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Astex Pharmaceuticals Discontinues Amuvatinib Clinical Development Program

DUBLIN, Calif., Sept. 21, 2012 (GLOBE NEWSWIRE) -- Astex Pharmaceuticals, Inc. (Nasdaq:ASTX), a pharmaceutical company dedicated to the discovery and development of novel small molecule therapeutics, today announced that clinical development of amuvatinib (MP-470), a multi-targeted tyrosine kinase inhibitor that inhibits the mutant forms of c-Kit and PDGFR alpha and disrupts DNA repair likely through suppression of homologous recombination protein Rad51, has been discontinued.

Amuvatinib was being investigated in the Phase 2 ESCAPE (Tr**E**atment of **S**mall **C**ell lung cancer with **A**muvatinib in combination with **P**latinum **E**toposide) study. The study used a Simon 2-stage design with the primary objective in stage 1 of excluding the statistical probability with 90% confidence that the drug has less than 10% response rate in platinum refractory small cell lung cancer (SCLC) patients. Response evaluation by RECIST criteria showed 2 partial responses in the 21 evaluable patients of stage 1 (9.5% Response Rate). No new safety issues were identified, and biological markers studies are ongoing. There were several patients with prolonged stable disease. The results will be presented in a future scientific meeting.

"This clinical proof of concept (cPOC) amuvatinib trial was designed in two parts to define clinical activity and confirm clinical benefit and safety in combination with chemotherapy," said James S.J. Manuso, PhD, chairman and chief executive officer. "We have decided to end the clinical development of amuvatinib despite the favorable safety and preliminary clinical activity we observed in the first stage of this Phase 2 trial and in the earlier Phase 1b trial in combination platinum-etoposide based chemotherapy. We will consider the possibility of licensing the compound to any partners who would be interested in its further development."

"Amuvatinib's performance in the clinic was promising in the Phase 1b combination trial with DNA damaging agents," said Mohammad Azab, MD, chief medical officer. "There is no effective treatment for SCLC patients with truly platinum-refractory disease similar to the patients enrolled in this study. While some clinical activity was observed, the ESCAPE study response rate in stage 1 fell short of fully meeting our pre-specified primary endpoint. Consistent with our corporate strategy to move into advanced clinical stages only those agents that meet our pre-specified primary endpoints in the cPOC stage, we decided to discontinue the internal development of this program."

About Amuvatinib

Amuvatinib is an oral multi-targeted tyrosine kinase inhibitor which inhibits the mutant forms of c-Kit and PDGFR alpha. It also disrupts DNA repair likely through suppression of homologous recombination protein Rad51, an important survival pathway in many human cancers. In vitro and in vivo data have demonstrated amuvatinib synergy with DNA damaging agents including etoposide and doxorubicin. Overall, in the amuvatinib clinical development program, over 200 subjects were exposed to at least one dose of amuvatinib. In the Phase 1b clinical study in combination with carboplatin and etoposide, responses in SCLC, neuroendocrine as well as other tumor types were observed. Human pharmacokinetic data suggest that co-administration of amuvatinib did not alter exposures of standard of care agents including carboplatin, etoposide, doxorubicin, paclitaxel, topotecan or erlotinib as measured by overall exposure. In the first-in-human study, durable clinical benefit was observed in the gastrointestinal stromal tumors (GIST) with modulation of Rad51 observed in skin punch biopsies. In clinical trials, amuvatinib has demonstrated a wide therapeutic window and shows minimal toxicity in the expected therapeutic dose range, despite suppressing several signaling pathways within cells.

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

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