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**Astellas and Seattle Genetics Present ASG-15ME and ASG-22ME Phase I Clinical Data in Metastatic Urothelial Cancer at ASCO Annual Meeting**

*-Clinical Data Indicating Antitumor Activity Presented from Two Antibody-Drug Conjugate Programs-*

**TOKYO and CHICAGO, JUNE 6, 2016** – Astellas Pharma Inc. (TSE: 4503) and Seattle Genetics, Inc. (NASDAQ: SGEN) today presented first clinical data for ASG-15ME and ASG-22ME at the American Society of Clinical Oncology (ASCO) 51<sup>st</sup> Annual Meeting being held June 3-7, 2016 in Chicago, IL.

ASG-15ME and ASG-22ME are investigational antibody-drug conjugates (ADCs) that consist of monoclonal antibodies designed to deliver microtubule-disrupting agents selectively to tumor cells. This approach is intended to spare non-targeted cells and thus reduce many of the toxic effects of traditional chemotherapy while enhancing antitumor activity. ASG-15ME and ASG-22ME target SLITRK6 and Nectin-4, respectively, proteins that are highly expressed in urothelial cancers, particularly bladder cancer. Under the collaboration, the companies are co-developing and plan to globally co-commercialize ASG-15ME and ASG-22ME.

“Bladder cancer is the fifth most common cancer in the U.S. and there have been few treatment advances over the past three decades. For metastatic disease, the five-year survival rate is only 15 percent, representing a significant unmet need to identify additional treatment options,” said Len Reyno, M.D, senior vice president and chief medical officer, Agensys, an affiliate of Astellas. “We are pleased to present these first data for ASG-15ME and ASG-22ME in urothelial cancers, which have a particularly high unmet medical need.”

“The clinical data from the phase I presented at ASCO from the ASG-15ME and ASG-22ME programs in heavily pretreated metastatic bladder cancer patients show a manageable safety profile along with objective response rates that are higher than historical rates seen with taxanes,” said Jonathan Drachman, M.D., chief medical officer and executive vice president,

Research and Development at Seattle Genetics. “We will continue enrolling patients in the ongoing phase 1 clinical trials to determine the recommended dose for further development.”

The following data were presented during poster sessions on Monday, June 6, 2016:

- **Anti-Tumor Activity, Safety and Pharmacokinetics (PK) of AGS15E (ASG-15ME) in a Phase I Dose Escalation Trial in Patients (Pts) with Metastatic Urothelial Cancer (mUC) (Abstract #4532, poster presentation on Monday, June 6, 2016)**
  - Data were reported from 49 patients with metastatic urothelial cancer. The median age of patients was 64 years. Of the 49 patients, 48 patients (98 percent) had undergone treatment with a platinum-based chemotherapy regimen, including 33 patients (67 percent) with a cisplatin-based regimen, and 14 patients (29 percent) who had progressed on or after treatment with checkpoint inhibitors. Twenty-nine patients (59 percent) had received two or more prior systemic therapies. The primary endpoints of the ongoing clinical trial are to evaluate escalating doses, pharmacokinetics and safety of ASG-15ME as a monotherapy. In addition, the trial is evaluating antitumor activity, objective response rate and disease control rate. In this dose-escalation study, patients received ASG-15ME at 0.1 to 1.25 milligrams per kilogram (mg/kg) weekly for three of every four week cycles. Key findings include:
    - Of the 43 patients evaluable for response, 14 patients (33 percent) had an objective response, including one patient (two percent) who achieved a complete response and 13 patients (30 percent) who achieved a partial response. While the study is ongoing, preliminary estimates show median duration of response at 16.1 weeks. Disease control was achieved for 27 patients (63 percent), defined as achieving complete remission, partial remission or stable disease.
    - In 16 patients treated at the 1.0 mg/kg dose level, seven patients (44 percent) had an objective response. In five patients treated at the 1.25 mg/kg dose level, two patients (40 percent) had an objective response.
    - In the 13 patients whose cancer had metastasized to the liver, four patients (31 percent) achieved a partial remission. Bladder cancer that metastasizes to the liver typically has a poor prognosis.
    - In the 14 patients who had previously been treated with checkpoint inhibitors, five patients (36 percent) achieved a partial remission.
    - The most common treatment related adverse events of any grade occurring in 15 percent or more of patients were fatigue (43 percent) and nausea (20 percent). Peripheral neuropathy was observed in 10 patients (19 percent) at Grade 1 and six patients (11 percent) at Grade 2. No Grade 3 or 4 peripheral neuropathy was reported.
    - In the study, eight patients developed ocular symptoms with corneal abnormalities. The majority of patients were managed with dose reductions and recovered
    - Enrollment is ongoing at 1 and 1.25 mg/kg to identify a recommended dose for future studies.
- **Anti-Tumor Activity, Safety and Pharmacokinetics (PK) of ASG-22CE (ASG-22ME; ASG-22ME) in a Phase I Dose Escalation Trial in Patients (Pts) with Metastatic Urothelial Cancer (mUC) (Abstract #4533, poster presentation on Monday, June 6, 2016)**

- Data were reported from 44 patients with metastatic urothelial cancer. The median age of patients was 66.5 years. Of the 44 patients, 43 patients (98 percent) had undergone treatment with a platinum-based chemotherapy regimen, including 30 patients (68 percent) with a cisplatin-based regimen, and 12 patients (27 percent) who had progressed on or after treatment with checkpoint inhibitors. Twenty-eight patients (64 percent) had received two or more prior systemic therapies.
- The primary endpoints of the ongoing clinical trial are to evaluate escalating doses, pharmacokinetics and safety of ASG-22ME as a monotherapy. In addition, the trial is evaluating antitumor activity, objective response rate and disease control rate. In this dose-escalation study, patients received ASG-22ME at 0.5 to 1.25 mg/kg weekly for three of every four week cycles. Key findings include:
  - Of the 36 patients evaluable for response, 10 patients (28 percent) achieved a partial response. While the study is ongoing, preliminary estimates show median duration of response at 16.1 weeks. Disease control was achieved for 25 patients (69 percent), defined as achieving complete remission, partial remission or stable disease.
  - In eight patients treated at the 1.25 mg/kg dose level, four patients (50 percent) had an objective response.
  - In the 10 patients whose cancer had metastasized to the liver, four patients (40 percent) achieved a partial remission. Bladder cancer that metastasizes to the liver typically has a poor prognosis.
  - In the 12 patients who had previously been treated with checkpoint inhibitors, three patients (25 percent) achieved a partial remission.
  - The most common treatment related adverse events of any grade occurring in 15 percent or more of patients were pruritis and nausea (30 percent each), fatigue (25 percent), diarrhea (21 percent) and rash (18 percent). Peripheral neuropathy was observed in 11 patients (19 percent) at Grade 1 and three patients (five percent) at Grade 2. No Grade 3 or 4 peripheral neuropathy was reported.
  - In the study, two patients developed ocular symptoms with corneal abnormalities. The patients were managed with dose reductions and/or steroid eye drops.
  - Enrollment is ongoing at 1 and 1.25 mg/kg to identify a recommended dose for future studies.

The ASG-15ME and ASG-22ME phase I clinical trials are ongoing to identify a recommended dose for future clinical evaluation. More information about the clinical trials, including enrolling centers, is available by visiting [www.clinicaltrials.gov](http://www.clinicaltrials.gov).

### **About Bladder Cancer**

Bladder cancer begins when cells in the urinary bladder start to grow uncontrollably. Most bladder cancers start in the innermost lining of the bladder, which is called the urothelium or transitional epithelium. Urothelial carcinoma, also known as transitional cell carcinoma (TCC), is the most common type of bladder cancer. Urothelial carcinoma starts in the urothelial cells that line the inside of the bladder.

While patients with early stage bladder cancer are treated with curative intent, outcomes are poor for patients diagnosed with locally advanced or metastatic disease. For the

approximately 10 percent of patients with urothelial bladder cancer whose initial diagnoses occur when they have metastatic disease, the average five-year survival is approximately 15 percent. According to the American Cancer Society, in 2016 approximately 77,000 people will be diagnosed and more than 16,000 will die from urothelial bladder cancer.

#### **About ASG-15ME and ASG-22ME**

ASG-15ME is an investigational antibody-drug conjugate (ADC) composed of an anti-SLITRK6 monoclonal antibody attached to a microtubule-disrupting agent, monomethyl auristatin E (MMAE), using Seattle Genetics proprietary, industry-leading linker technology. ASG-15ME is the first and only agent to target SLITRK6, a transmembrane protein identified as an ADC target by Agensys, which is expressed on many solid tumors. Preclinical data demonstrate that ASG-15ME effectively binds to target cells, internalizes and induces cell-killing activity.

ASG-22ME is an investigational ADC composed of an anti-Nectin-4 monoclonal antibody attached to a microtubule-disrupting agent, MMAE, using Seattle Genetics proprietary, industry-leading linker technology. ASG-22ME is the first and only agent to target Nectin-4, a cell adhesion molecule identified as an ADC target by Agensys, which is expressed on many solid tumors. Preclinical data demonstrate that ASG-22ME effectively binds to target cells, internalizes and induces cell-killing activity.

#### **About Astellas**

Astellas Pharma Inc., based in Tokyo, Japan, is a company dedicated to improving the health of people around the world through the provision of innovative and reliable pharmaceutical products. We focus on Urology, Oncology, Immunology, Nephrology and Neuroscience as prioritized therapeutic areas while advancing new therapeutic areas and discovery research leveraging new technologies/modalities. We are also creating new value by combining internal capabilities and external expertise in the medical/healthcare business. Astellas is on the forefront of healthcare change to turn innovative science into value for patients. For more information, please visit our website at [www.astellas.com/en](http://www.astellas.com/en).

#### **About Seattle Genetics**

Seattle Genetics is an innovative biotechnology company that develops and commercializes novel antibody-based therapies for the treatment of cancer. The company's industry-leading antibody-drug conjugate (ADC) technology harnesses the targeting ability of antibodies to deliver cell-killing agents directly to cancer cells. ADCETRIS® (brentuximab vedotin), the company's lead product, in collaboration with Takeda Pharmaceutical Company Limited, is the first in a new class of ADCs approved globally in more than 60 countries for relapsed classical Hodgkin lymphoma (HL) and relapsed systemic anaplastic large cell lymphoma (sALCL). Seattle Genetics is also advancing vadastuximab talirine (SGN-CD33A; 33A), an ADC in a phase 3 trial for acute myeloid leukemia. Headquartered in Bothell, Washington, Seattle Genetics is also advancing a robust pipeline of innovative therapies for blood-related cancers and solid tumors designed to address significant unmet medical needs and improve treatment outcomes for patients. The company has collaborations for its proprietary ADC technology with a number of companies including AbbVie, Astellas, Bayer, Genentech, GlaxoSmithKline and Pfizer. More information can be found at [www.seattlegenetics.com](http://www.seattlegenetics.com)

#### **About the Astellas and Seattle Genetics Collaboration**

Agensys (subsequently acquired by Astellas) and Seattle Genetics entered into the ADC collaboration in January 2007 and expanded it in November 2009. Under the collaboration,

the companies are co-developing and will globally co-commercialize for ASG-15ME and ASG-22ME.

### **Forward Looking Statements for Seattle Genetics**

Certain of the statements made in this press release are forward looking, such as those, among others, relating to the therapeutic potential of ASG-15ME and ASG-22ME, their possible safety and efficacy and anticipated development activities including 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 inability to show sufficient activity in the clinical trials and risk of adverse events as ASG-15ME and ASG-22ME advance in clinical trials even after promising results in earlier clinical trials. In addition, as our drug candidates or those of our collaborators advance in clinical trials, adverse events and/or regulatory actions may occur which affect the future development of those drug candidates and possibly other compounds using similar technology. More information about the risks and uncertainties faced by Seattle Genetics is contained under the caption "Risk Factors" included in the company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2016 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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