# US FDA approves BOOSTRIX for immunisation during pregnancy for the prevention of whooping cough in newborn infants

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For media and investors only

- BOOSTRIX is the first vaccine indicated in the US to help protect infants younger than two months from pertussis (whooping cough)

GSK plc (LSE/NYSE: GSK) today announced that the US Food and Drug Administration (FDA) has approved BOOSTRIX (Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine, Adsorbed; Tdap) for immunisation during the third trimester of pregnancy to help prevent pertussis (whooping cough) in infants younger than two months of age.

Since 2010, the Centers for Disease Control and Prevention (CDC) has reported 15,000 to 48,000 pertussis cases among people of all ages in the United States each year. Infants are at high risk of complications from whooping cough because their immune systems are still developing.

According to the CDC, the Tdap vaccination given during pregnancy provides the best protection to infants against whooping cough in the first months of life. When pregnant women are vaccinated, protective antibodies are passed from mother to child.

Roger Connor, President, Vaccines and Global Health, GSK, said:

> We’re immensely proud to have the first-ever Tdap vaccine approved by the FDA specifically for this use during pregnancy. We believe this approval may help protect more infants from the potentially life-threatening implications of whooping cough.

BOOSTRIX is currently approved in over 80 countries worldwide,

including the US, most European Union countries, Canada, Australia and New Zealand for immunisation against tetanus, diphtheria and pertussis.

Boostrix is indicated in the US for:

- Active booster immunisation against tetanus, diphtheria and pertussis in individuals aged 10 years and older.

- Immunisation during the third trimester of pregnancy to help prevent pertussis (whooping cough) in infants less than two months of age.

The US Prescribing Information is available at: https://gskpro.com/content/dam/global/hcpportal/en_US/Prescrib...

Important Safety Information for BOOSTRIX in the US

The following is based on the US Prescribing Information for BOOSTRIX. Please consult the full Prescribing Information for all the labeled safety information.

- Contraindications for BOOSTRIX are: a known history of severe allergic reaction (e.g., anaphylaxis) to any component of the vaccine or after a previous dose of any tetanus toxoid-, diphtheria toxoid-, or pertussis antigen-containing vaccine; and encephalopathy within 7 days of administration of a previous dose of a pertussis antigen-containing vaccine.

- Appropriate medical treatment to manage allergic reactions must be immediately available in the event an acute allergic reaction occurs following administration of BOOSTRIX.

- The tip caps of the prefilled syringes for BOOSTRIX contain natural rubber latex, which may cause allergic reactions.

- 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.

- If BOOSTRIX is administered to immunosuppressed persons, including individuals receiving immunosuppressive therapy, the expected immune response may not be obtained.

- Syncope (fainting) may occur in association with administration of injectable vaccines. Procedures should be in place to avoid injury from fainting.

- Common solicited adverse reactions (≥15%) in adolescents (aged 10 to 18 years) were pain, redness and swelling at the injection site; increase in arm circumference of the injected arm; headache; fatigue; and gastrointestinal symptoms.

- Common solicited adverse reactions (≥15%) in adults (aged 19 to 64 years) were pain, redness and swelling at the injection site; headache; fatigue; and gastrointestinal symptoms

- The most common solicited adverse reaction (≥15%) in the elderly (aged 65 years and older) was pain at the injection site.

- Pregnancy: Available data from a controlled clinical study showed that the use of the non-US formulation of BOOSTRIX* during the third trimester of pregnancy did not reveal any vaccine-related adverse effects on pregnancy or on the fetus/newborn child.

- Pregnancy Registry: Healthcare providers are encouraged to register pregnant individuals by calling 1-888-452-9622 or visiting http://pregnancyregistry.gsk.com/boostrix.html.

- Vaccination with BOOSTRIX may not result in protection in all vaccine recipients.

* The non-US formulation of BOOSTRIX is manufactured to contain 0.5 mg aluminum per dose. The US formulation is manufactured to contain 0.3 mg aluminum per dose.

GSK is a global biopharma company with a purpose to unite science, technology, and talent to get ahead of disease together. Find out more at gsk.com/company

Cautionary statement regarding forward-looking statements

GSK cautions investors that any forward-looking statements or projections made by GSK, including those made in this announcement, are subject to risks and uncertainties that may cause actual results to differ materially from those projected. Such factors include, but are not limited to, those described in the Company's Annual Report on Form 20-F for 2021, GSK's Q2 Results for 2022 and any impacts of the COVID-19 pandemic.

Centers for Disease Control and Prevention. Pertussis Cases by Year (1922-2019). Available at:

https://www.cdc.gov/pertussis/surv-reporting/cases-by-year.html. Accessed October 2022.

Centers for Disease Control and Prevention. Whooping Cough is Deadly for Babies. Available at:

https://www.cdc.gov/pertussis/pregnant/mom/deadly-disease-for-.... Accessed October 2022.

Centers for Disease Control and Prevention. Get the Whooping Cough Vaccine During Each Pregnancy. Available at: https://www.cdc.gov/pertussis/pregnant/mom/get-vaccinated.html. Accessed October 2022.

*Press release distributed by Wire Association on behalf of GSK, on Oct 10, 2022. For more information subscribe and follow us.*

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