Stock-exchange announcement
For media and investors only

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GSK's *Shingrix* new prefilled syringe presentation accepted for review by US FDA

- **If approved, the new presentation will offer a convenient administration option to healthcare professionals**
- **Over 90 million doses of GSK's shingles vaccine have been distributed in the US since 2017[1]**
- **An FDA decision on the application is expected by June 20, 2025**

GSK plc (LSE/NYSE: GSK) today announced that the US Food and Drug Administration (FDA) has accepted for review the regulatory application of a prefilled syringe presentation of *Shingrix* (GSK's Recombinant Zoster Vaccine or RZV) for the prevention of shingles (herpes zoster).

The new prefilled syringe removes the need to reconstitute separate vials prior to administration, offering a convenient option for pharmacists, physicians and other healthcare professionals who administer vaccinations. The current presentation of the vaccine consists of a lyophilised (powder) antigen and a liquid adjuvant, which healthcare professionals combine prior to administering. The new presentation has the same composition as the reconstituted vaccine and the submission is based on data demonstrating comparability between the two.[1]

Today's announcement marks an important regulatory milestone for GSK's shingles vaccine, which has been approved in the US for the prevention of shingles in adults aged 50 years and older since 2017; and in adults 18 years and older, who are or will be at increased risk of shingles due to immunodeficiency or immunosuppression caused by known disease or therapy, since 2021.[2] It reflects GSK's continued innovation on its commercialized portfolio to meet the needs of the healthcare community.

About shingles

Shingles is a painful, blistering rash that can last for weeks. Approximately 99% of US adults over 50 years old have the virus that causes shingles inside their body, although not everyone will develop shingles.[3] An estimated one million people develop shingles annually in the US.[3]

Shingles is caused by the reactivation of the varicella-zoster virus (VZV), the same virus that causes chickenpox.[4] By age 50, VZV is present in most adults[5] and may reactivate with advancing age.[6] As people age, the strength of the immune system response to infection wanes, increasing the risk of developing shingles.[6]

About *Shingrix* (Recombinant Zoster Vaccine or RZV)

Shingrix (GSK's Recombinant Zoster Vaccine or RZV) is a non-live, recombinant subunit vaccine indicated for the prevention of shingles in adults 50 and over. It combines an antigen, glycoprotein E, with an adjuvant system, AS01B, and may help overcome the natural age-related decline in responses to immunisation that contributes to the challenge of protecting adults aged 50 and over from shingles.[7,8] RZV is not indicated to prevent primary varicella infection (chickenpox). In several countries, RZV is also approved for adults aged 18 years or over at increased risk for shingles. The use of RZV should be in accordance with official recommendations and local product label.

Important safety information for *Shingrix*

The following information is based on the US Prescribing Information (PI) for *Shingrix*. Please refer to the US PI at this link:
https://gskpro.com/content/dam/global/hcpportal/en_US/Prescribing_Information/Shingrix/pdf/SHINGRIX.PDF

- Shingrix is contraindicated in anyone with a history of a severe allergic reaction (e.g., anaphylaxis) to any component of the vaccine or after a previous dose of Shingrix.
- Review immunization history for possible vaccine sensitivity and previous vaccination-related adverse reactions. Appropriate medical treatment and supervision must be available to manage possible anaphylactic reactions following administration of Shingrix.
- In a post marketing observational study, an increased risk of Guillain-Barré syndrome was observed during the 42 days following vaccination with Shingrix.
- Syncope (fainting) can be associated with the administration of vaccines, including Shingrix. Procedures should be in place to avoid falling injury and to restore cerebral perfusion following syncope.
- In individuals aged 50 years and older: Solicited local adverse reactions were pain, redness, and swelling. Solicited general adverse reactions were myalgia, fatigue, headache, shivering, fever, and gastrointestinal symptoms.
- The data are insufficient to establish if there is vaccine-associated risk with Shingrix in pregnant women.
- It is not known whether Shingrix is excreted in human milk. Data are not available to assess the effects of Shingrix on the breastfed infant or on milk production/excretion.
- Vaccination with Shingrix may not result in protection of all vaccine recipients.

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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3. CDC. About Shingles (Herpes Zoster). Available at https://www.cdc.gov/shingles/about/index.html. Last accessed: January 2025.
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6. Mueller, N.H., et al. Varicella zoster virus infection: clinical features, molecular pathogenesis of disease, and latency. Neurologic clinics. 2008;26(3):675–97.
7. Cunningham, AL, et al. Efficacy of the Herpes Zoster Subunit Vaccine in Adults 70 Years of Age or Older. New England Journal of Medicine. 2016;375(11):1019–32.
8. The GSK proprietary AS01 adjuvant system contains QS-21 Stimulon® adjuvant licensed from Antigenics LLC, a wholly owned subsidiary of Agenus Inc. (NASDAQ: AGEN), MPL and liposomes.