Positive Outcome of Phase 3 Study of GSK Shingles Vaccine Containing Agenus Adjuvant

December 18, 2014

GSK's ZOE-50 Phase 3 study meets primary endpoint of reducing the risk of shingles in people aged 50 and older

Agenus is entitled to receive royalties on potential commercial sales of HZ/su

LEXINGTON, Mass., Dec. 18, 2014 (GLOBE NEWSWIRE) -- Agenus Inc. (Nasdaq:AGEN), an immuno-oncology company developing a broad portfolio of checkpoint modulators (CPMs) and heat shock protein peptide-based vaccines as well as adjuvants, announced that its partner GlaxoSmithKline (NYSE:GSK) reported that the ZOE-50 Phase 3 study 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.

HZ/su is a novel candidate vaccine that combines gE, a protein found on the varicella-zoster virus that causes shingles, with GSK's Adjuvant System, $AS01_B$, which serves to stimulate a stronger immunological response to the vaccine. Agenus' QS-21 Stimulon® adjuvant is one of the key components of AS01, which is used in other vaccine candidates undergoing clinical development.

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"*We are thrilled with the results of this important study*," said Garo Armen, Ph.D., Chief Executive Officer of Agenus, "*The results indicate unprecedented protection against shingles. HZ/su is the second candidate vaccine containing QS-21 saponin to produce positive phase 3 results."*

The study, which started in August 2010, is a randomized, placebo-controlled, multicenter, international study involving 16,136 adults aged 50 and older. An additional GSK trial to evaluate the ability of HZ/su to prevent shingles is underway in adults aged 70 and older (ZOE-70). This study will provide additional information on the efficacy of HZ/su vaccine candidate in preventing some of the complications of shingles, the most common being chronic neuropathic pain, also known as post-herpetic neuralgia (PHN)[i].

Data from GSK's ZOE-50 study are expected to be presented at a forthcoming scientific conference and will be submitted for publication in a peer-reviewed journal.

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 scarring, vision complications, secondary infection, nerve palsies and PHN, the most common complication. The lifetime risk of developing shingles is approximately 1 in 3.

About QS-21 Stimulon

Agenus' flagship adjuvant, QS-21 Stimulon® adjuvant, is a saponin extracted from the bark of the Quillaja saponaria tree, also known as the soap bark tree, an evergreen tree native to warm temperate central Chile. Agenus' QS-21 Stimulon has become a key component in the development of investigational preventive vaccine formulations across a wide variety of infectious diseases and in several investigational therapeutic vaccines intended to treat cancer and degenerative disorders. QS-21 Stimulon has been widely studied in approximately 50,000 people. Agenus is generally entitled to receive milestone payments as QS-21 Stimulon containing programs advance, as well as royalties for 10 years after commercial launch, with some exceptions.

About Agenus

Agenus is an immuno-oncology company developing a portfolio of checkpoint modulators (CPMs), heat shock protein peptide-based vaccines and adjuvants. Agenus' checkpoint modulator programs target GITR, OX40, CTLA-4, LAG-3, TIM-3 and PD-1. 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' heat shock protein vaccines for cancer and infectious disease are in Phase 2 studies. The company's QS-21 Stimulon® adjuvant platform is extensively partnered with GlaxoSmithKline and Janssen and includes several vaccine candidates in Phase 2 and Phase 3 clinical trials. For more information, please visit www.agenusbio.com, or connect with the company on Facebook, LinkedIn, Twitter and Google+.

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 research and development and clinical trial activities and results, the presentation and publication of data, potential revenue streams, and the potential application of the Company's and its licensee's technologies and product candidates in the prevention and treatment of diseases. These forward-looking statements are subject to risks and uncertainties that could cause actual results to differ materially from those projected. These risks and uncertainties include, among others, the factors described under the Risk Factors section of our most recently filed Quarterly Report on Form 10-Q 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 document, 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. Agenus' business is subject to substantial risks and uncertainties, including those identified above. When evaluating Agenus' business and securities, investors should give careful consideration to these risks and uncertainties.

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[i] Johnson, RW et al N Engl J Med 2014;371:1526-33

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