GSK’s Malaria Vaccine Phase 3 Study Containing Agenus’ QS-21 Published in The Lancet

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- **Final study results show significant reduction in malaria cases**
- **EMA currently reviewing the regulatory application**

LEXINGTON, Mass.--(BUSINESS WIRE [11])--Agenus Inc. (NASDAQ: AGEN), an immunology company developing innovative treatments for cancers and other diseases, announced today that final results from a large-scale Phase 3 study of GlaxoSmithKline’s (NYSE: GSK) malaria vaccine candidate, RTS,S, were published in *The Lancet*. The study demonstrated a statistically significant reduction against malaria in children who received RTS,S followed by a booster shot of the vaccine at 18 months. RTS,S incorporates QS-21 Stimulon®, Agenus’ adjuvant designed to increase the immune response to antigens in vaccines.

The study results also showed:
- RTS,S reduced the number of cases of clinical malaria in young children (aged 5-17 months at first vaccination) by 36%, and in infants (aged 6-12 weeks) by 26% over an average follow-up period of 48 months.
- This resulted in an average reduction of 1,774 cases of clinical malaria for every 1,000 children vaccinated (aged 5-17 months), and an average reduction of 983 cases of clinical malaria for every 1,000 infants vaccinated over an average 36-month follow-up. Children receiving the vaccine candidate but not a booster dose had lower rates of protection. The study showed that RTS,S averted even more cases of malaria in areas with higher transmission rates.

“We’re proud to be a part of this malaria vaccine initiative, which has the potential to save tens of thousands of lives each year,” said Garo Armen, Ph.D., Chairman and CEO of Agenus. “These compelling results demonstrate for the first time that a vaccine and adjuvant can significantly reduce suffering by young children in areas hardest hit by malaria. We look forward to RTS,S potentially achieving regulatory approval and being made available to the millions of children who are at risk of severe malaria in sub-Saharan African countries.”

Agenus is eligible for a milestone payment upon approval of RTS,S and royalties from potential commercial sales. QS-21 Stimulon is being evaluated in more than 12 additional vaccine candidates.

RTS,S trial data were submitted to the European Medicines Agency (EMA) in June 2014 for review by their Committee for Medicinal Products for Human Use (CHMP). A positive opinion from the CHMP, together with a potential policy recommendation from the World Health Organization (anticipated by the end of 2015), would be the basis for licensure applications to the National Regulatory Authorities (NRAs) in sub-Saharan African countries.

Eleven research centers in seven African countries conducted the trial, in partnership with GSK and the Path Malaria Vaccine Initiative (MVI), with grant funding from the Bill & Melinda Gates Foundation to MVI. The trial, launched in 2009 and concluded in January 2014, enrolled 15,459 young child (5-17 months) and infant (6-12 weeks) participants.

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 Cellexion, 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[^2], 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 regulatory approval of GSK’s malaria vaccine candidate, RTS,S, the potential for RTS,S to save lives each year, potential commercial sales of RTS,S and the potential for Agenus to receive milestone and royalty payments for product candidates containing Agenus’s 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.

**Language:**

English

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