



## **FOR IMMEDIATE RELEASE**

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## **GLAXOSMITHKLINE SUBMITS BIOLOGICS LICENSE APPLICATION FOR FDA APPROVAL OF BOOSTRIX™**

***New Vaccine Candidate Would Boost Protection Against Pertussis (Whooping Cough) – The Only Disease On The Rise in the United States for Which Children Are Routinely Vaccinated***

PHILADELPHIA, PA, July 7, 2004 – GlaxoSmithKline (NYSE: GSK) today announced it has submitted a Biologics License Application (BLA) for *Boostrix*™ [Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine, Adsorbed (Tdap)], to the United States (U.S.) Food and Drug Administration (FDA). GlaxoSmithKline is seeking U.S. marketing approval for the booster vaccine candidate, a similar formulation of which is available in Australia and a number of countries in Europe, South America and Asia, as a vaccination against the diseases diphtheria, tetanus and pertussis. Currently, pertussis vaccination in the U.S. is available only to children below the age of seven. *Boostrix* was developed to offer extended protection against pertussis to adolescents between the ages of 10 and 18 by combining a pertussis vaccine with the routine tetanus/diphtheria booster.

Cases of pertussis have increased since the mid-1970s. In fact, pertussis is the only disease for which children are routinely vaccinated that is currently on the rise in the U.S., with approximately 10,000 cases in 2003 – the highest number of cases reported to the Centers for Disease Control and Prevention (CDC) in more than 35 years. According to the CDC, from 1997 to 2000, about one-third of all reported pertussis cases occurred in adolescents 10 years of age or older. Adolescents, in whom classic signs and symptoms of pertussis are often absent, may go undiagnosed and be the source of infection for susceptible infants and other family members.

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“We are delighted that our efforts to develop a Tdap vaccine have resulted in filing a BLA with the FDA. GlaxoSmithKline is seeking approval for this new booster vaccine which would help address a large unmet need and offer important protection against pertussis where the disease is growing the most – the adolescent population,” said Barbara Howe, M.D., vice president, Clinical Research and Development and Medical Affairs, Vaccines North America, GlaxoSmithKline.

### **Whooping Cough Cases Reach Highest Level in 35 Years**

Pertussis, commonly known as “whooping cough,” is a highly contagious bacterial infection of the respiratory system that causes spasms of severe coughing. 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 dry cough. Symptoms generally progress to more severe coughing episodes, often with a high-pitched whoop, followed by vomiting. These severe coughing spells can last for more than two months. A person experiencing these severe coughing spells may become blue in the face, and infants may actually stop breathing for a few seconds. 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. While pertussis is threatening to all, this highly contagious disease can be deadly in infants who are too young to be fully immunized.

Pertussis also causes significant morbidity resulting in prolonged cough illness and lost days of school for adolescents. The economic costs of pertussis disease, including visits to the emergency room and occasional hospitalization, along with antibiotics prescribed and days lost from school or work are considerable.

Reported cases of pertussis – once a common childhood illness – dropped dramatically after routine childhood immunization was introduced in the 1940s. However, reports of pertussis in the U.S. have been rising since the mid-1970s. There were approximately 10,000 cases in 2003 – the highest

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number of reported cases in more than 35 years. Pertussis, significantly under-reported and under-recognized, is a common cause of prolonged cough illness in adolescents and adults. In fact, in a clinical study involving 442 adolescents and adults who had a cough-related illness for more than seven days, approximately 20 percent of these patients had laboratory-documented pertussis.

“Pertussis is a serious and growing public health threat with recent outbreaks occurring nationwide, particularly among adolescents,” said Dr. Kathryn Edwards, professor of pediatrics, Division of Infectious Diseases, Vanderbilt University School of Medicine. “Adolescents are an important reservoir for the disease and often the source of infection for infants. Immunity from childhood vaccination generally wanes after five to 10 years, leaving many adolescents susceptible to this serious and highly contagious disease. 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 – and may help reduce the risk of transmission to infants.”

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.

“As a leader in combination vaccines, GlaxoSmithKline is extremely pleased that our efforts to develop a booster vaccine for pertussis have resulted in filing a BLA with the FDA,” said Jo LeCoulliard, vice president, Vaccines Business Unit, GlaxoSmithKline. “*Boostrix* is the first of a number of new and important candidate vaccines from our pipeline specifically targeted at preventing disease in adolescents.”

### **About Pertussis, Tetanus and Diphtheria**

Pertussis, tetanus and diphtheria are all serious diseases caused by bacteria. Pertussis (whooping cough) can be a severe illness, resulting in prolonged coughing spells that can last for many weeks. These spells can make it difficult for a person to eat, drink, sleep or breathe. In some adolescent cases, pertussis can lead to hospitalization and pneumonia. While pertussis is a threat to all, it can be deadly in infants who are too young to be fully immunized. Pertussis is highly contagious. Up to 90 percent of unvaccinated

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household members may develop the disease when exposed to people infected with pertussis.

Tetanus (lockjaw) is a severe, often fatal disease. The bacteria that cause tetanus are widely found in soil and the manure of many animals. Infants of unvaccinated mothers are at risk for neonatal tetanus.

Almost all cases of tetanus occur in persons who have never been vaccinated or in adolescents and adults who have not had a booster vaccination in the preceding 10 years. 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.

Diphtheria is a serious disease that results in the death of approximately 5-10 percent of infected persons. Symptoms may include sore throat, low-grade fever and neck swelling. In more serious cases, a membrane can form over the airway and result in choking. Causes of death can also include heart failure. Most cases of diphtheria occur among unvaccinated or inadequately vaccinated persons.

### **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.

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