# Press release

For media and investors only

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# GSK is first to ship influenza vaccine doses for the 2023-24 flu season in US

- GSK supports annual flu immunization with its shipping of FLULAVAL QUADRIVALENT and FLUARIX QUADRIVALENT

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GSK plc (LSE/NYSE: GSK) today announced it has started shipping doses of its quadrivalent influenza vaccines to US healthcare providers and pharmacies in preparation for the 2023-24 flu season. This immediately follows a licensing and lot-release approval from the US Food and Drug Administration (FDA).

GSK expects to distribute over 40 million doses of its influenza vaccine to the US market. Both FLULAVAL QUADRIVALENT and FLUARIX QUADRIVALENT will be available in a 0.5mL, single-dose, pre-filled syringe, and are indicated for patients six months and older.

CDC recommends an annual flu vaccination for anyone aged six months and older who does not have contraindications.

According to CDC, annual influenza vaccination is the best way to help protect against the flu, with September and October being the best time for most people to be vaccinated.[1] CDC estimates that, from October 1, 2022 through April 30, 2023, there have been 27 – 54 million flu illnesses, 300,000 – 650,000 flu hospitalizations and 19,000 – 58,000 flu deaths.[2]

**About Influenza**
The flu (influenza) is a contagious respiratory illness caused by influenza viruses that infect the nose, throat, and sometimes the lungs. It can cause mild to severe illness, and at times can lead to death.[3]

Anyone can get the flu, however, it can be serious for young children, adults 65 years and older, pregnant women and people with pre-existing chronic health conditions, such as asthma.[4]

For more information about the flu, visit https://www.cdc.gov/flu/about/keyfacts.htm.

**Indication for FLUARIX QUADRIVALENT and FLULAVAL QUADRIVALENT**
FLUARIX QUADRIVALENT and FLUAVAL QUADRIVALENT are vaccines indicated for active immunization for the prevention of disease caused by influenza A subtype viruses and type B viruses contained in the vaccines. FLUARIX QUADRIVALENT and FLULAVAL QUADRIVALENT are approved for use in persons aged 6 months and older.

**Important Safety Information for FLUARIX QUADRIVALENT and FLULAVAL QUADRIVALENT**

- Do not administer FLUARIX QUADRIVALENT or FLULAVAL QUADRIVALENT to anyone with a history of severe allergic reactions (eg, anaphylaxis) to any component of the vaccine, including egg protein, or following a previous dose of any influenza vaccine

- If Guillain-Barré syndrome has occurred within 6 weeks of receipt of a prior influenza vaccine, the decision to give FLUARIX QUADRIVALENT or FLULAVAL QUADRIVALENT should be based on careful consideration of the potential benefits and risks

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- Syncope (fainting) can occur in association with administration of injectable vaccines, including FLUARIX QUADRIVALENT or FLULAVAL QUADRIVALENT. Procedures should be in place to avoid falling injury and to restore cerebral perfusion following syncope

- If FLUARIX QUADRIVALENT or FLULAVAL QUADRIVALENT is administered to immunosuppressed persons, including individuals receiving immunosuppressive therapy, the immune response may be lower than in immunocompetent persons

- In clinical trials with FLUARIX QUADRIVALENT in adults, the most common solicited local adverse reaction was pain and the most common systemic adverse reactions were muscle aches, headache, and fatigue. In children 6 through 35 months of age, the most common solicited local adverse reactions were pain and redness and the most common systemic adverse reactions were irritability, loss of appetite, and drowsiness. In children 3 through 17 years of age, the solicited local adverse reactions were pain, redness, and swelling. In children 3 through 5 years of age, the most common systemic adverse reactions were drowsiness, irritability, and loss of appetite. In children 6 through 17 years of age, the most common systemic adverse reactions were fatigue, muscle aches, headache, arthralgia, and gastrointestinal symptoms. (See Adverse Reactions section of the Prescribing Information for FLUARIX QUADRIVALENT for other potential adverse reactions and events)

- In clinical trials with FLULAVAL QUADRIVALENT in adults, the most common solicited local adverse reaction was pain and the most common solicited systemic adverse reactions were muscle aches, headache, fatigue, and arthralgia. In children 6 through 35 months of age, the most common solicited local adverse reaction was pain and the most common solicited systemic adverse reactions were irritability, drowsiness, and loss of appetite. In children 3 through 17 years of age, the most common solicited local adverse reaction was pain. In children 3 through 4 years of age, the most common solicited systemic adverse reactions were irritability, drowsiness, and loss of appetite. In children 5 through 17 years of age, the most common solicited systemic adverse reactions were muscle aches, fatigue, headache, arthralgia, and gastrointestinal symptoms. (See Adverse Reactions section of the Prescribing Information for FLULAVAL QUADRIVALENT for other potential adverse reactions and events)

- Vaccination with FLUARIX QUADRIVALENT or FLULAVAL QUADRIVALENT may not result in protection in all vaccine recipients

Please see full Prescribing Information for FLUARIX QUADRIVALENT and for FLULAVAL QUADRIVALENT.

**About GSK**
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.

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**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 under Item 3.D 'Risk factors" in the company's Annual Report on Form 20-F for 2022, and Q1 Results for 2023 and any impacts of the COVID-19 pandemic.

**References**


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2. Centers for Disease Control and Prevention. 2022-2023 U.S. Flu Season: Preliminary In-Season Burden Estimates. Available at: https://www.cdc.gov/flu/about/burden/preliminary-in-season-estimates.htm. Accessed July 11, 2023
3. Centers for Disease Control and Prevention. About Flu. Available at: https://www.cdc.gov/flu/about/index.html. Accessed July 11, 2023.
4. Centers for Disease Control and Prevention. Key Facts About Influenza (Flu). Availabe at: https://www.cdc.gov/flu/about/keyfacts.htm. Accessed July 11, 2023. Accessed July 11, 2023.