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## **GlaxoSmithKline receives FDA approval for BOOSTRIX® to help prevent whooping cough in adults 65 years and older**

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The U.S. Food and Drug Administration (FDA) has approved BOOSTRIX® [Tetanus Toxoid, Reduced Diphtheria Toxoid, and Acellular Pertussis Vaccine, Adsorbed (Tdap)] for use in adults 65 years of age and older for active booster immunization against tetanus, diphtheria and pertussis (whooping cough). This approval makes BOOSTRIX the first Tdap vaccine approved for use in this age group. With this expanded indication, BOOSTRIX is now approved for use as a single dose in individuals 10 years of age and older – the broadest age range for any Tdap vaccine.

The approval of BOOSTRIX for use in adults 65 years of age and older was based on two clinical trials in which more than 1,100 U.S. subjects received BOOSTRIX.

“A growing segment of our population, adults aged 65 and older, can now help protect themselves from whooping cough, a serious and highly contagious respiratory disease,” said Leonard Friedland, Vice President, Clinical and Medical Affairs, North America, GlaxoSmithKline Pharmaceuticals. “Although many people may have been vaccinated against whooping cough as children, immunity can wear off over time. Adults, including those aged 65 and older, should speak with their health-care providers to make sure their vaccinations are up to date and to discuss the Centers for Disease Control and Prevention’s (CDC) recommendations for preventing tetanus, diphtheria and pertussis.”

Whooping cough is one of the most commonly occurring vaccine-preventable diseases in the U.S.

In 2010, the State of California declared a whooping cough epidemic. Several other states, including Michigan, Ohio, New York and Pennsylvania, reported increases in cases in 2010 compared to 2009. One study estimates that pertussis may affect as many as 3.3 million adolescents and adults in the U.S. each year.

### **About Whooping Cough (Pertussis)**

Pertussis, also known as whooping cough, is a highly contagious respiratory disease characterized by severe coughing fits. Whooping cough starts off like the common cold and can turn into a persistent cough over time.

### **About BOOSTRIX**

BOOSTRIX is now approved for use as a single dose for active booster immunization against tetanus, diphtheria and pertussis (whooping cough) in individuals 10 years of age and older. In the U.S., BOOSTRIX was first approved for individuals aged 10-18 in May 2005. In December 2008, the vaccine was approved for use in adults 19-64 in the U.S. Since May 2005, more than 20 million doses of BOOSTRIX have been distributed in the U.S. to help protect adolescents and adults from whooping cough, as well as tetanus and diphtheria.

### **Important Safety Information for BOOSTRIX**

- In clinical studies, common adverse events were injection-site reactions (pain, redness, swelling, and increase in arm circumference), headache, fatigue, and gastrointestinal symptoms
- Severe allergic reaction after a previous dose of any tetanus toxoid-, diphtheria toxoid-, or pertussis antigen-containing vaccine, or to any component of BOOSTRIX, or encephalopathy within 7 days of a previous pertussis antigen-containing vaccine is a contraindication
- BOOSTRIX is available in vials and 2 types of prefilled syringes. One type of prefilled syringe has a tip cap which may contain natural rubber latex and a plunger which does not contain latex. The other

type has a tip cap and a rubber plunger which contain dry natural latex rubber. Use of these syringes may cause allergic reactions in latex sensitive individuals. The vial stopper does not contain latex

- The decision to give BOOSTRIX should be based on benefits and risks if Guillain-Barré syndrome occurred within 6 weeks of receipt of a prior tetanus toxoid-containing vaccine
- Progressive or unstable neurologic conditions are reasons to defer vaccination with a pertussis-containing vaccine, including BOOSTRIX
- Persons who experienced an Arthus-type hypersensitivity reaction following a prior dose of tetanus toxoid-containing vaccine should not receive BOOSTRIX unless 10 years have elapsed since the last dose of a tetanus toxoid-containing vaccine
- BOOSTRIX may not protect 100% of individuals receiving the vaccine

Boostrix is a registered trademark of GlaxoSmithKline Pharmaceuticals [NYSE: GSK].

## GlaxoSmithKline Biologicals

GlaxoSmithKline Biologicals (GSK Biologicals), GlaxoSmithKline's vaccines business, is one of the world's leading vaccine companies and a leader in innovation. The company is active in vaccine research, development and production with over 30 vaccines approved for marketing and 20 more in development - both in the prophylactic and therapeutic fields. Headquartered in Belgium, GSK Biologicals has 14 manufacturing sites strategically positioned around the globe. In 2010, GSK Biologicals distributed 1.43 billion doses of vaccines to 179 countries in both the developed and the developing world.

Through its accomplished and dedicated workforce, GSK Biologicals applies its expertise to the discovery of innovative vaccines that contribute to the health and well-being of people of all generations around the world.

## GlaxoSmithKline

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### Cautionary statement regarding forward-looking statements

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