ATLANTA, Sept. 16, 2013 /PRNewswire/ -- Atlanta-based pharmaceutical discovery and development company, Celtaxsys, Inc., announced today the achievement of a significant clinical milestone for its lead clinical stage drug candidate, CTX-4430, for treatment of Cystic Fibrosis (CF) lung disease. Celtaxsys has successfully completed the first of two clinical trials in its Phase 1 program, and the first trial conducted through its Australia subsidiary, Celtaxsys Aus Pty Ltd. In this First-in-Human trial, CTX-4430 was administered orally to Healthy Volunteers in escalating doses (up to 200 mg/day for 2 weeks) and was well-tolerated at all doses. Results of the trial will be presented at the 27th Annual North American Cystic Fibrosis Conference in October.

"This was a robust First-in-Human clinical trial assessing safety in 96 subjects. We're very pleased with the safety outcomes of CTX-4430 in this Healthy Volunteer study," said Dr. Ed Philpot, Celtaxsys CMO. "These results support the continued clinical development of CTX-4430 as a once-daily oral treatment for pulmonary inflammation in CF."

CTX-4430 also exhibited excellent pharmacokinetic and pharmacodynamic properties in this study. "The 100 mg dose achieved maximal effect on its intended target, Leukotriene A4 Hydrolase, for the entire 24 hour period between doses," said Dr. Eric Springman, Celtaxsys CSO. "Having a biomarker to directly probe mechanism of action provides us with a much better understanding of the relationship between dose and effect and will be a tremendous help in the further clinical development of CTX-4430."

Said Mr. Ralph Grosswald, VP of Operations at Celtaxsys, "We had a great experience conducting our initial Phase 1 study of CTX-4430 in Australia. The entire process from start to finish was very efficient and the facilities were second to none."

CTX-4430 will now progress into a Phase 1B trial to assess the safety and pharmacokinetics of once-daily oral treatment for lung disease in Cystic Fibrosis patients.

About Cystic Fibrosis: Cystic Fibrosis is the most common life-shortening autosomal

recessive disease among Caucasians, and lung disease is the leading cause of hospitalizations and death in adult CF patients. A hallmark of CF lung disease is excessive recruitment of blood polymorphonuclear neutrophils (PMNs) into the small airways (bronchioles) causing inflammation that results in elastic tissue destruction and progressive loss of lung function.

About CTX-4430: CTX-4430 is a once-daily oral drug candidate currently undergoing clinical trials for treatment of CF lung disease. It is a novel small molecule inhibitor of Leukotriene A4 Hydrolase (LTA4H), the key enzyme in production of the potent inflammatory mediator Leukotriene B4 (LTB4). LTA4H and LTB4 are strongly implicated in the pathogenesis of pulmonary inflammation in CF.

About Celtaxsys: Celtaxsys is a privately-held clinical stage drug discovery and development company focused on developing new treatments for inflammatory diseases by modulating innate immunity. The company is building a sustainable pipeline of first-in-class drugs with novel mechanisms of action. For more information, please visit **www.celtaxsys.com** .

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