



## **GSK's MAGE-A3 Cancer Immunotherapeutic Phase 3 Study in Non-small Cell Lung Cancer Misses First Co-primary Endpoints**

March 20, 2014

### **GSK to continue study until third co-primary endpoint is assessed**

Agenus Inc. (Nasdaq: AGEN) today announced that GlaxoSmithKline's (NYSE: GSK) MAGRIT<sup>i</sup> study, a Phase 3 randomized, blinded, placebo-controlled MAGE-A3<sup>ii</sup> cancer immunotherapeutic trial in non-small cell lung cancer patients, which contains Agenus' QS-21 Stimulon® adjuvant, did not meet its first or second co-primary endpoint. The study did not significantly extend the disease-free survival (DFS)<sup>iii</sup> period when compared to placebo in the overall MAGE-A3 positive patients or patients who did not receive chemotherapy.

GSK announced that it will continue the study until an analysis of the third co-primary endpoint is complete. The third co-primary endpoint is based on predefined criterion that was discussed with regulatory authorities. This analysis is based on gene signature and designed to prospectively identify MAGE-A3 positive patients who may benefit more from treatment. If further analysis shows that the predefined gene signature subset data are successful, there is the potential for regulatory filing. GSK anticipates that these data should be available in 2015. Until then, GSK will remain blinded to all safety and efficacy data.

The Independent Data Monitoring Committee for the MAGRIT study indicated that a review of the safety information raised no specific concern for the continuation of the trial.

### **About GSK's MAGRIT Program**

In this study, patients were given up to 13 intramuscular injections of either the MAGE-A3 immunotherapeutic or placebo over a period of 27 months.

GSK currently remains blinded to further details of the analysis of the first two co-primary endpoints in order to allow for the unbiased generation of a mathematical model to assess the third co-primary endpoint<sup>iv</sup>, which is expected to be known in 2015. GSK is also continuing to evaluate whether a gene signature can identify a population that would benefit from the same investigational MAGE-A3 cancer immunotherapeutic in DERMA, another Phase 3 trial in melanoma, which reported on the first co-primary endpoint in September 2013.

For additional information, please visit GSK's website at [www.gsk.com](http://www.gsk.com).

### **About Agenus**

Agenus is a biopharmaceutical company developing a portfolio of immuno-oncology candidates, including checkpoint modulators (CPMs), heat shock protein vaccines and adjuvants. The company's proprietary discovery engine Retrocyte Display® is designed to rapidly generate high quality therapeutic antibody drug candidates using a high-throughput approach incorporating full-length IgG format human antibody libraries expressed in mammalian B-lineage cells. A portfolio of checkpoint modulator programs is advancing in preclinical development. The company's heat shock protein vaccines for cancer and infectious disease are in Phase 2 studies. Agenus' QS-21 Stimulon adjuvant platform is extensively partnered with GlaxoSmithKline and Janssen and includes several candidates in Phase 3 trials. Among Agenus and its partners, 23 programs are in clinical development. For more information, please visit [www.agenusbio.com](http://www.agenusbio.com), or connect with the company on Facebook, LinkedIn, Twitter and Google+.

i A double-blind, randomised, placebo-controlled Phase III trial to assess the efficacy of recMAGE-A3 + AS15 antigen-specific cancer immunotherapeutic as adjuvant therapy in patients with MAGE-A3 positive NSCLC (MAGRIT, NCT00480025).

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

iv Access to a proportion of the data (the training set) will allow for the unbiased generation of a mathematical model to assess the third co-primary endpoint in the remainder of the data (the test set).

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### **Forward-Looking Statement**

*This press release contains forward-looking statements, including statements regarding the Company's and/or its licensees' clinical trial activities, the publication of data, and the potential application of 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 Annual Report on Form 10-K filed with the Securities and Exchange Commission for the year ended December 31, 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.*

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