Stock-exchange announcement
For media and investors only

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GSK's *Shingrix* new prefilled syringe presentation accepted for review by European Medicines Agency

- If approved, the new presentation will offer a convenient administration option to healthcare professionals
- Globally, up to 1 in 3 adults will develop shingles in their lifetime[1,2,3,4]
- Over 25 million people in Europe have received GSK's shingles vaccine since 2018[5]

GSK plc (LSE/NYSE: GSK) today announced that the European Medicines Agency (EMA) 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 physicians, pharmacists 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.[5]

This European regulatory review follows the file acceptance by the US FDA on 8 January 2025 for the new prefilled syringe presentation, continuing GSK's commitment to providing solutions to increasing adult immunisation. GSK is also investigating submission of this presentation to other markets. GSK's shingles vaccine has been approved in the European Union for the prevention of herpes zoster (HZ) and post-herpetic neuralgia (PHN) in adults aged 50 years and older since 2018; and in adults 18 years and older at increased risk of HZ, since 2020.[6]

About shingles
Shingles typically presents as a rash, with painful blisters across the chest, abdomen or face.[7] Following the rash, up to 30% of people experience PHN,[8] a long-lasting nerve pain that can last weeks or months and can occasionally persist for several years.[1] Shingles is also associated with significant healthcare and human cost, with 57% of people with shingles reported missing work for an average of 9.1 days.[9]

Shingles is caused by the reactivation of the varicella-zoster virus (VZV), the same virus that causes chickenpox.[1] By age 50, VZV is present in most adults[10] and in some 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 (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.[11,12] 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.

Please refer to the Product Information (PI) for important dosage, administration, and safety information in Europe available at this link: https://www.ema.europa.eu/en/medicines/human/EPAR/shingrix

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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12. 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.