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Astex Pharmaceuticals Announces Initiation of the Phase 2 Expansion of the SGI-110 Clinical Trial in MDS and AML Patients

DUBLIN, Calif., June 22, 2012 (GLOBE NEWSWIRE) -- Astex Pharmaceuticals, Inc. (Nasdaq:ASTX), a pharmaceutical company dedicated to the discovery and development of novel small molecule therapeutics, announced that it has initiated the Phase 2 dose expansion segment of the clinical trial of SGI-110, a novel hypomethylating agent, in patients with intermediate-2 or high-risk myelodysplastic syndromes (MDS) or acute myeloid leukemia (AML). Treatment-naive MDS and elderly AML (≥65 years) will be enrolled in the dose expansion.

Enrollment in the Phase 2 segment is currently open, and the first patient has been dosed. The Phase 2 segment includes expansion of the number of patients to approximately 90 patients treated on the five day subcutaneous dosing schedule to better evaluate both efficacy and safety in MDS and AML patients.

"The initiation of SGI-110's Phase 2 expansion of the clinical trial marks an important milestone for our company as we advance the development of our second-generation hypomethylating agent," said James S.J. Manuso, PhD, chairman & chief executive officer.

"We are pleased with the advancement of SGI-110 into the Phase 2 segment of the clinical trial. The allowance of treatment-naive MDS and elderly AML patients will be important in evaluating efficacy and safety of SGI-110 in this patient population and to further characterize the clinical differentiation of the drug," said Mohammad Azab, MD, chief medical officer.

Interim Phase 1 clinical data from subcutaneous SGI-110 was previously reported at the American Association for Cancer Research (AACR) 2012 Annual Meeting in Chicago, IL. The data showed that SGI-110 has a clear pharmacokinetic differentiation from Dacogen® (decitabine) for Injection given as an IV infusion. The drug achieved excellent hypomethylation, and major clinical responses in heavily pre-treated AML patients were observed.

Solid tumor Phase 2 trials of SGI-110 are expected to begin before the end of 2012.

Stand Up To Cancer (SU2C) has provided funding for the Epigenetics Dream Team that is collaborating on the scientific evaluation of SGI-110.

About the Study

The primary objective in the dose expansion segment will be estimating overall remission rates. Secondary objectives include estimating the incidence and severity of dose limiting toxicity (DLT), the PK profile of SGI-110 and decitabine, rates of hematologic improvement and duration of remission, time to disease progression, overall survival rate, and incidence of blood and platelet transfusions.

A copy of the 2012 AACR oral presentation, "Interim results from a randomized Phase 1-2 first-in-human-(FIH) study of PK/PD guided escalating doses of SGI-110, a novel subcutaneous (SQ) second generation hypomethylating agent (HMA) in relapsed/refractory MDS and AML" is available in the pipeline, presentations and publications section of the Astex Pharmaceuticals website, www.astx.com.

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.

The Astex Pharmaceuticals, Inc. logo is available at http://www.globenewswire.com/newsroom/prs/?pkgid=12273

Forward-Looking Statements

This press release contains "forward-looking" statements within the meaning of Section 21A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, and is subject to the safe harbor created thereby. These statements are typically preceded by words such as "believes," "expects," "anticipates," "intends," "will," "may," "should," or similar expressions. Actual results could differ materially from those projected in the forward-looking statements as a result of a number of risks and uncertainties. These forward-looking statements include, but are not limited to, expectations regarding the advancement of drug candidates in the clinic; the Company's ability to develop the current and future pipeline into commercially viable drugs; the expectations regarding our clinical trials including the timing of clinical proof of concept data from these trials. Important factors that could cause actual results to differ materially from the expectations reflected in the forward-looking statements include, but are not limited to: the outcomes of the on-going clinical trials; risks and uncertainties related to the research and development of SGI-110. References made to the discussion of risk factors are detailed in the Company's filings with the Securities and Exchange Commission including reports on its most recently filed Form 10-K and Form 10-Q. These forward-looking statements are made only as of the date hereof, and we disclaim any obligation to update or revise the information contained in any such forward-looking statements, whether as a result of new information, future events or otherwise.

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