GSK's Malaria Vaccine Containing Agenus' QS-21 Stimulon® Receives Positive Opinion from European Regulators for Prevention of Malaria in Young Children in Sub-Saharan Africa

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LEXINGTON, Mass.--(BUSINESS WIRE)--Agenus Inc. (NASDAQ:AGEN), an immunology company discovering and developing innovative treatments for cancers and other diseases, today announced that GlaxoSmithKline (NYSE: GSK) received a positive opinion for its Malaria vaccine candidate from the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA). The vaccine candidate, named Mosquirix™ (RTS,S) is the first QS-21 Stimulon containing product to receive a positive regulatory decision. Agenus' adjuvant QS-21 is designed to increase immune response to antigens in vaccines. The positive opinion signals that Mosquirix meets the necessary quality, safety and efficacy requirements according to EU standards.

"This is a significant milestone for the field of Malaria and our QS-21 Stimulon, which is an integral component of the adjuvant contained in Mosquirix, the first malaria candidate vaccine to generate positive Phase 3 data, now awaiting the World Health Organization's recommendations and approvals by African Health authorities," commented Garo Armen, Ph.D., Chairman and CEO of Agenus. "We look forward to seeing Mosquirix achieve the required final clearances so it can begin benefiting children at risk of contracting and dying from Malaria."

The CHMP scientific opinion is a key step in the regulatory process toward making a vaccine against Malaria available. The positive opinion follows review by the CHMP of the candidate vaccine's safety, efficacy and quality. Clinical data supporting the filing were mainly from a Phase 3 clinical program involving more than 16,000 infants and young children.

Following the CHMP positive opinion, two of the World Health Organization's (WHO) independent advisory groups, the Strategic Advisory Group of Experts (SAGE) on Immunization and the Malaria Policy Advisory Committee (MPAC), will now jointly review the evidence base for the vaccine candidate and make a joint policy recommendation for how the vaccine should be used in the event that it ultimately is approved by the national regulatory authorities in the sub-Saharan African countries for which the vaccine is intended. The WHO has indicated that such a policy recommendation may be possible by end of this year.

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 individuals and patients. Agenus is entitled to receive a modest milestone payment upon approval of the first licensed product with GSK, as well as low single digit royalties on potential commercial sales for 10 years after commercial launch, with some exceptions.

About Agenus

Agenus is an immunology company engaged in the discovery and development of 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 and other undisclosed checkpoints in partnered and internal programs. Agenus' heat shock protein vaccine, Prophage, has successfully completed Phase 2 studies in newly diagnosed glioblastoma multiforme. The Company's QS-21 Stimulon® adjuvant is extensively partnered with GlaxoSmithKline and Janssen Sciences Ireland UC, and two vaccine candidates containing QS-21 have successfully completed Phase 3 trials. For more information, please visit www.agenusbio.com, or follow the company on Twitter @Agenus_Bio; information that may be important to investors will be routinely posted in these locations.

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 expected benefit from GSK's Mosquirix™ vaccine, the potential milestone and royalties payable to Agenus and the Company's potential to create best-in-class combination therapies for treating patients with cancer. 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' Prospectus Supplement filed with the Securities and Exchange Commission on May 21, 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.

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