Sunesis Pharmaceuticals Initiates Leukemia Clinical Trial

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SOUTH SAN FRANCISCO, Calif., Nov 15, 2005 /PRNewswire-FirstCall via COMTEX News Network/ -- Sunesis Pharmaceuticals, Inc. (Nasdaq: SNSS) today announced that patient treatment has commenced in a Phase I clinical trial of SNS-595, the company's lead anti- cancer small molecule drug, in patients with refractory acute leukemias. The trial is an open-label, multi-center, dose-escalation study designed to examine the safety, tolerability and pharmacokinetics of SNS-595 in order to establish an optimal dosing regimen for use in planned Phase II clinical testing of patients with relapsed or refractory acute myelocytic leukemia (AML) and potentially other acute leukemias. SNS-595 is a first-in-class cell cycle modulator that kills proliferating cancer cells by inducing apoptosis, or programmed cell death, as cells progress through the S phase of the cell cycle.

"The commencement of this Phase I trial for SNS-595 allows us to explore the potential benefits of SNS-595 in patients with acute leukemias. Based on the strong myelosuppressive effects of SNS-595 seen at higher doses in our Phase I clinical trials in patients with advanced solid malignancies, we believe SNS-595 has the potential to offer a significant advance in the treatment of acute leukemias," said Daniel Adelman, M.D., Senior Vice President of Research and Development at Sunesis.

Patients with acute refractory leukemias will be enrolled at three centers in the United States, including the H. Lee Moffitt Cancer Center & Research Institute, MD Anderson Cancer Center and the Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins University. Eligible patients will receive SNS-595 by one of two treatment schedules. In one regimen, patients will be administered three weekly doses of SNS-595 per treatment cycle. In the second regimen, patients will receive twice weekly administration of SNS-595 for four doses per treatment cycle. In addition to promising clinical activity seen in Phase I clinical studies in other cancer settings, xenograft studies in mice have demonstrated robust anti-leukemia activity, as well as marked potency and superior activity of SNS-595 when compared to several marketed cytotoxic drugs. In addition, SNS-595 has shown strong activity in drug-resistant tumor models.

About SNS-595

SNS-595 is a first-in-class cytotoxic with a novel mechanism of action. SNS-595 acts during the S phase of the cell cycle to induce rapid apoptosis of cells that are actively synthesizing DNA. In clinical trials conducted to date, SNS-595 has been well-tolerated and has shown promising signs of clinical activity. In addition, SNS-595 has exhibited broad activity in xenograft studies and drug-resistant tumor models. SNS-595 is currently being evaluated in Phase I clinical studies and will be soon entering Phase II clinical trials in lung cancer.

About Sunesis Pharmaceuticals

Sunesis is a clinical-stage biopharmaceutical company focused on the discovery, development and commercialization of novel small molecule therapeutics for oncology and other serious diseases. Sunesis has built a broad product candidate portfolio through internal discovery and in-licensing of novel cancer therapeutics. Sunesis is advancing its product candidates through in-house research and development efforts and strategic collaborations with leading pharmaceutical and biopharmaceutical companies.

Forward-Looking Statements

This press release may contain forward-looking statements that involve substantial risks and uncertainties. Sunesis may not actually achieve the plans, intentions or expectations contained in such forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations contained in such forward-looking statements. Sunesis does not assume any obligation to update any such forward-looking statements. For further information on Sunesis Pharmaceuticals, please visit www.sunesis.com.

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