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Astex Pharmaceuticals Announces Initiation of AT13387 Phase 2 Study in Non-Small Cell Lung Cancer

DUBLIN, Calif., Oct. 24, 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 an open label, randomized, controlled, multi-center, Phase 2 clinical trial, evaluating HSP90 inhibitor AT13387 in anaplastic lymphoma kinase positive (ALK +) non-small cell lung cancer patients or other potentially crizotinib-sensitive NSCLC patients who have been receiving crizotinib. The trial will evaluate AT13387 as both single agent and in combination with crizotinib in these patients.

The AT13387 study will consist of three parts. Part A is a lead-in, single arm, dose escalation segment of the trial in patients with NSCLC who have already been receiving crizotinib, to establish the Maximum Tolerated Dose (MTD) of the combination. Once the MTD is defined in Part A, and depending on the patient's response to crizotinib, Parts B and C will ensue in which patients will be randomized to continue to receive crizotinib alone, AT13387 alone, or the combination of AT13387 with crizotinib.

"This is the most comprehensive study designed to date to investigate the efficacy and safety of an HSP90 inhibitor in patients who are sensitive to an ALK+ inhibitor," said Mohammad Azab, MD, chief medical officer. "The study will permit us to identify a clear role of HSP90 inhibition by AT13387 both as a single agent and in combination with an ALK+ inhibitor in the treatment of NSCLC."

About the Study

The primary objective of Part A of this trial is to determine the safety and tolerability of combination therapy with AT13387 and crizotinib and to determine the MTD for Parts B and C. The primary objective in Part B will be to compare the efficacy by response rate between continued administration of single agent crizotinib versus the combination of AT13387 plus crizotinib in patients who were treated for at least 8 weeks with crizotinib and have not yet progressed. Lastly, the primary objective of Part C will be to test the efficacy by response rate of single agent AT13387 and the combination of AT13387 and crizotinib in patients who progressed on treatment with crizotinib.

Additional information about the study can be found online at clinicaltrials.gov: http://clinicaltrials.gov/ct2/show/NCT01712217

About AT13387

AT13387 is a small molecule inhibitor of HSP90, a heat shock protein believed to be responsible for supporting the development of cancer in many tumor cells. HSP90 acts as a "molecular chaperone," stabilizing and preventing the breakdown of key oncogenic proteins. These client proteins, including HER2 (the target for Herceptin® in the treatment of breast cancer), androgen (the target for Zytiga® in prostate cancer), mutant B-raf (the target for Zelboraf® in melanoma), ALK (the target for Xalkori® in lung cancer), c-kit (the target for Gleevec® in gastrointestinal tumors) and mutant EGFr (the target for Tarceva® and Iressa® in the treatment of non-small cell lung cancers) are associated with different tumor types.

Although AT13387 is a targeted inhibitor of HSP90, it has the potential to control the proliferation of multiple solid tumors and hematological malignancies where uncontrolled cell growth is dependent on the interaction between HSP90 and its client proteins. These include tumor types that have become resistant to initial therapy.

Astex Pharmaceuticals has an ongoing Phase 2 study in patients with refractory gastrointestinal stromal tumors (GIST) and a Phase 2 trial in patients with castration-resistant prostate cancer (CRPC) who are no longer responding to treatment with the standard of care therapies, abiraterone acetate and steroids.

In November 2009, Astex Pharmaceuticals entered into a CRADA with the US National Cancer Institute (NCI) to support the further clinical development of AT13387 over the next 5 years. The CRADA will enable a number of single agent and combination Phase 1/2a and Phase 2 studies.

AT13387, a proprietary compound, 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 AT13387. 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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