GSK'S MAGE-A3 Cancer Immunotherapeutic Phase 3 Study in Melanoma Misses First Co-Primary Endpoint

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In Line with Independent Data Monitoring Committee's (IDMC) Unanimous Recommendation, GSK will Continue Study Until Second Co-primary Endpoint is Assessed

Agenus Inc. (Nasdaq: AGEN) today announced that GlaxoSmithKline's (NYSE: GSK) DERMA [i] study, a Phase 3 randomized, blinded, placebo-controlled MAGE-A3 cancer immunotherapeutic[ii] (CI) trial, which contains Agenus'QS-21 Stimulon® adjuvant [iii], a component of GSK's novel adjuvant system AS15, did not meet its first co-primary endpoint. In an independent analysis, the study did not significantly extend the disease-free survival (DFS)[iv] period when compared to placebo in the overall MAGE-A3 positive trial population.

In line with the Independent Data Monitoring Committee's (IDMC) unanimous recommendation, GSK will continue the study until the second co-primary endpoint is assessed. This co-primary endpoint is based on predefined criterion that was agreed upon by regulatory authorities. This analysis, which is based on gene signature, is designed to prospectively identify patients who may have the capability to be more immunologically responsive and therefore can potentially benefit from treatment. If further analysis shows that the predefined gene signature subset data are successful, there is the potential that a regulatory filing could be considered. GSK anticipates that these data will be available in 2015. Until then, GSK will remain blinded to all safety and efficacy data.

The IDMC for the DERMA study indicated that the current review of the safety information raised no concern for the continuation of the trial.

"We continue to believe that cancer immunotherapeutics have the potential to deliver significant benefits to patients and we look forward to the analysis of gene signature data," said Garo H. Armen, Ph.D., chairman and CEO of Agenus Inc. "In the near future, we expect to report results of several other QS-21 Stimulon adjuvant containing programs."

QS-21 Stimulon adjuvant is key component of many vaccines currently in clinical development. Agenus expects to report Phase 2 data for HerpV, Agenus'QS-21 Stimulon containing investigational therapeutic vaccine for genital herpes, during the fourth quarter of 2013. GSK is expected to announce Phase 3 results from MAGRIT, the MAGE-A3 non-small cell lung cancer (NSCLC) clinical trial during the first half of 2014. In addition, GSK is expected to provide an update to the RTS,S program for the prevention of malaria.

About MAGE-A3 and GSK's Cancer Immunotherapeutics (CIs)

MAGE-A3 is a tumor-specific antigen that is expressed in a large variety of cancers, including melanoma, NSCLC, head and neck cancer, and bladder cancer, with no expression in normal cells[v]. GSK's CIs represent a class of novel investigational compounds that are based on tumor antigens presented to the patient's immune system as recombinant proteins in combination with a GSK novel adjuvant system. CIs are designed to trigger a specific immune response against tumor cells expressing these proteins, rallying antibodies and T-cells to recognize and attack the cancer cells in a highly specific manner and eventually eliminate them.

This approach primarily aims at reducing the risk of tumor recurrence following surgery. The highly targeted mode of action of GSK CIs against specific cancer antigens expressed by tumor cells may allow selection of patients eligible for the treatment depending on the expression of the tumor antigens. This may help oncologists to select patient populations most likely to respond to the treatment. GSK's MAGE-A3 CI contains a purified recombinant MAGE-A3 protein combined with GSK's novel AS15 adjuvant system. It was developed with the goal of inducing strong and sustained immune responses. AS15 is composed of the QS-21 Stimulon adjuvant, monophosphoryl lipid A (MPL), and CpG7909, a TLR-9 agonist, in a liposomal formulation.

Adjuvants are substances, which when used in combination with antigens in vaccines, enhance the immune response.

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' 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 with data expected during the fourth quarter 2013. 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 GSK's DERMA Program

The GSK DERMA study evaluated the efficacy and safety of the MAGE-A3 cancer immunotherapeutic, when compared to placebo, in MAGE-A3 positive patients (those whose tumor shows expression of the MAGE-A3 gene) with Stages IIIB/C surgically resected melanoma. The MAGE-A3 antigen is expressed in approximately 65% of tumors in Stage III melanoma patients. The DERMA trial randomized 1,345 patients and is being conducted in 33 countries. In accordance with the study protocol, patients were given up to 13 injections into the muscle of the upper arm or thigh, over a period of 27 months.

For additional information, please visit GSK's website at www.gsk.com

About Melanoma

Melanoma is the most aggressive form of all skin cancers and its incidence is rising at a rate exceeding all other cancers.[1,2] Worldwide, it is believed that approximately 160,000 people will be diagnosed with melanoma each year.[3] If detected in its earliest stages and treated properly, melanoma is curable, however, melanoma is more likely than other skin tumors to spread to other parts of the body. Patients with stage IIB-C and stage III (locoregional lymph-node involvement) melanoma have a high risk of relapse following surgery (60% and 75% risk of recurrence, respectively).[4] There are limited options for patients with advanced melanoma disease,[5] highlighting that this type of melanoma represents an area of high unmet medical need.

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. For more information, please visit www.agenusbio.com.

Notes to editors

[i] Adjuvant immunotherapy with MAGE-A3 in melanoma GSK 2132231A Antigen-Specific Cancer Immunotherapeutic in patients with resected melanoma.

[ii] MAGE-A3 cancer immunotherapeutic consists of recombinant MAGE-A3 protein and a novel immunostimulant AS15 (a combination of QS-21 Stimulon® adjuvant, monophosphoryl lipid A, and CpG7909, a TLR-9 agonist, in a liposomal formulation).

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

[iv] DFS is defined as the time from randomization to the date of first recurrence of the disease or of death, whichever comes first.

[v] The exception is testicular cells and placental cells.

References

[1] Lens MB, Dawes M Global perspectives of contemporary epidemiological trends of cutaneous malignant melanoma. Br J Dermatol 2004; 150:179-185.

[2] Fitzgerald K. Mechanisms of metastasis. Cellix's VenaFlux platform pursue metastatic movement. Screening 2008; 2: 2-3.

[3] Ferlay J, Bray F, Pisani P et al. GLOBOCAN 2002 Cancer Incidence, Mortality and Prevalence Worldwide. IARC CancerBase No. 5, version 2.0. IARCPress, Lyon, 2004.

[4] Kirkwood JM, Ibrahim JG, Sondak VK et al. High and low dose interferon alfa-2b in high-risk melanoma: first analysis of intergroup trial E1690 / S9111 / C9190. J Clin Oncol 2000; 18(12): 2444-2458.

[5] Tarhini AA, Agarwala SS. Cutaneous melanoma: available therapy for metastatic disease. Dermatologic Therapy 2006; 19(1): 19-25.

Forward-Looking Statement

This press release contains forward-looking statements, including statements regarding clinical trial activities, the publication of data, and the potential application of the Company'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. 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.