

# 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<sup>1</sup>
- An FDA decision on the application is expected by 20 June 2025

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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.<sup>1</sup>

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.<sup>2</sup> It reflects GSK's continued innovation on its commercialised 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.<sup>3</sup> An estimated one million people develop shingles annually in the US.<sup>3</sup>

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

### **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.<sup>7,8</sup> 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.

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/hcportal/en\\_US/Prescribing\\_Information/Shingrix/pdf/SHINGRIX.PDF](https://gskpro.com/content/dam/global/hcportal/en_US/Prescribing_Information/Shingrix/pdf/SHINGRIX.PDF)

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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](https://www.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 GSK's Annual Report on Form 20-F for 2023, and GSK's Q3 Results for 2024.

## Registered in England & Wales:

No. 3888792

## Registered Office:

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## References

1. GSK data on file 2024.
2. Shingrix prescribing information. [SHINGRIX \(Zoster Vaccine Recombinant, Adjuvanted\), suspension for intramuscular injection](#). Last accessed: January 2025.
3. CDC. About Shingles (Herpes Zoster). Available at <https://www.cdc.gov/shingles/about/index.html>. Last accessed: January 2025.
4. 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.
5. Johnson, R.W., et al. Herpes zoster epidemiology, management, and disease and economic burden in Europe: a multidisciplinary perspective. *Therapeutic advances in vaccines*. 2015;3(4):109–20.
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.