Shingrix approved in the US for prevention of shingles in immunocompromised adults

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GlaxoSmithKline plc today announced that the US Food and Drug Administration (FDA) has approved Shingrix (Zoster Vaccine Recombinant, Adjuvanted) for the prevention of shingles (herpes zoster) in adults aged 18 years and older who are or who will be at increased risk of shingles due to immunodeficiency or immunosuppression caused by known disease or therapy. Immunocompromised individuals are at greater risk of shingles and associated complications than immunocompetent individuals.

Shingrix, a non-live, recombinant sub-unit adjuvanted vaccine, given intramuscularly in two doses, was initially approved by FDA in 2017 for the prevention of shingles in adults 50 years of age or older. Shingrix is not indicated for prevention of primary varicella infection (chickenpox). The approval for this new population expands the number of people who can be protected against shingles by Shingrix.

> We’re proud to offer Shingrix in the US for the prevention of shingles in those who are immunocompromised, with FDA granting a broad indication for use in adults at increased risk of this disease,” said Thomas Breuer, Chief Medical Officer, GSK Vaccines. “Older age and being immunocompromised are the most common risk factors for shingles disease. GSK is committed to this important patient population at increased risk for shingles disease and its complications by bringing them a vaccine option that can help prevent this painful condition.

The GSK Clinical Development Program evaluated the benefit-risk profile of Shingrix in heterogeneous immunocompromised patient populations.

This approval 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 hematopoietic stem cell transplant (auHSCT) and those undergoing treatment for hematological 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 tumors, and renal transplants.,,,,,

> In addition to this new patient population, there are more than 100 million adults 50 years and older in the US already recommended to receive Shingrix," said Breuer. "We know many of these individuals missed recommended vaccines during the pandemic and we hope this can be a reminder to them to catch up on all their immunizations, including Shingrix.

According to recently published report from Avalere Health and supported by GSK, more than 17 million doses of recommended vaccines, including Shingrix, were missed by adults during the pandemic.

Shingrix is the first shingles vaccine indicated for use in those who are at increased risk of the disease due to being immunodeficient or immunosuppressed due to disease or therapy. It 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. For adults aged 50 years and older. 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 US Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices (ACIP) has begun discussions to consider recommendations for use of Shingrix in immunocompromised adults.

Shingrix was previously approved by the European Commission (EC) 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 authorization on August 25, 2020.

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, and Singapore 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 authorization 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.

GSK is a science-led global healthcare company with a special purpose: to help people do more, feel better, live longer. For further

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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 in the Company's Annual Report on Form 20-F for 2020 and any impacts of the COVID-19 pandemic.

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