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Astex Pharmaceuticals Announces Initiation of SGI-110 Phase 2 Trial in Advanced Hepatocellular Carcinoma (HCC) Patients

DUBLIN, Calif., Jan. 2, 2013 (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 a Phase 2, open-label, single-arm, non-randomized clinical trial, evaluating SGI-110 in the treatment of advanced hepatocellular carcinoma (HCC) patients who failed prior treatment with Nexavar (sorafenib).

Advanced Hepatocellular Carcinoma (HCC) is a disease with a very high unmet medical need and patients who do not respond to the frontline standard of care, sorafenib, have few therapeutic options. The Phase 2 study is based on preclinical work showing that SGI-110 is effective in inducing global DNA and gene specific hypomethylation, thus enabling the re-expression of tumor suppressor genes in HCC cell lines (Jueliger, S. 2012, November. Poster presentation, EORTC-NCI-AACR, Dublin, Ireland).

"There is a high unmet need for therapies for advanced HCC patients who have failed sorafenib treatment," said Mohammad Azab, MD, chief medical officer. "We are pleased to initiate this study which expands the investigational breadth of our development program for SGI-110 to include HCC in addition to the ongoing studies in myelodysplastic syndromes (MDS), acute myeloid leukemia (AML) and ovarian cancer."

About the Study

The study uses a Simon's 2-stage design. Part A would enroll 15 patients in Stage 1 who will be evaluated for safety, disease control, and for methylation status of certain tumor suppressor genes known to be involved in HCC. If Part A is successful, Part B will enroll 31 additional patients in Stage 2. The primary endpoint of the study is disease control rate (DCR) at 16 weeks, defined as percentage of patients who achieve a best clinical response of complete or partial response, or stable disease at that time. Secondary endpoints of the study include the incidence and severity of adverse events, global DNA methylation levels, methylation status of selected tumor suppressor genes in tumor tissue, progression-free survival and overall survival.

Additional information about the study can be found online at clinicaltrials.gov: http://clinicaltrials.gov/ct2/show/NCT01752933

About SGI-110

SGI-110 is a small molecule, DNA-hypomethyating agent with demonstrated activity in restoring silenced tumor suppressor gene expression in cancer cells by reversal of DNA methylation. SGI-110 is being evaluated in a first-in-human Phase 1-2 clinical trial in patients with intermediate or high-risk myelodysplastic syndromes (MDS) and acute myeloid leukemia (AML), in collaboration with multiple cancer centers, including clinical investigators of the Stand Up to Cancer Epigenetics Dream Team. SGI-110 is also being investigated in a Phase 2 clinical trial in combination with carboplatin in platinum-resistant recurrent ovarian cancer patients.

SGI-110 is wholly owned by Astex Pharmaceuticals.

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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