



Astex Pharmaceuticals Announces Subcutaneous SGI-110 Interim Phase 1/2 MDS and AML Data Presentation at AACR

DUBLIN, Calif., April 3, 2012 (GLOBE NEWSWIRE) -- Astex Pharmaceuticals, Inc. (Nasdaq:ASTX), a pharmaceutical company dedicated to the discovery and development of novel small molecule therapeutics, announced that interim Phase 1/2 clinical data from subcutaneous SGI-110, a novel hypomethylating agent, demonstrated differentiated PK profile, good tolerability, and preliminary promising complete responses in heavily pretreated acute myelogenous leukemia (AML) patients enrolled in the Phase 1 segment of the trial. The data was presented at an oral session at the American Association for Cancer Research (AACR) 2012 Annual Meeting in Chicago, IL and was featured in a joint AACR-Stand Up To Cancer (SU2C) media forum. SU2C has provided funding for the Epigenetics Dream Team that is collaborating on the scientific evaluation of SGI-110.

The randomized Phase 1/2 first-in-human dose escalation study enrolled 66 patients with previously treated intermediate or high-risk myelodysplastic syndromes (MDS) or AML as of March 28, 2012. Of seven evaluable refractory AML patients who had adequate hypomethylation with no prior resistance to hypomethylating agents (HMAs), two showed complete response, and one showed partial response. Additionally, the pharmacokinetic (PK) data suggests delivery of decitabine by SGI-110 achieves high decitabine exposure and longer half life than decitabine intravenous (IV) infusion. The pharmacodynamic (PD) data shows potent dose-dependent hypomethylation induction in the daily regimen.

"This interim SGI-110 data is very encouraging for refractory AML patients," said Jean-Pierre Issa, MD, professor of medicine and director of the Fels Institute for Cancer Research and Molecular Biology at Temple University. "With the optimal biologically effective dose reached, this provides a firm basis to begin the dose expansion segment of the trial for treatment of elderly AML and previously untreated MDS."

"This is a great example of collaboration between SU2C and industry," said Stephen B. Baylin, MD, professor of oncology and medicine, deputy director of the Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins; co-leader of the Epigenetics Dream Team of SU2C. "The trial used a biologically driven design where dose escalation was based on biological efficacy of the drug and not just toxicities as is often the case with cancer drugs. Achieving clinical efficacy at the biologically effective doses is a validation of this innovative design."

About the Study

The primary objective in the dose escalation segment was to estimate the optimal biologically effective dose (BED) and/or the maximum tolerated dose (MTD). 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. The PD studies suggest the optimal BED was reached prior to the MTD.

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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