GSK announces US FDA approval of Priorix for the prevention of measles, mumps and rubella in individuals 12 months of age and older

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For investors and media only

- Priorix becomes an additional source of measles, mumps and rubella vaccine for US patients

GSK plc (LSE/NYSE: GSK) today announced that the US Food and Drug Administration (FDA) has approved Priorix (Measles, Mumps and Rubella Vaccine, Live) for active immunisation for the prevention of measles, mumps and rubella (MMR) in individuals 12 months of age and older.

Priorix is currently licenced in more than 100 countries worldwide, including all European countries, Canada, Australia and New Zealand, with more than 800 million doses distributed to date.

> We’re proud to make Priorix available in the US for the first time, adding a choice for providers to help protect patients against these highly-contagious diseases and to further strengthen offerings in our paediatric vaccine portfolio,

said Judy Stewart, Senior Vice President and Head of US Vaccines, GSK.

Measles, mumps and rubella are acute and highly-contagious viral diseases responsible for considerable morbidity and mortality throughout the world. In recent years, measles outbreaks have occurred in the US and globally, with more than 400,000 cases confirmed in 2019, reversing decades of progress toward measles elimination in many countries.

According to a recent US Centers for Disease Control and Prevention (CDC) report, vaccine ordering in the past two years through the CDC's Vaccines For Children programme, the federal programme through which about half of the children in the country are immunised, dropped more than 10%, indicating that fewer vaccinations in children were occurring. The report also noted 400,000 fewer children entered kindergarten in the 2020-2021 school year than expected nationally, meaning those children may not be up to date on childhood immunisations like their MMR vaccination.

> Outbreaks of measles in recent years demonstrate how quickly diseases can return without widespread immunisation. Missed vaccinations during the pandemic makes children even more vulnerable to vaccine-preventable diseases like measles," said Temi Folaranmi, MD, Vice President and Vaccines Therapeutic Area Head, US Medical Affairs, GSK. "Making Priorix available to patients in the US will ensure health care professionals have more than one option for this critical vaccine as they work to catch their patients up on recommended vaccinations.

The safety of Priorix was evaluated in six clinical studies, in which a total of 12,151 participants (6,391 in the US) received at least one dose of Priorix: 8,780 children (4,148 in the US) 12 through 15 months of age; 2,917 children (1,950 in the US) 4 through 6 years of age; and 454 adults and children (293 in the US) 7 years of age and older. The most commonly reported adverse reactions were pain, redness, swelling, loss of appetite, irritability, drowsiness and fever. The efficacy of Priorix was demonstrated based on immunogenicity data versus the comparator vaccine.

Priorix will provide US healthcare professionals with another MMR vaccine choice. Priorix may be administered as a first dose, followed by a second dose of Priorix. Priorix may also be administered as a second dose to individuals who have previously received the first dose of another MMR-containing vaccine.

The CDC recommends people get a MMR vaccine to protect against measles, mumps and rubella. Children should get two doses of MMR vaccine, starting with the first dose at 12 through 15 months of age, and the second dose at 4 through 6 years of age. Teens and adults should also be up to date on their MMR vaccination.

Priorix is scheduled to be on the agenda for the June CDC Advisory Committee on Immunization Practices (ACIP) meeting for consideration of formal inclusion into the vaccine schedule and recommendations.

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

Important Safety Information

- The following is based on the US Prescribing Information for Priorix. Please consult the full Prescribing information for all the labelled safety information.

- Contraindications for Priorix are: severe allergic reaction (e.g., anaphylaxis) to any component of Priorix, or after a previous dose of any measles-, mumps- and rubella-containing vaccine; severe immunodeficiency; and pregnancy or planning to become pregnant within the next month.

- Appropriate medical treatment and supervision must be available to manage possible anaphylactic reactions following administration of Priorix.

- There is a risk of febrile seizure following immunisation with Priorix.

- Thrombocytopenia and thrombocytopenic purpura have been reported following vaccination with Priorix.

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

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

- Vaccination with Priorix may not protect all susceptible individuals.

- Most common solicited adverse reactions in clinical trial participants: 12 through 15 months of age: local reactions were pain, and redness; systemic reactions were irritability, loss of appetite, drowsiness and fever; 4 through 6 years of age: local reactions were pain, redness and swelling; systemic reactions were loss of appetite, drowsiness

and fever; and 7 years of age and older: local reactions were pain and redness.

GSK is a science-led global healthcare company. For further information please visit

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 Q1 Results for 2022 and any impacts of the COVID-19 pandemic.

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