New Shingrix data demonstrate 100% vaccine efficacy in the prevention of shingles in adults aged 50 and over in China

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For media and investors only

- No cases of shingles (herpes zoster) reported among the participants who received Shingrix (Recombinant Zoster Vaccine or RZV) in the randomised clinical trial1

- The data come from the first efficacy trial of Shingrix in China

- The trial's safety and efficacy data were consistent with GSK's pivotal phase III trials ZOE-50 and ZOE-701

GSK plc (LSE/NYSE: GSK) today announced positive results from the first-ever efficacy trial of Shingrix (Recombinant Zoster Vaccine or RZV) in China. These results come from the post-license phase IV trial (ZOSTER-076), which evaluated the efficacy and safety of RZV in preventing shingles in adults aged 50 and over. The trial included almost 6,000 participants randomised 1:1 to the RZV or placebo group and followed in an observer-blind design. No cases of shingles were reported among the participants who received RZV, compared to 31 cases in the placebo arm.1

The results are in line with findings from the pivotal phase III trials ZOE-50 and ZOE-70 investigating the efficacy and safety of RZV, showing vaccine efficacy was up to 97%2 in adults aged 50 and over, over a follow-up period of approximately four years.2,3 The safety profile observed in this trial was consistent with the established safety profile of the vaccine.1 The new data add to the growing body of evidence affirming the efficacy and safety profile of RZV in preventing shingles in adults aged 50 and over.1

Globally, the varicella zoster virus (VZV) is present in over 90% of

adults.4,5 VZV remains dormant in the nervous system, waiting to reactivate as shingles with advancing age.8,9 The population of people aged 65 and over in China is rapidly increasing, with a predicted percentage increase from 6.8% in 2000 to 23.6% by 2050.6 It is estimated that there are approximately 6 million cases of shingles in China each year6, and this number is expected to increase in line with local population ageing.

RZV was first licensed for use in China in 2019 for the prevention of herpes zoster in adults aged 50 and over. This post-licence trial was undertaken to fulfil the requirement of regulatory authorities to evaluate the vaccine efficacy and safety of two doses of RZV for the prevention of shingles in China. The trial further demonstrates RZV's efficacy in preventing herpes zoster in adults aged 50 and over irrespective of sex, geographic region and ancestry/ethnicity.

Results from this phase IV trial will be submitted for publication in a peer-reviewed scientific journal later this year.

About the ZOSTER-076 trial

ZOSTER-076 was a phase IV, randomised, observer-blind, placebo-controlled, multi-centre trial to assess the prophylactic efficacy against herpes zoster (HZ) and the immunogenicity and safety of RZV when administered intramuscularly on a 2-dose schedule in adults aged 50 and over in China.1

The trial was conducted between 2021 and 2023. It included almost 6,000 adults (n=5,956). Vaccine efficacy was 100% (95% CI: 89.82%-100%). HZ incidence rate of 0/1,000 person years in the RZV arm versus an incidence rate of 8.2/1,000 person years in the placebo arm, p

Shingles, also known as herpes zoster, is caused by a reactivation of the varicella-zoster virus (VZV) – the same virus that causes chickenpox.7 Globally, most people aged 50 and over have the dormant VZV in their nervous system and are at risk of developing shingles.4,5 As people age, the strength of the immune system wanes, leading to a decreased response to infection and thus increasing the risk of developing shingles.4,5,7,8,9 People with a suppressed or compromised immune system are also at risk of shingles.10

Shingles typically presents as a rash, with painful blisters across the chest, abdomen or face.7 The pain is often described as aching, burning, stabbing or shock-like.9 Following the rash, a person can also experience postherpetic neuralgia (PHN), a long-lasting nerve pain that can continue for weeks or months and in some cases can persists for several years.9 PHN is the most common complication of shingles, occurring in 5-30% of all shingles cases depending on the individual's age.11

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, 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.12,13 RZV is not indicated to prevent primary varicella infection (chickenpox). In some countries, RZV is also approved for adults aged 18 years or over who are at increased risk for shingles.

Please refer to the Product Information (PI) for important dosage, administration and safety information in China available at this link: https://portaldev2.igskapp.com/media/916483/欣安立适说明书.pdf

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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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 the company's Annual Report on Form 20-F for 2022, and Q1 Results for 2023 and any impacts of the COVID-19 pandemic.

- [2] Lal H et al. Efficacy of an Adjuvanted Herpes Zoster Subunit Vaccine in Older Adults. N Engl J Med. 2015;372:2087-96.

- [3] Cunningham AL, Lal H, Kovac M, et al. Efficacy of the Herpes Zoster Subunit Vaccine in Adults 70 Years of Age or Older. N Engl J Med. 2016;375(11):1019-1032. doi:10.1056/NEJMoa1603800

- [4] Bollaerts K et al. A systematic review of varicella seroprevalence in European countries before universal childhood immunization: deriving incidence from seroprevalence data. Epidemiol Infect 2017;145:2666–2677.

- [5] Bricout H et al. Herpes zoster-associated mortality in Europe: a systematic review. BMC Public Health 2015;15:466.

- [6] Zhang Z et al. The incidence of herpes zoster in China: A meta-analysis and evidence quality assessment. Hum Vaccin Immunother. 2023;19(2):2228169.

- [7] Mueller, NH et al. Varicella Zoster Virus Infection: Clinical Features, Molecular Pathogenesis of Disease and Latency. Neurologic Clinics, 2008; 26;675-697

- [8] Johnson RW et al. Herpes zoster epidemiology, management, and disease and economic burden in Europe: a multidisciplinary perspective. Therapeutic Advances in Vaccines. 2015;3(4):109-120.

- [9] 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.

- [10] Huang C-T et al. Association Between Diabetes Mellitus and the Risk of Herpes Zoster: A Systematic Review and Meta-analysis. J Clin Endocrinol Metab 2022;107:586–597.

- [11] Kawai K, Gebremeskel BG, Acosta CJSystematic review of incidence and complications of herpes zoster: towards a global perspectiveBMJ Open 2014;4:e004833. doi: 10.1136/bmjopen-2014-004833

- [12] Cunningham et al. Vaccine profile of herpes zoster (HZ/su) subunit vaccine. Expert Review of Vaccines. 2017;16:7;661-670.

- [13] 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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