus, diphtheria and pertussis as a single dose in individuals 10 –18 years of age. *Boostrix* can be given if at least five years have elapsed since the last recommended series of childhood diphtheria, tetanus and pertussis vaccine. In clinical studies, adverse events included injection-site pain, headache, and fatigue. As with other vaccines, rare adverse events may occur.

**GlaxoSmithKline: A Leader in Vaccines**

GlaxoSmithKline, with U.S. operations in Philadelphia, PA, and Research Triangle Park, N.C., is one of the world's leading research-based pharmaceutical and healthcare companies and is committed to improving the quality of human life by enabling people to do more, feel better and live longer.

**Forward-Looking Statements**

*Under the safe harbor provisions of the US Private Securities Litigation Reform Act of 1995, the company cautions investors that any forward-looking statements or projections made by the company, including those made in this Announcement, are subject to risks and uncertainties that may cause actual results to differ materially from those projected. Factors that may affect the Group's operations are described under 'Risk Factors' in the Operating and Financial Review and Prospects in the company's Annual Report on Form 20-F for 2004.*

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