GSK files regulatory submission of candidate vaccine for prevention of shingles in Canada

Mississauga, Ontario – November 21, 2016 - GlaxoSmithKline Inc. (GSK) has submitted a New Drug Submission (NDS) for its candidate shingles vaccine, seeking approval for the prevention of herpes zoster (shingles) and its complications in Canadians aged 50 years or over.

Dr Emmanuel Hanon, Senior Vice President and Head of Vaccines R&D, GSK said: “Shingles is a common and potentially serious condition. It can cause lasting pain and other complications which can severely impact the quality of people’s lives. The risk of developing shingles increases with age and experts estimate that up to one in three people will develop the condition over their lifetime. Today’s file submission puts us a step closer to making this vaccine available to help protect more people from shingles and the complications associated with it.”

The regulatory submission for the candidate shingles vaccine is based on a comprehensive phase III clinical trial program evaluating its efficacy, safety and immunogenicity in more than 37,000 people. This includes the ZOE-50 and ZOE-70 studies published in the New England Journal of Medicine in April 2015 and September 2016, respectively.1,2

GSK’s candidate shingles vaccine is not currently approved for use in Canada.

About GSK’s candidate shingles vaccine
The candidate vaccine is a non-live, recombinant vaccine to help prevent herpes zoster and its complications and combines glycoprotein E, a protein found on the varicella zoster virus (VZV) that causes shingles, with an adjuvant system, AS01B3.

About shingles
Shingles affects an estimated 130,000 Canadians annually and typically presents as a painful, itchy rash that develops on one side of the body, as a result of reactivation of latent chickenpox virus (varicella zoster virus)4. The most common complication from shingles is post-herpetic neuralgia, defined as a localized pain of significant intensity persisting at least 90 days after the appearance of the acute shingles rash. Other complications of shingles include ophthalmologic, neurological and cutaneous disease, which can result in severe disability5. Experts estimate that up to 30% of people develop shingles over their lifetime. Further, because risk rises with age, by age 85 approximately 50% of adults have had or will have shingles.5

References
3. 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.

GSK – one of the world’s leading research-based pharmaceutical and healthcare companies – is committed to improving the quality of human life by enabling people to do more, feel better and live longer. For further information please visit www.ca.gsk.com.

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