Stock-exchange announcement
For media and investors only

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US FDA approves GSK's SHINGRIX in a prefilled syringe presentation

- Prefilled syringe presentation offers a convenient administration option to healthcare professionals
- An estimated one million people develop shingles in the US each year[1]

GSK plc (LSE/NYSE: GSK) today announced that the US Food and Drug Administration (FDA) has approved a prefilled syringe presentation of SHINGRIX (Zoster Vaccine Recombinant, Adjuvanted) for the prevention of shingles (herpes zoster). The new prefilled syringe removes the need to reconstitute separate vials prior to administration, simplifying the vaccine administration process for healthcare professionals.

The existing vaccine presentation consists of two vials, a lyophilized (powder) antigen and a liquid adjuvant, which healthcare professionals combine prior to administering. The approval of the new presentation is based on data demonstrating technical comparability between the new and existing vaccine presentation .[2]

Brigid Groves, Vice President of Professional Affairs, American Pharmacists Association, said: "The prefilled syringe presentation of GSK's shingles vaccine is good news, providing a convenient method of administration. The FDA approval is a positive step toward driving prevention of this painful disease, and as a practicing pharmacist I welcome the availability of this new presentation."

Consistent with the existing indications for SHINGRIX, the prefilled syringe presentation is licensed in the US for immunization of adults aged 50 years and older, as well as those aged 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.[3] The US Centers for Disease Control and Prevention (CDC) recommends two doses of GSK's shingles vaccine to prevent shingles and related complications in adults aged 50 years or over, and two doses for adults aged 19 years or over who are or will be immunodeficient or immunosuppressed.[4]

Tony Wood, Chief Scientific Officer, GSK, said: "At GSK, we are committed to advancing scientific innovation and delivering practical solutions that address the needs of the healthcare community. This new presentation of *Shingrix* was developed to streamline the vaccination process, supporting healthcare professionals to provide protection against shingles, a disease that 1 in 3 US adults will develop in their lifetime."

The prefilled syringe presentation of GSK's shingles vaccine is also undergoing regulatory review by the European Medicines Agency (EMA), with filing acceptance received in January 2025, marking another important regulatory milestone. In addition to GSK exploring submission of this presentation to other markets, this highlights GSK's commitment to providing solutions to help increase adult immunization rates.

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.[1] An estimated one million people develop shingles annually in the US.[1]

Shingles is caused by the reactivation of the varicella-zoster virus (VZV), the same virus that causes chickenpox.[5] By age 50, VZV is present in most adults[6] and may reactivate with advancing age.[7] As people age, the strength of the immune system response to infection wanes, increasing the risk of developing shingles.[7]

About SHINGRIX (Recombinant Zoster Vaccine or RZV)

SHINGRIX (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, $AS01_B$, and may help overcome the natural age-related decline in responses to immunization that contributes to the challenge of protecting adults aged 50 and over from shingles.[8,9] 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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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 "Risk Factors" section in GSK's Annual Report on Form 20-F for 2024, and GSK's Q1 Results for 2025.

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[4] CDC. Shingles Vaccine Recommendations. Available at Shingles Vaccine Recommendations | Shingles (Herpes Zoster) | CDC. Last accessed: July 2025.
[5] Harpaz R, et al. Advisory Committee on Immunization Practices (ACIP), Centers for Disease Control and Prevention (CDC). Prevention of herpes zoster: recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR Recomm Rep. 2008;57(RR-5):1–30.
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[7] Mueller, N.H., et al. Varicella zoster virus infection: clinical features, molecular pathogenesis of disease, and latency. Neurologic clinics. 2008;26(3):675–97.
[8] 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.
[9] 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.