GSK's Vaccine Candidate Containing Agenus' QS-21 Stimulon® Reduces Malaria Infection in Phase 3 Trials of Over 15,000 Children

October 7, 2013

Significant protection shown 18 months post vaccination

RTS,S vaccine could have a major public health impact on malaria in Africa

GSK plans regulatory submission in 2014

Agenus entitled to receive milestone payment and royalties upon launch

Agenus Inc. (Nasdaq: AGEN) today announced that new Phase 3 data for GlaxoSmithKline's (NYSE: GSK) RTS,S malaria vaccine candidate, which contains Agenus' QS-21 Stimulon® [1] adjuvant, were presented at a Multilateral Initiative on Malaria Pan African Conference in Durban, South Africa. The abstract and presentation titled, "Efficacy of RTS,S/AS01 vaccine candidate against malaria in African infants and children 18 months post-primary vaccination series: a Phase 3 randomized, double-blind controlled trial," shows that RTS,S helped protect young children and infants from clinical malaria up to 18 months post vaccination. RTS,S is the most advanced malaria vaccine candidate in the world and the first vaccine candidate to show in clinical trials that it can help protect young children and infants living in malaria-endemic areas against clinical disease and infection caused by Plasmodium falciparum. Malaria claims over 600,000 lives a year, most of which are children in Sub-Saharan Africa.[2]

"These findings indicate that RTS,S has the potential to help prevent millions of malaria cases. We are very pleased that our QS-21 Stimulon adjuvant is a key component of AS01, a proprietary adjuvant system used in RTS,S," said Garo H. Armen, Ph.D., Chairman and CEO of Agenus Inc. "These results provide further support that QS-21 Stimulon can help advance challenging development programs targeting difficult diseases. Currently there are 21 development programs underway involving vaccines that include QS-21 Stimulon for many different types of cancer, infectious diseases and degenerative disorders."

RTS,S Efficacy

For the first time, the efficacy of the vaccine candidate was assessed at each trial site separately, which are in regions with different levels of malaria disease. Efficacy was found to be statistically significant at all sites in young children and at four sites in infants.

According to the results, children aged 5-17 months at first vaccination with RTS,S experienced 46% fewer cases of clinical malaria, compared to children immunized with a control vaccine. Recognizing that children can each be affected by more than one case of malaria, this results in 941 cases of clinical malaria prevented over 18 months of follow-up for every 1,000 children vaccinated. Severe malaria cases were reduced by 36%, resulting in 21 cases of severe malaria prevented over 18 months of follow-up for every 1,000 children vaccinated. Malaria hospitalizations were reduced by 42%. These results in children 5-17 months were statistically significant.

Infants aged 6-12 weeks at first vaccination with RTS,S had 27% fewer cases of clinical malaria, resulting in 444 cases of clinical malaria prevented over 18 months of follow-up for every 1,000 infants vaccinated. The reduction of severe malaria cases and malaria hospitalizations by 15% and 17%, respectively, were not statistically significant.

The reduction in number of malaria cases attributed to RTS,S was demonstrated in addition to the effect of existing malaria control measures such as insecticide treated bed nets that were used by 78% of children and 86% of infants in the trial.

Previous results from one year follow-up of the Phase 3 trial showed that efficacy of RTS,S was 56% against clinical malaria and 47% against severe malaria for the 5-17 month-old age group and 31% against clinical malaria and 37% against severe malaria in the 6-12 week-old age group.

RTS,S continued to display an acceptable safety and tolerability profile during the 18 month follow-up. No new safety signals were observed during this longer follow-up period. The incidence of severe adverse events overall was similar in participants in each group but the imbalance in reported cases of meningitis, noted previously[3],has persisted.

Further data from 32 months follow-up and the impact of a 'booster' dose given after 18 months are expected to become available in 2014.

About RTS,S

RTS,S is a scientific name given to this malaria vaccine candidate and represents the composition of this vaccine candidate that also contains the AS01 adjuvant system.[4] RTS,S aims to trigger the immune system to defend against the Plasmodium falciparum malaria parasite when it first enters the human host's bloodstream and/or when the parasite infects liver cells. It is designed to prevent the parasite from infecting, maturing, and multiplying in the liver, after which time the parasite would re-enter the bloodstream and infect red blood cells, leading to disease symptoms.

These new data support GSK's plans to submit a regulatory application in 2014 for a Scientific Opinion of the European Medicines Agency (EMA) on RTS,S safety, efficacy and quality. If the EMA give a positive opinion, and there is satisfactory public health information from the Phase 3 program, the World Health Organization has indicated that a policy recommendation for the RTS,S malaria vaccine candidate is possible in 2015, paving the way for potential decisions by African nations for large-scale implementation of the vaccine through their national immunization programs.

About GlaxoSmithKline

GSK is one of the world's leading research-based pharmaceutical and healthcare companies and committed to improving the quality of human life by enabling people to do more, feel better and live longer. For further information about the RTS,S program, please visit www.gsk.com.

About Agenus' QS-21 Stimulon® Adjuvant

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 or Soapbark, an evergreen tree native to warm temperate central Chile. Agenus' GMP QS-21 Stimulon has become a key component in the development of investigational preventive vaccine formulations across a wide variety of infectious diseases, and appears to be essential for several investigational therapeutic vaccines intended to treat cancer and degenerative disorders. QS-21 Stimulon has been widely studied and approximately 50,000 patients have received vaccines containing the adjuvant. QS-21 Stimulon is being studied in 21 vaccine indications, which include GSK's Phase 3 vaccine programs for RTS,S for malaria, MAGE-A3 cancer immunotherapeutic for non-small cell lung cancer and melanoma and HZ/su for shingles. In addition, Janssen's QS-21 Stimulon adjuvant-containing vaccine candidate is in Phase 2 trials for the treatment of Alzheimer's disease, and Agenus' HerpV, a therapeutic vaccine for the treatment of genital herpes, is in a Phase 2 trial. 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 Inc. is a biotechnology company working to develop treatments for cancers and infectious diseases. The company is focused on immunotherapeutic products based on strong platform technologies with multiple product candidates advancing through the clinic, including several product candidates that have advanced into late-stage clinical trials through corporate partners. Between Agenus and its partners, 23 programs are in clinical development. For more information, please visit www.agenusbio.com, or connect with the company on Facebook, LinkedIn, Twitter and Google+.

1. QS-21 Stimulon® adjuvant and the related agreements, and HerpV are assets of Antigenics Inc., a wholly owned subsidiary of Agenus Inc.

2. http://www.who.int/malaria/world_malaria_report_2011/en/index.html

3. The RTS,S Clinical Trials Partnership. NEJM. 2011; DOI 10.1056/NEJMoa1102287; The RTS,S Clinical Trials Partnership. NEJM. 2012; DOI: 10.1056/NEJMoa1208394

4. The GSK proprietary AS01 adjuvant system contains QS-21 Stimulon® adjuvant, MPL and liposomes.

Stimulon is a registered trademark of Agenus Inc. and its subsidiaries.

Forward-Looking Statement

This press release contains forward-looking statements, including statements regarding the potential application product candidates containing the Company's QS-21 Stimulon Adjuvant in the prevention and treatment of diseases, and revenue streams to Agenus in connection therewith. 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 Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission for the period ended June 30, 2013. 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. 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.