NEJM Publishes Study Showing GSK's Shingles Vaccine Containing Agenus' QS-21 Stimulon® Adjuvant Provides over 97% Protection in People Over the Age of 50

April 28, 2015

Data simultaneously presented at ECCMID

HZ/su vaccine achieves nearly 98% protection in people 70 or older

This marks the second successful Phase 3 clinical program incorporating Agenus' QS-21 Stimulon adjuvant

LEXINGTON, Mass.--(BUSINESS WIRE)--Agenus Inc. (NASDAQ: AGEN), an immunology company developing innovative treatments for cancers and other diseases, announced today that primary and secondary endpoint data from GlaxoSmithKline's (LSE/NYSE: GSK) randomized Phase 3 trial of HZ/su, a vaccine candidate for the prevention of shingles, was simultaneously presented at the 25th Scientific Conference of the European Society of Clinical Microbiology and Infectious Disease (ECCMID) in Copenhagen, and published in the *New England Journal of Medicine*. GSK's HZ/su incorporates Agenus' QS-21 Stimulon® adjuvant, which is designed to increase immune response to antigens.

The data show that GSK's HZ/su reduced the risk of shingles (herpes zoster) by 97.2% in adults aged 50 and older, compared to placebo. Importantly, the protection was maintained across all studied age groups, ranging from 96.6% in subjects aged 50-59, 97.4% in those aged 60-69, and 97.9% in those aged 70 or older. No major safety concerns were identified in the study. The most common reported adverse event was pain at injection site, fatigue and myalgia.

"The vast majority of adults over age 50 are at high risk of reactivating the varicella zoster virus, which leads to shingles and its painful and debilitating symptoms. These clinical results point to the broad benefits that widespread use of this vaccine could bring to adults over 50 worldwide," said Garo Armen, Ph.D., Chairman and CEO of Agenus. "These data, and those from GSK's RTS,S malaria vaccine now undergoing regulatory review by the EMA, highlight the importance and value that we believe QS-21 Stimulon brings to vaccines and to Agenus."

The HZ/su vaccine candidate combines gE, a protein that is part of the virus that causes shingles, with the AS01 adjuvant system, which enhances the immune response to gE. The AS01 adjuvant system contains Agenus' QS-21 Stimulon, MPL (3-O-desacyl-4'-monophosphoryl lipid A) and liposomes.

Agenus is eligible to receive a milestone payment upon GSK's first approval of a QS-21 Stimulon-containing product and royalties from any potential commercial product sales of HZ/su. QS-21 Stimulon is being evaluated in more than 12 additional vaccine candidates.

The HZ/su shingles study is a randomized, observer-blind, placebo-controlled Phase 3 trial involving over 16,000 adults aged 50 years and older. The study started in August 2010 and is still ongoing. In addition to older adults, HZ/su is being evaluated in immunocompromised patient populations, including solid and hematological cancer patients, hematopoietic 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). Complications from shingles can include chronic pain, scarring, vision complications, secondary infection, nerve palsies and hospitalization. A person's risk for shingles increases sharply after 50 years of age. The individual lifetime risk of developing shingles is approximately one in three people; however, for individuals aged 85 and over, this risk increases to one in two people.[i]

About QS-21 Stimulon®

QS-21 Stimulon is a saponin extracted from the bark of the *Quillaja saponaria* tree, an evergreen also known as the soap bark tree. The adjuvant is a key component of investigational vaccines to prevent a wide variety of infectious diseases, and therapeutic vaccines for cancer and degenerative disorders. QS-21 Stimulon has been evaluated in approximately 50,000 patients. Agenus is generally entitled to receive milestone payments as QS-21 Stimulon containing programs advance, as well as royalties on potential commercial sales for 10 years after commercial launch, if ever, with some exceptions.

About Agenus

Agenus is an immunology company developing a series of Checkpoint Modulators for the treatment of patients with cancer, infectious diseases, and other immune disorders, heat shock protein (HSP)-based vaccines, and immune adjuvants. These programs are supported by three separate technology platforms. Agenus' internal and partnered checkpoint modulator programs target GITR, OX40, CTLA-4, LAG-3, TIM-3, PD-1 and other undisclosed programs. The company's proprietary discovery engine Retrocyte Display ™ is used to generate fully human and humanized therapeutic antibody drug candidates. The Retrocyte Display platform uses a high-throughput approach incorporating IgG format human antibody libraries expressed in mammalian B-lineage cells. Agenus recently acquired a powerful yeast antibody display platform termed SECANT, developed by Celexion, LLC. SECANT allows rapid generation of soluble, full-length human antibodies. SECANT and Agenus' mammalian antibody display platform have complementary strengths and further bolster Agenus' abilities to generate and optimize fully human monoclonal antibodies. Agenus' heat shock protein-based vaccines have completed Phase 2 studies in newly diagnosed glioblastoma multiforme, and in the treatment of herpes simplex viral infection; the heat shock protein-based vaccine platform can generate personalized as well as off the shelf products. The company's QS-21 Stimulon® adjuvant platform is extensively partnered with GlaxoSmithKline and with Janssen Sciences Ireland UC and includes several candidates in Phase 2 trials, as well as shingles and malaria vaccines which have successfully completed Phase 3 clinical trials. For more information, please visit www.agenusbio.com, or connect with the company on Facebook, LinkedIn, Twitter and Google+; information that may be important to investors will be routinely posted in these locations.

Forward-Looking Statement

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 therapeutic benefit of GSK's singles vaccine candidate HZ/su in adults over the age of 50 worldwide, potential commercial sales of HZ/su and the potential for Agenus to receive milestone and royalty payments for product candidates containing Agenus' QS-21 Stimulon generally. 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 our most recent Quarterly Report on Form 10-Q or annual report on Form 10-K filed with the Securities and Exchange Commission. 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] 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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