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Astex Pharmaceuticals Announces Presentation of Updated Results of SGI-110-01 Study in Patients With Intermediate or High Risk Relapsed or Refractory Myelodysplastic Syndromes at the European Hematology Association

Results Confirm Clinical Activity of the Novel Hypomethylating Agent SGI-110 in Intermediate or High Risk MDS Patients Previously Treated With Azacitidine or Decitabine

DUBLIN, Calif., June 14, 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 updated clinical results of its novel hypomethylating agent, SGI-110, were presented in a poster session at the 18th Congress of the European Hematology Association (EHA) being held June 13-16, 2013 in Stockholm, Sweden.

The update focused on details of the biological and clinical activity as well as safety in the group of intermediate or high risk relapsed or refractory myelodysplastic syndromes (r/r MDS) patients treated in the dose-escalation phase 1 part of the SGI-110-01 study. The study enrolled 15 intermediate or high risk MDS patients including chronic myelomonocytic leukemia who were heavily pretreated with a median number of prior regimens of 2 (range 2-6 prior regimens). All 15 patients had received prior azacitidine or decitabine, and 40% of them previously received both agents.

Of the 15 patients, six achieved a clinical response (4 patients with hematological improvement or HI, and 2 patients with marrow CR or mCR) for an overall response rate of 40% (95% CI of 16-68%). The median duration of response was 92 days (range 28-126 days). The two mCR patients received prior treatment with both azacitidine and decitabine, and they demonstrated pronounced DNA demethylation of > 10% as measured by the LINE-1 assay (19% and 38% demethylation of LINE-1). SGI-110 subcutaneous treatment was well tolerated. The most common adverse events were injection site pain (mostly Grade 1), and myelosuppression.

"We are pleased with the updated results that continue to demonstrate promising clinical activity of SGI-110 in MDS patients who were heavily pre-treated. These data confirm the potent demethylation activity of this medicine," commented James S.J. Manuso, Ph.D., Astex Pharmaceuticals chief executive officer and chairman. "We are proceeding aggressively with the enrollment in the dose-expansion phase 2 part of the study of intermediate and high risk MDS patients who are either relapsed/refractory or treatment-naive to prior hypomethylating agents."

More than 40 MDS patients who are treatment-naive to prior hypomethylating agents have already been enrolled out of a target of 50 patients. Other patients being treated in the phase 2 expansion part of the study include: relapsed/refractory MDS; relapsed/refractory AML; and treatment-naive elderly AML patients who are unfit for induction chemotherapy.

This poster will be available for viewing on the company's website, www.astx.com, in the pipeline, presentations and publications section.

Further presentations on all 4 cohorts in the phase 2 part of the study are planned in future scientific meetings with the first presentation being planned for the upcoming American Society of Hematology (ASH) meeting in New Orleans in December.

About SGI-110:

SGI-110 is a novel small molecule, DNA-hypomethylating agent administered as a single small 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 MDS and AML patients (Study SGI-110-01):

The SGI-110-01trial 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, in the pipeline, presentations and publications section.

This study is currently in the phase 2 dose expansion segment (Part B) of the study. Its primary objective is to estimate overall response rates in four 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/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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