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Astex Pharmaceuticals Announces Initiation of HSP90 Inhibitor AT13387 Clinical Trial in Prostate Cancer Patients

DUBLIN, Calif., Sept. 10, 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 a clinical trial with HSP90 inhibitor AT13387 in prostate cancer patients. The AT13387-04 study is a Phase 1-2, open label, randomized study in patients with castration-resistant prostate cancer (CRPC) who are no longer responding to treatment with standard of care therapies abiraterone acetate and steroids. CRPC patients who do not respond to abiraterone acetate and steroids currently have limited treatment options.

In Part A (Phase 1) of the study, patients will continue to receive the same doses of abiraterone acetate and steroids received prior to entering the trial, and will be randomized to receive one of two different treatment regimens of AT13387 in combination with abiraterone acetate.

Part A will enroll up to 52 patients and will establish safety of the combination, clinical activity, and confirm biological activity by monitoring depletion of androgen receptors in tumor and Circulating Tumor Cells (CTCs) samples following treatment with AT13387. The best combination regimen in Part A will then move forward to Part B (Phase 2) where patients will be randomized to receive either the selected treatment regimen and dose of AT13387 in combination with abiraterone acetate or AT13387 alone. Part B will enroll up to 112 patients.

"We are extremely pleased with the initiation of our HSP90 inhibitor study in prostate cancer patients. With the incidence of prostate cancer in the U.S. at 215,000, and 28,000 deaths annually, this is a disease which is the second leading cause of cancer death among American men," said James S.J. Manuso, PhD, chairman & chief executive officer. "Despite developments in the treatment landscape, prostate cancer patients will continue to need new products, particularly ones that might be used in combination with other therapies, during the course of their disease."

"This is the first HSP90 inhibitor study that is rigorously assessing activity in CRPC both as single agent and in combination. The confirmation of biological activity in Part A will be critical in the decision to move forward to Part B," said Mohammad Azab, MD, chief medical officer. "The combination of AT13387 with hormonal manipulation such as abiraterone acetate treatment may provide multiple mechanisms of targeting CRPC through androgen deprivation combined with degradation of several oncogenic kinases."

About the Study

The primary objective of the AT13387-04 study is assessment of safety, tolerability and antitumor activity of AT13387 and abiraterone acetate in CRPC patients. Secondary objectives include assessment of pharmacokinetics, pharmacodynamics, progression-free survival and overall survival of combination treatment of AT13387 and abiraterone acetate. Other exploratory objectives include identifying potential biomarkers for predicting antitumor activity.

About AT13387

AT13387 is a small molecule inhibitor of HSP90, a heat shock protein, believed to be responsible for supporting many tumor cells becoming cancerous. HSP90 acts as a "molecular chaperone" stabilizing and preventing the breakdown of key oncogenic proteins. These client proteins and their association with different tumor types include HER2 (the target for Herceptin® in breast cancer), the androgen receptor (the target for hormone therapy in prostate cancer), mutant B-raf (melanoma), 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).

Although AT13387 is a targeted inhibitor of HSP90, the functional role of HSP90 means the product 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).

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 with a number of single agent and combination phase 1/2a and phase 2 studies planned.

AT13387 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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