Approval Date: May 17, 2019

Product: SHINGRIX

Proper Name: Zoster Vaccine Recombinant, Adjuvanted

Manufacturer: GlaxoSmithKline Biologicals

Indication: Indicated for prevention of herpes zoster (shingles) in adults aged 50 years and older.

Description:

SHINGRIX (Zoster Vaccine Recombinant, Adjuvanted) is a sterile suspension for intramuscular injection. The vaccine is supplied as a vial of lyophilized recombinant varicella zoster virus surface glycoprotein E (gE) antigen component, which must be reconstituted at the time of use with the accompanying vial of AS01B adjuvant suspension component.

Approval Date: May 17, 2019 | September 18, 2018 | October 20, 2017

BLA: 125614

Regulatory Milestone: No data available

PDUFA Goal Date: October 21, 2017

Package Insert: Package Insert - SHINGRIX

Summary Basis for Regulatory Approval: October 20, 2017 Summary Basis for Regulatory Action - SHINGRIX

European Public Assessment Report: January 25, 2018 Assessment report - SHINGRIX

Advisory Committee:

A Vaccines and Related Biological Products Committee (VRBPAC) meeting was convened on September 13, 2017. The Committee voted unanimously (11 votes) that the efficacy and safety data supported the licensure of SHINGRIX for prevention of HZ in individuals 50 years of age and older.

Safety: No data available

NCT Numbers:

- NCT00434577
- NCT02690207
- NCT04210752
- NCT03493776
- NCT03953196
- NCT04176939
- NCT04091451
- NCT03886038
- NCT03771157
- NCT04047979
- NCT04403139
- NCT04169009
- NCT03894969
- NCT03798691
- NCT03993717
- NCT03591770
- NCT04128189
- NCT03702231
- NCT04523246

EudraCT Numbers:

- 2019-002529-31
- 2018-002977-24
- 2016-000744-34
- 2019-001815-21
- 2015-003333-95

Publications:

- Lal, H., Zahaf, T., & Heineman, T. C. (2013). Safety and immunogenicity of an AS01-adjuvanted varicella zoster virus subunit candidate vaccine (HZ/su): a phase-I, open-label study in Japanese adults. Human vaccines & immunotherapeutics, 9(7), 1425–1429. https://doi.org/10.4161/hv.24269

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- Cunningham, A. L., Lal, H., Kovac, M., Chlibek, R., Hwang, S. J., Díez-Domingo, J., Godeaux, O., Levin, M. J., McElhaney, J. E., Puig-Barberà, J., Vanden Abeele, C., Vesikari, T., Watanabe, D., Zahaf, T., Ahonen, A., Athan, E., Barba-Gomez, J. F., Campora, L., de Looze, F., Downey, H. J., … ZOE-70 Study Group (2016). Efficacy of the Herpes Zoster Subunit Vaccine in Adults 70 Years of Age or Older. The New England journal of medicine, 375(11), 1019–1032. https://doi.org/10.1056/NEJMoa1603800
- Vink, P., Shiramoto, M., Ogawa, M., Eda, M., Douha, M., Heineman, T., & Lal, H. (2017). Safety and immunogenicity of a Herpes Zoster subunit vaccine in Japanese population aged ≥50 years when administered subcutaneously vs. intramuscularly. Human vaccines & immunotherapeutics, 13(3), 574–578. https://doi.org/10.1080/21645515.2016.1232787
- Godeaux, O., Kovac, M., Shu, D., Grupping, K., Campora, L., Douha, M., Heineman, T. C., & Lal, H. (2017). Immunogenicity and safety of an adjuvanted herpes zoster subunit candidate vaccine in adults ≥ 50 years of age with a prior history of herpes zoster: A

phase III, non-randomized, open-label clinical trial. Human vaccines & immunotherapeutics, 13(5), 1051–1058. https://doi.org/10.1080/21645515.2016.1265715

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- Grupping, K., Campora, L., Douha, M., Heineman, T. C., Klein, N. P., Lal, H., Peterson, J., Vastiau, I., & Oostvogels, L. (2017). Immunogenicity and Safety of the HZ/su Adjuvanted Herpes Zoster Subunit Vaccine in Adults Previously Vaccinated With a Live Attenuated Herpes Zoster Vaccine. The Journal of infectious diseases, 216(11), 1343–1351. https://doi.org/10.1093/infdis/jix482
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