US Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices votes unanimously to recommend Shingrix for immunocompromised adults aged 19 and up

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GlaxoSmithKline plc today announced that the US Centers for Disease Control and Prevention's (CDC) Advisory Committee on Immunization Practices (ACIP) voted unanimously to recommend two doses of Shingrix (Zoster Vaccine Recombinant, Adjuvanted) for the prevention of shingles (herpes zoster) and its complications in adults 19 years of age and older who are or will be immunodeficient or immunosuppressed due to disease or therapy.

Today's vote means that millions of adults in the US aged 19 years and older who are at increased risk of shingles due to immunodeficiency or immunosuppression are now recommended to receive Shingrix.

"Today's recommendation is an important clinical advancement in providing protection from shingles and its complications to adults with immunodeficiency or immunosuppression," said Sabine Luik, Chief Medical Officer & SVP Global Medical Regulatory & Quality, GSK.

> The ACIP's vote helps to address an existing unmet need as individuals who are immunocompromised are at an increased risk of the disease.

This approval and recommendation for a new population was based on clinical studies examining the safety and efficacy of Shingrix in adults (≥18 years of age) who had undergone an autologous haematopoietic stem cell transplant (auHSCT) and those undergoing treatment for haematological malignancies (post-hoc analysis). Further safety and immunogenicity data were generated in adults who were, or were anticipated to be, immunodeficient or immunosuppressed due to known disease or therapy, including patients with HIV, solid tumours, and renal transplants.

Shingrix combines a non-live antigen, to trigger a targeted immune response, with a specifically designed adjuvant system to generate a Varicella Zoster Virus (VZV)-specific immune response. Shingrix is not indicated for prevention of primary varicella infection (chickenpox).

For immunocompetent adults, Shingrix is intended to be administered in two doses, 2 to 6 months apart. However, for adults who are or will be immunodeficient or immunosuppressed due to known disease or therapy and who would benefit from a shorter vaccination schedule, the second dose can be administered 1 to 2 months after the first dose.

The ACIP recommendations will be forwarded to the director of the CDC and the US Department of Health and Human Services for review and approval. Once approved, the final recommendations will be published in a future Morbidity and Mortality Weekly Report (MMWR).

Shingles is caused by the reactivation of the varicella zoster virus (VZV), the same virus that causes chickenpox. Nearly all older adults have the VZV dormant in their nervous system, waiting to reactivate with advancing age. As people age, the cells in the immune system lose the ability to maintain a strong and effective response to VZV reactivation.

Shingles typically presents as a painful, itchy rash that develops on one side of the body and can last for two to four weeks. The pain associated with shingles is often described as burning, shooting or stabbing. Even once the rash is gone, a person can experience postherpetic neuralgia (PHN), pain lasting from at least three months up to several years. PHN is the most common complication of shingles, occurring in 10 to 18 percent of all shingles cases.

There are an estimated 1 million cases of shingles in the United States each year. More than 99 percent of those over 50 years old are infected with VZV, and one in three Americans will develop shingles in their lifetime. The risk increases to one in two for adults aged 85 years and older.

Shingrix is a non-live, recombinant subunit vaccine approved in the United States, Canada, EU, UK, China, Japan, Hong Kong, Australia, New Zealand, Singapore, Brazil and Korea to help prevent shingles (herpes zoster) in people aged 50 years or older. It combines an antigen, glycoprotein E, and an adjuvant system, AS01B, intended to generate a Varicella Zoster Virus (VZV)-specific immune response immune response that can help overcome the decline in immunity as people age.

Shingrix was previously approved by the European Commission (EC) and in the UK for prevention of shingles and post-herpetic neuralgia (PHN) in adults 18 years of age or older at increased risk of shingles and granted marketing authorisation on August 25, 2020.

The updated US Prescribing Information will be available soon at www.gskpro.com.

Important Safety Information for Shingrix

The following is based on the US Prescribing Information for Shingrix. Please consult the full Prescribing information for all the labeled safety information.

- Shingrix is contraindicated in anyone with a history of a severe allergic reaction (e.g., anaphylaxis) to any component of the vaccine or after a previous dose of Shingrix.

- Review immunization history for possible vaccine sensitivity and previous vaccination-related adverse reactions. Appropriate medical treatment and supervision must be available to manage possible anaphylactic reactions following administration of Shingrix.

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

- Syncope (fainting) can be associated with the administration of

vaccines, including Shingrix. Procedures should be in place to avoid falling injury and to restore cerebral perfusion following syncope.

- In individuals aged 50 years and older: Solicited local adverse reactions were pain, redness, and swelling. Solicited general adverse reactions were myalgia, fatigue, headache, shivering, fever, and gastrointestinal symptoms.

- In autologous hematopoietic stem cell transplant recipients (aged 18 to 49 and ≥50 years of age): Solicited local adverse reactions were pain, redness, and swelling. Solicited general adverse reactions were fatigue, myalgia, headache, gastrointestinal symptoms, shivering, and fever.

- The data are insufficient to establish if there is vaccine-associated risk with Shingrix in pregnant women.

- It is not known whether Shingrix is excreted in human milk. Data are not available to assess the effects of Shingrix on the breastfed infant or on milk production/excretion.

- Vaccination with Shingrix may not result in protection of all vaccine recipients.

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