



**FOR RELEASE: Monday, June 4, 2012  
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## **Agensys and Seattle Genetics Announce Interim Phase I Data from ASG-5ME Clinical Trial for Prostate Cancer**

*-Dose-Escalation Completed and Preliminary Antitumor Activity Observed-*

Santa Monica, CA and Bothell, WA – June 4, 2012 – Agensys, Inc., an affiliate of Tokyo-based Astellas Pharma Inc., and Seattle Genetics, Inc. (Nasdaq: SGEN) today announced interim data from a phase I clinical trial evaluating ASG-5ME for the treatment of castration-resistant prostate cancer (CRPC). ASG-5ME is an antibody-drug conjugate (ADC) targeting the SLC44A4 antigen that is being co-developed by both companies for the treatment of solid tumors. The data are being presented at the American Society of Clinical Oncology (ASCO) annual meeting being held June 1-5, 2012 in Chicago, IL.

“SLC44A4 is an attractive target in prostate cancer and is present in the majority of patients with both localized and metastatic disease,” said Leonard Reyno, M.D., Senior Vice President and Chief Medical Officer of Agensys. “The current Phase I data demonstrates the tolerability of this antibody drug conjugate and further evaluation of safety and antitumor activity in patients with castration resistant prostate cancer is ongoing.”

“It is encouraging to observe these preliminary data with ASG-5ME in prostate cancer, a disease for which late-stage patients need additional therapeutic options,” said Jonathan Drachman, M.D., Senior Vice President, Research and Translational Medicine of Seattle Genetics. “In addition to prostate cancer, our two companies are continuing to evaluate the potential use of ASG-5ME in other solid tumor indications. In parallel, we are collaborating with Agensys to co-develop ASG-22ME, an ADC targeting Nectin-4 for solid tumors.”

### **Phase 1 trial of ASG-5ME in metastatic castration-resistant prostate cancer (CRPC) (Abstract #4568)**

ASG-5ME is being evaluated in a single-agent phase I clinical trial to determine the maximum tolerated dose (MTD) and to assess the safety, pharmacokinetic profile and antitumor activity of escalating doses of ASG-5ME. At the time of data analysis, 26 patients were enrolled. The median age of the patients was 69.5 years and the median baseline prostate-specific antigen (PSA) level was 82.25.

Key findings, presented by Dr. Michael Morris from Memorial Sloan Kettering Cancer Center in New York, NY, and clinical investigator on the study include:

- ASG-5ME was given to cohorts of patients with CRPC as a single IV infusion every three weeks at doses ranging from 0.3 milligrams per kilogram (mg/kg) to 3.0 mg/kg. The MTD was exceeded at 3.0 mg/kg.
- Across all dose cohorts, the most common Grade 1 and 2 adverse events occurring in more than 20 percent of patients included fatigue (50.0 percent), decreased appetite (42.3 percent), peripheral neuropathy (34.6 percent) and nausea (23.0 percent).
- PSA reductions were observed in several patients, providing preliminary evidence of antitumor effect with ASG-5ME treatment.

The phase I trial is ongoing, with enrollment to two expansion cohorts in chemotherapy naïve and chemotherapy exposed CRPC patients planned.

Seattle Genetics and Agensys recently completed enrollment in a phase I pancreatic cancer trial of ASG-5ME dosed weekly. The companies plan to evaluate ASG-5ME in patients with gastric cancer based on preclinical expression data.

#### **About ASG-5ME**

ASG-5ME is an ADC composed of a fully human antibody directed to SLC44A4, a solute carrier antigen family member identified by Agensys to be overexpressed in epithelial cancers, including more than 80 percent of samples derived from patients with prostate, pancreatic and gastric cancers. The antibody is attached to monomethyl auristatin E (MMAE) via an enzyme-cleavable linker using Seattle Genetics' proprietary technology. The ADC is designed to be stable in the bloodstream, but to release MMAE upon internalization into SLC44A4-expressing tumor cells, resulting in targeted cell-killing.

Seattle Genetics and Agensys are co-developing and will globally co-commercialize and share profits on a 50:50 basis for ASG-5ME and ASG-22ME. Seattle Genetics also has an option for 50:50 cost and profit-sharing of a third ADC program at the time of investigational new drug submission.

#### **About Agensys**

Agensys, Inc., an affiliate of Astellas Pharma Inc., is developing a pipeline of therapeutic fully human monoclonal antibodies (MAbs) to treat cancer. The MAb product pipeline is being generated to Agensys' diverse portfolio of proprietary, clinically relevant cancer targets. Agensys' target portfolio and related products are protected by a large patent estate. The company has full capabilities to generate, develop and manufacture antibody products. Agensys is progressing a pipeline of both naked and antibody-drug conjugated (ADC) therapeutic antibodies, directed at a variety of cancer indications, including those of the prostate, kidney, pancreas, ovary, bladder, lung, colon, breast and skin. ADC products are based on drug platform technologies developed by Seattle Genetics. Agensys is developing a growing pipeline of clinical stage functional MAbs and ADC products.

#### **About Astellas**

Astellas Pharma Inc., located in Tokyo, Japan, is a pharmaceutical company dedicated to improving the health of people around the world through the provision of innovative and reliable pharmaceutical products. Astellas has approximately 17,000 employees worldwide. The organization is committed to becoming a global category leader in urology, immunology & infectious diseases, oncology, neuroscience, DM complications & metabolic diseases. For more information on Astellas Pharma Inc., please visit [www.astellas.com/en](http://www.astellas.com/en).

#### **About Seattle Genetics**

Seattle Genetics is a biotechnology company focused on the development and commercialization of monoclonal antibody-based therapies for the treatment of cancer. The U.S. Food and Drug Administration granted accelerated approval of ADCETRIS<sup>®</sup> (brentuximab vedotin) in August 2011 for two indications. ADCETRIS is being developed in collaboration with Millennium: The Takeda Oncology Company. In addition, Seattle Genetics has three other clinical-stage ADC programs: SGN-75, ASG-5ME and ASG-22ME. Seattle Genetics has collaborations for its ADC technology with a number of leading biotechnology and pharmaceutical companies, including Abbott, Bayer, Celldex Therapeutics, Daiichi Sankyo, Genentech, GlaxoSmithKline, Millennium, Pfizer and Progenics, as well as ADC co-development agreements with Agensys, an affiliate of Astellas, and Genmab. More information can be found at [www.seattlegenetics.com](http://www.seattlegenetics.com).

For Seattle Genetics:

Certain of the statements made in this press release are forward looking, such as those, among others, relating to further evaluation of ASG-5ME and the initiation of future clinical trials. Actual results or developments may differ materially from those projected or implied in these forward-looking statements. Factors that may cause such a difference include the risk of adverse events as ASG-5ME advances in clinical trials. More information about the risks and uncertainties faced by Seattle Genetics is contained in the company's 10-Q for the quarter ended March 31, 2012 filed with the Securities and Exchange Commission. Seattle Genetics disclaims any intention or obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.

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