Stock-exchange announcement
For media and investors only

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GSK's *Shingrix* new prefilled syringe presentation receives positive CHMP opinion

- Prefilled syringe offers a convenient ready-to-use administration option to healthcare professionals
- Marketing authorisation in EU expected in December 2025
- Shingles affects approximately 1.7 million people in Europe each year[1]

GSK plc (LSE/NYSE: GSK) today announced that the European Medicine Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) has issued a positive opinion to support the approval of *Shingrix* (GSK's Recombinant Zoster Vaccine or RZV) in a prefilled syringe. Currently, the vaccine presentation consists of two vials, a lyophilised powder antigen and a liquid adjuvant, which are combined prior to administration. After approval by the European Commission, expected in December 2025, the new prefilled syringe will remove the need to reconstitute separate vials, simplifying the vaccine administration process for healthcare professionals.

Tony Wood, Chief Scientific Officer, GSK, said: "At GSK, we are dedicated to driving innovation to continually enhance our world-class vaccines. The CHMP positive opinion on our new presentation of Shingrix reflects our commitment to supporting the healthcare community, making it easier for healthcare professionals to provide protection against shingles, a painful disease affecting well over a million people in Europe each year."

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 or older since 2018; and in adults 18 years or older at increased risk of HZ, since 2020. GSK's RZV is specifically designed to enhance the varicella-zoster virus (VZV)-specific immune response of a declining or compromised immune system.[2,3] This positive CHMP opinion is based on data confirming technical comparability between the prefilled syringe and the existing vaccine presentation.[4]

About shingles
Shingles is caused by the reactivation of the varicella-zoster virus (VZV), the same virus that causes chickenpox.[5] Globally, up to 1 in 3 adults will develop shingles in their lifetime.[5,6,7,8] Over 90% of adults have the varicella-zoster virus (VZV) dormant in their nervous system, waiting to reactivate.[6,9,10,11] In addition to advancing age, chronic conditions like cardiovascular disease, chronic kidney disease, chronic obstructive pulmonary disease, asthma, and diabetes are all linked to higher risk of shingles.[5,12]

Shingles typically presents as a rash, with painful blisters across the chest, abdomen or face.[9] Following the rash, up to 30% of people experience PHN,[13] a long-lasting nerve pain that can last weeks or months and can occasionally persist for several years.[5] Shingles is also associated with significant healthcare and human cost, with one in three patients with shingles taking an average of 12.5 days of sick leave and patients with PHN taking sick leave for an average of two months.[14]

About *Shingrix* (Recombinant Zoster Vaccine or RZV)
Shingrix combines an antigen, glycoprotein E, with an adjuvant system, $AS01_B$, 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.[2,3] RZV is not indicated to prevent primary varicella infection (chickenpox). 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

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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 Q2 Results for 2025.

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[3] 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.
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