GSK's candidate Shingles Vaccine Containing Agenus' QS-21 Stimulon® Demonstrates 90% Efficacy against Shingles and 89% Efficacy against Post-Herpetic Neuralgia in Adults aged 70 Years and Older

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LEXINGTON, Mass.--(BUSINESS WIRE)--Agenus Inc. (NASDAQ:AGEN), an immunology company discovering and developing innovative treatments for cancer and other diseases, announced today that GlaxoSmithKline's plc (LSE/NYSE:GSK) second pivotal Phase III efficacy study of its shingles vaccine candidate containing Agenus' QS-21 Stimulon® adjuvant demonstrated 90% overall efficacy against shingles compared to placebo. In this trial known as ZOE-70 (Zoster efficacy in adults aged 70 years and over) the vaccine candidate HZ/su was studied in adults aged 70 years and older.[i] These results are consistent with the first pivotal Phase III study, ZOE-50, which demonstrated an efficacy of 97.2% in adults age 50 years and older. In ZOE-50, 53% of the subjects were over 60, and almost 24% were over 70 years of age.[ii]

"We are pleased by the consistent, positive results from studies of the candidate vaccine containing our adjuvant, QS-21 Stimulon," said Dr. Garo Armen, Ph.D., Chairman and Chief Executive Officer of Agenus. "We look forward to worldwide regulatory filings of HZ/su for the many millions of people, especially older individuals, at risk of shingles."

The HZ/su vaccine candidate combines the glycoprotein E (gE) from the chickenpox virus, Varicella, a protein that is part of the virus that causes shingles, with the AS01 adjuvant system, which is designed to enhance the immune response to gE. The AS01 adjuvant system contains Agenus' QS-21 Stimulon, MPL (3-O-desacyl-4'-monophosphoryl lipid A) and liposomes. GSK intends to submit a regulatory application to the US Food and Drug Administration (FDA), and regulatory agencies in Japan and EU for HZ/su in mid-2016.

About ZOE-70

The ZOE-70 HZ/su shingles study is a randomized, observer-blind, placebo controlled Phase III trial involving approximately 14,800 adults. The vaccine candidate is also being evaluated in immune compromised patient populations in other clinical trials.

About Shingles

Shingles typically presents as a painful, itchy rash that develops in a circumscribed region of the body, as a result of reactivation of latent chickenpox virus (varicella zoster virus, VZV). Complications from shingles can include post-herpetic neuralgia (PHN), a condition of chronic neuropathic pain, as well as scarring, vision complications, secondary infection, and nerve palsies. A person's risk for shingles increases after 50 years of age. The individual lifetime risk of developing shingles is approximately one in three people; however, for individuals who reach the age of 85, this risk increases to one in two people.[iii]

About Agenus

Agenus is an immunology company engaged in the discovery and development of immuno-therapies, including novel checkpoint modulators, vaccines and adjuvants to treat cancer and other diseases. Using its proprietary platforms Retrocyte Display™ and SECANT®, the Company is discovering and developing novel antibodies to target GITR, OX40, CTLA-4, LAG-3, TIM-3, PD-1, CEACAM1 and other undisclosed checkpoints in partnered and internal programs. The Company's QS-21 Stimulon® adjuvant is partnered with GlaxoSmithKline and Janssen Sciences Ireland UC. Agenus' heat shock protein vaccine, Prophage™, has successfully completed Phase 2 studies in newly diagnosed glioblastoma multiforme. For more information, please visit www.agenusbio.com; information that may be important to investors will be routinely posted on our website.

Forward-Looking Statements

This press release contains forward-looking statements that are made pursuant to the safe harbor provisions of the federal securities laws, including statements regarding the potential benefits of GSK's HZ/su vaccine candidate. These forward-looking statements are subject to risks and uncertainties that could cause actual results to differ materially. These risks and uncertainties include, among others, the factors described under the Risk Factors section of Agenus' Form 10-Q filed with the Securities and Exchange Commission on August 3, 2015. Agenus cautions investors not to place considerable reliance on the forward-looking statements contained in this release. These statements speak only as of the date of this press release, and Agenus undertakes no obligation to update or revise the statements, other than to the extent required by law. All forward-looking statements are expressly qualified in their entirety by this cautionary statement.

[i] https://clinicaltrials.gov/ct2/show/NCT01165229?term=zoster+022&rank=1

[ii] Lal H, Cunningham AL, Godeaux O, Chlibek R, Diez-Domingo J, Hwang SJ, Levin MJ, McElhaney JE, Poder A, Puig-Barberà J, Vesikari T, Watanabe D, Weckx L, Zahaf T, Heineman TC; ZOE-50 Study Group. Efficacy of an adjuvanted herpes zoster subunit vaccine in older adults. N Engl J Med. 2015; 372(22):2087-96

[iii] S. Pinchinat *et al*.: Similar herpes zoster incidence across Europe: results from a systematic literature review. BMC Infectious Diseases 2013, 13:170

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