



April 10, 2013

## **Astex Pharmaceuticals Provides SGI-110 Update**

### **Oral Presentation at AACR Supports Potential of SGI-110 In The Treatment Of Platinum-Resistant Ovarian Cancer**

#### **Clinical Update on SGI-110-01 Study**

DUBLIN, Calif., April 10, 2013 (GLOBE NEWSWIRE) -- Astex Pharmaceuticals, Inc. (Nasdaq:ASTX), a pharmaceutical company dedicated to the discovery and development of novel small molecule therapeutics, today announced that SGI-110 was featured in an oral presentation on Tuesday, April 9 at the American Association of Cancer Research (AACR) in Washington, DC.

Researchers from Indiana University presented data from preclinical models supporting the ovarian cancer epigenetic chemosensitization effect of SGI-110. In established ovarian cancer xenograft models, SGI-110 in combination with platinum significantly delayed tumor growth compared to platinum alone. The researchers also showed that SGI-110 induced demethylation and increased expression of several tumor suppressor and tumor differentiation genes. In addition, SGI-110 slowed the repair of platinum DNA damage.

These data support the ongoing clinical randomized phase 2 study in which SGI-110 in combination with carboplatin is being studied in platinum-resistant ovarian cancer patients (Study SGI-110-02).

The company also announced that the ongoing clinical phase 2 expansion study (Part B of Study SGI-110-01) in patients with myelodysplastic syndromes (MDS) and acute myeloid leukemia (AML) has been expanded to approximately 200 patients by including an additional cohort of relapsed/refractory MDS patients to the ongoing three other cohorts (front-line MDS; front-line elderly AML; and relapsed/refractory AML). The phase 2 expansion trial has already enrolled more than half of the patients needed to complete the study. While data were not mature enough for presentation at the upcoming American Society of Clinical Oncology (ASCO) meeting, more mature data presentations will be submitted to other scientific conferences. The trial is still on track to submit data from the relapsed/refractory AML cohort in the phase 2 expansion study to the American Society of Hematology (ASH) meeting for presentation in December this year.

#### **About SGI-110**

SGI-110 is a novel small molecule, DNA-hypomethylating agent administered as a single low volume subcutaneous injection. SGI-110 demonstrated activity in restoring silenced tumor suppressor gene expression in cancer cells by reversal of DNA methylation and inducing responses in previously treated MDS and AML patients. SGI-110 is wholly owned by Astex Pharmaceuticals.

#### **About the SGI-110 study in Ovarian Cancer (Study SGI-110-02)**

Study SGI-110-02 is a phase 2, open label, randomized, multi-center, controlled clinical trial, evaluating SGI-110 in combination with carboplatin in platinum-resistant recurrent ovarian cancer patients. The trial consists of two parts. In Part A, patients will receive escalating doses of SGI-110 and carboplatin to define the Maximum Tolerated Dose (MTD) and preliminary biological and clinical activity. In Part B, patients will be randomized to receive SGI-110 plus carboplatin at the MTD identified in Part A, or one of three treatment of choice, standard of care agents, as determined by the clinical investigator: topotecan, pegylated liposomal doxorubicin, or paclitaxel. The primary endpoint in Part B will be a comparison of progression free survival (PFS) between SGI-110 plus carboplatin, and treatment of choice study arms. Response rate and overall survival will be among the secondary endpoints. Additional information about the study can be found online at [clinicaltrials.gov](http://clinicaltrials.gov): <http://clinicaltrials.gov/ct2/show/NCT01696032>.

#### **About the SGI-110 study in MDS and AML patients (Study SGI-110-01)**

The SGI-110-01 is a randomized phase 1/2 study in patients with MDS and AML. The trial completed its phase 1 dose escalation segment (Part A) and the results were presented at the December 2012 ASH meeting, "Results From the Dose Escalation Phase of a Randomized Phase 1-2 First-in-Human (FIH) Study of SGI-110, a Novel Low Volume Stable Subcutaneous (SQ) Second Generation Hypomethylating Agent (HMA) in Patients with Relapsed/Refractory MDS and AML." A copy of this presentation is available on the Astex Pharmaceuticals website, [www.astx.com](http://www.astx.com), in the pipeline, presentations and

publications section.

This study is currently in the phase 2 dose expansion segment (Part B) of which the primary objective will be estimating overall response rates in 4 patient cohorts (relapsed/refractory AML; relapsed-refractory MDS; front-line elderly AML not suitable for induction chemotherapy; and front-line MDS). Secondary objectives include estimating the incidence and severity of adverse events, duration of response, overall survival, and the correlation of demethylation, genetic, and pharmacologic biomarkers with response. Additional information about the study can be found online at [clinicaltrials.gov](http://clinicaltrials.gov): <http://clinicaltrials.gov/ct2/show/NCT01261312>.

### **About Astex Pharmaceuticals**

Astex Pharmaceuticals is dedicated to the discovery and development of novel small molecule therapeutics with a focus on oncology. The Company is developing a proprietary pipeline of novel therapies and is creating de-risked products for partnership with leading pharmaceutical companies. Astex Pharmaceuticals developed DACOGEN® (decitabine) for Injection and receives significant royalties on global sales.

For more information about Astex Pharmaceuticals, Inc., please visit <http://www.astx.com>.

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