PRESS RELEASE

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Pivotal phase III study of GSK shingles candidate vaccine meets its primary endpoint

GSK today announced that a pivotal phase III study to assess the efficacy of HZ/su, an investigational vaccine for the prevention of shingles, has met its primary endpoint.

Analysis of the primary endpoint showed that HZ/su reduced the risk of shingles by 97.2 per cent in adults aged 50 years and older compared to placebo. These are the first results from the ZOster Efficacy study in adults aged 50 years and over (ZOE-50). The study, which started in August 2010, is ongoing in 18 countries and involves more than 16,000 individuals.

Alain Brecx, MD, Vaccine Development Leader at GSK said: "It's great news that the ZOE-50 trial has met its primary endpoint and I would like to thank all those involved in the clinical development programme. If approved, this candidate vaccine may offer an important option for the prevention of shingles, a painful disease that negatively impacts peoples' health and quality of life. We look forward to sharing these compelling results and additional data from the ZOE-50 study and the broader HZ/su clinical development programme with the scientific and regulatory communities."

HZ/su is a new candidate vaccine that combines gE, a protein found on the virus that causes shingles, with an adjuvant system, $AS01_B$,[i] which is intended to enhance the immunological response.

The full set of safety data from the ZOE-50 trial is currently being analysed and will be disclosed in the coming months. The Independent Data Monitoring Committee (IDMC) for the ZOE-50 study, in its ongoing review of the safety information up to 31 May 2014, raised no concerns regarding the continuation of the trial. At this time, the safety profile of HZ/su in older adults is based on data from more than 440 subjects who received HZ/su in phase I and II clinical trials. The most common adverse events seen with HZ/su from these studies included local reactions (pain, redness, swelling at the injection site) and systemic symptoms (muscle pain, fatigue and headache).

Data from the ZOE-50 trial are expected to be presented at a forthcoming scientific conference and submitted for publication in a peer-reviewed journal.

Additional trials to evaluate the ability of HZ/su to prevent shingles are underway in people aged 70 and older and in immunocompromised people. These studies will evaluate the efficacy, safety, and immunological response of HZ/su in specific populations and whether it can prevent some of the complications of shingles, such as chronic neuropathic pain, also known as post-herpetic neuralgia (PHN).[ii]

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Notes to editors

About the ZOE-50 trial

The ZOE-50 study is a randomised, observer-blind, placebo-controlled, multicentre, multinational (North America, Europe, Latin America, Asia-Pacific) phase III trial involving 16,160 adults aged

50 years and older. Doses were given intramuscularly on a 2-dose schedule at 0 and 2 months. The primary endpoint of this study is the overall vaccine efficacy (VE) of the candidate vaccine HZ/su across all age cohorts compared to placebo in reducing the risk of developing shingles. The study includes subjects in the age ranges 50-59, 60-69, 70-79, and ≥80 years.

About the phase III HZ/su study programme

Involving more than 37,000 subjects globally, the phase III programme for candidate vaccine HZ/su will evaluate its efficacy, safety and immunogenicity. In addition to older adults, HZ/su is being evaluated in immunocompromised patient populations, including solid and haematological cancer patients, haematopoietic stem cell and renal transplant recipients and HIV-infected people.

About shingles

Shingles 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, VZV). Anyone who has been infected with VZV is at risk of developing shingles, with age and altered immune system being recognised as the main risk factors.[iii] Complications from shingles can include scarring, vision complications, secondary infection, nerve palsies and PHN, the most common complication.[ii,iii]

Data from many countries indicate that more than 90 per cent of adults are at risk for HZ,[iii,iv] and a person's risk for shingles increases sharply after 50 years of age. Risk of complications, including PHN and hospitalisation, also increase with age. The individual lifetime risk of developing HZ is approximately one in three people; however, for individuals aged 85 and over, this risk increases to one in two people.[v]

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Cautionary statement regarding forward-looking statements

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 under Item 3.D 'Risk factors' in the company's Annual Report on Form 20-F for 2013.

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[i] The GSK proprietary AS01 adjuvant system contains QS-21 Stimulon® adjuvant licensed from Antigenics Inc, a wholly owned subsidiary of Agenus Inc. (NASDAQ: AGEN), MPL and liposomes
[ii] Johnson, RW et al N Engl J Med 2014;371:1526-33
[iii] Shingles (Herpes Zoster) Clinical Overview. US Centers for Disease Control and Prevention, May 1st 2014. Accessed at: http://www.cdc.gov/shingles/hcp/clinical-overview.html on 3rd November 2014.
[iv] Sadzot-Delvaux, et al., 2008; JID (suppl). 197:S185
[v] S. Pinchinat et al: Similar herpes zoster incidence across Europe: results from a systematic literature review. BMC Infectious Diseases 2013, 13:170