New data show Shingrix can provide at least 10 years of protection against shingles in adults aged 50 years and over

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For media and investors only

- Overall, the clinical benefit was sustained through the current follow-up period of up to 10 years after vaccination in adults aged 50 years and over

- In the primary endpoint, the interim data demonstrated overall efficacy of greater than 80% over the follow-up period of approximately six to 10 years after initial vaccination

- No new safety concerns were identified during the follow-up period

GSK plc (LSE/NYSE: GSK) today announced positive interim results from the ZOSTER-049 extension study showing that overall Shingrix (Zoster Vaccine Recombinant, Adjuvanted) can provide at least a decade of protection against shingles (herpes zoster) after initial vaccination. The interim analysis data will be presented on 20 October 2022 at the IDWeek congress in Washington, DC, USA.

These results come from ZOSTER-049 (ZOE-LTFU), an extension from two phase III clinical trials ZOE-50 and ZOE-70. From those trials, vaccine efficacy was 97% in adults 50 years and above and 91% in adults 70 years and above over a follow-up period of approximately four years. The ZOE-LTFU study, which follows participants from the ZOE-50 and ZOE-70 clinical trials for an additional six years, is ongoing and will continue to evaluate the longer-term efficacy, immunogenicity and safety of the vaccine.

Dr. Javier Díez-Domingo, Principal Investigator, FISABIO (Foundation for the Promotion of Health and Biomedical Research of the Valencian Community, Spain), said:

> Shingles is a painful disease that one in three adults will develop in their lifetime. We can now – for the first time – confirm that the clinical benefit of the Recombinant Zoster Vaccine overall, continues for at least 10 years after vaccination, giving patients and their healthcare providers peace of mind about the duration of protection against shingles.

Sabine Luik, Chief Medical Officer & SVP Global Medical Regulatory & Quality, GSK, said:

> We are delighted to see the continuing longevity of protection from our shingles vaccine. The findings from ZOE-LTFU demonstrate that it can provide a decade of protection against the pain, debilitating impact and potentially severe complications that shingles can cause in people aged 50 and over. These data significantly add to, and complement, the existing body of evidence demonstrating the long-term benefit of the vaccine, and we look forward to seeing additional results from this ongoing study.

Shingles is caused by the reactivation of the varicella zoster virus (VZV), the same virus that causes chicken pox.,, As people age, the immune system loses the ability to mount a strong and effective immune response, increasing the risk of developing shingles.,, The disease can cause unbearable pain and, in some cases, intense pain continues after the shingles rash fades, that nerve pain (called post-herpetic neuralgia [PHN]) can last for months or even years.

The Recombinant Zoster Vaccine (RZV) is the first approved shingles vaccine to combine a non-live antigen with GSK's adjuvant and may help overcome the natural age-related decline in immunity that contributes to the challenge of protecting adults aged 50 years and above from this disease.,

ZOSTER-049 is an open-label, long-term follow-up (LTFU) study from two pivotal phase III randomised clinical trials (ZOE-50, ZOE-70). The study is evaluating the efficacy, safety and immunogenicity for six additional years after completion of the ZOE-50 and ZOE-70 studies. In the interim analysis conducted over the ≥4 years of long-term follow-up, representing up to 10 years since immunisation (mean: from 5.6 (±0.3) to 9.6 (±0.3) years post-vaccination), vaccine efficacy was 81.6%. From 1 month post-second dose in those initial studies up to

year 10 post-vaccination (mean: 9.6 (±0.3) years post-vaccination), vaccine efficacy was 89.0%. The safety profile observed in this extension study is consistent with the established safety profile of the vaccine. No new safety concerns were identified. The incidence of serious adverse events was consistent with the age of the study population. No deaths or other Safety Adverse Events (SAE) considered related to vaccination were reported. Five cases of HZ-related complications (PHN - 3 cases and HZ disseminated disease - 2 cases) were reported.

A total of 7,413 participants were enrolled in the study's Safety cohort. The participants were 60.7% female and 39.3% male. Participants were 76.0% White-Caucasian/European heritage, 18.7% Asian and 5.3% Other. ZOSTER-049 is being conducted in 18 countries/regions including Australia, Brazil, Canada, Czech Republic, Estonia, Finland, France, Germany, Hong Kong, Italy, Japan, Republic of Korea, Mexico, Spain, Sweden, Taiwan, the United Kingdom and the United States.

Shingles typically presents as a rash, with painful blisters across the chest, abdomen or face. The pain is often described as aching, burning, stabbing or shock-like. Following the rash, a person can also experience post-herpetic neuralgia (PHN) pain lasting from at least three months up to several years from the onset of rash. PHN is the most common complication of shingles, occurring in 5-25% of all shingles cases, depending on the patients' age.

Shingrix [Herpes Zoster vaccine (recombinant, AS01B adjuvanted)] is a non-live, recombinant subunit vaccine which combines a recombinant antigen, glycoprotein E and the adjuvant system, AS01B.,

In the EU, RZV is indicated for the prevention of shingles (herpes zoster) and, in some markets, for post-herpetic neuralgia (PHN), in adults 50 years of age and above. Full EU prescribing information.

In several countries, including the European Economic Area (EEA), the vaccine is also approved for adults aged 18 or above who are at increased risk of shingles. It is the only shingles vaccine approved for this at-risk patient population.

In the US, RZV is licensed for prevention of HZ (shingles) in adults aged 50 years and above, and in adults aged 18 years and above who

are or will be at increased risk of HZ due to immunodeficiency or immunosuppression caused by known disease or therapy. It is not indicated for prevention of primary varicella infection (chickenpox). Full US prescribing information is available at us.gsk.com or US Prescribing Information for RZV.

Important Safety information

The following is based on the EU and UK Prescribing Information for RZV. Please consult the full Prescribing Information for all the labelled safety information.

- RZV is contraindicated in anyone who is hypersensitive to the active substances or to any of the excipients of RZV.

- As with all injectable vaccines, appropriate medical treatment and supervision should always be readily available in case of an anaphylactic event following the administration of the vaccine.

- RZV should be given with caution to individuals with thrombocytopenia or any coagulation disorder since bleeding may occur following intramuscular administration to these subjects.

- In a post marketing observational study, an increased risk of Guillain-Barré syndrome was observed during the 42 days following vaccination with RZV.

- Syncope (fainting) can be associated with the administration of vaccines, including RZV. Procedures should be in place to avoid falling injury and to restore cerebral perfusion following syncope.

- In adults aged 50 years and above, the most frequently reported adverse reactions were pain at the injection site, myalgia, fatigue and headache. Most of these reactions were not long-lasting.

- In adults ≥ 18 years of age who are immunodeficient or immunosuppressed due to disease or therapy, the safety profile was consistent with that observed in adults 50 years and above.

- There are no safety, immunogenicity or efficacy data to support replacing a dose of RZV with a dose of another HZ vaccine. There are limited data to support the use of RZV in individuals with a history of HZ. Healthcare professionals therefore need to weigh the benefits and

risks of HZ vaccination on an individual basis.

- There are no data from the use of RZV in pregnant women. As a precautionary measure, it is preferable to avoid the use of RZV during pregnancy.

- The effect on breast-fed infants of administration of Shingrix to their mothers has not been studied. It is unknown whether RZV is excreted in human milk.

- As with any vaccine, a protective immune response may not be elicited in all vaccines.

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/company

Cautionary statement regarding forward-looking statements

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ZOE-50 and ZOE-70 are placebo-controlled trials with two doses of recombinant zoster vaccine (RZV) two months apart. Vaccine efficacy (VE) was assessed in the modified Total Vaccinated Cohort (mTVC) of 7277 participants, i.e. excluding adults who did not receive second dose of vaccine or who had confirmed diagnosis of herpes zoster (HZ) ≤1 month after second dose. Data in subjects ≥70 years old were from pre-specified pooled analyses of ZOE-50/70, as these provide robust estimates for VE. HZ cases in RZV vs. placebo: ≥50 years (ZOE-50; median follow-up of 3.1 years): 6/7344 vs. 210/7415 and ≥70 years (pooled analysis ZOE-50 & ZOE-70; median follow-up of 4 years): 25/8250 vs. 284/8346 cases

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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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