Sunesis Pharmaceuticals Commences Clinical Trials of SNS-595 and SNS-314

September 12, 2007 1:28 PM ET

SOUTH SAN FRANCISCO, Calif., Sept 12, 2007 /PRNewswire-FirstCall via COMTEX News Network/ --

Sunesis Pharmaceuticals, Inc. (Nasdaq: SNSS) announced today that patient dosing has commenced in clinical trials to evaluate two of the company's anti-cancer product candidates, SNS-595 and SNS-314.

Sunesis' lead product candidate, SNS-595, is being evaluated in combination with cytarabine in a Phase 1b clinical trial of patients with relapsed and/or refractory acute leukemias. This clinical trial is designed to evaluate the safety, tolerability and initial indications of anti-cancer activity of escalating doses of SNS-595 when administered with a fixed dose of cytarabine. Non-clinical studies demonstrated that SNS-595 acts synergistically with cytarabine, the current standard of care in acute leukemias.

SNS-314, an Aurora kinase inhibitor, is being studied in its first clinical trial. The Phase 1 dose-escalating trial of SNS-314 in patients with advanced solid malignancies will examine safety and tolerability, as well as preliminary anti-tumor activity. The open-label trial is being conducted by leading investigators at five U.S. clinical sites. Patients in this trial will receive three once-weekly doses of SNS-314 per four-week cycle. In non-clinical studies, SNS-314 demonstrated robust anti-tumor activity in tumor models of diverse tissue types.

"We are pleased to have these two trials up and running. In addition to the single-agent activity we've observed for SNS-595 in acute leukemia patients, SNS-595 has demonstrated impressive synergy with cytarabine in non-clinical studies. Testing the potential benefits of a combination regimen is a key element of our comprehensive strategy to develop SNS-595 for the treatment of acute leukemia," said Daniel C. Adelman, M.D., Senior Vice President, Development and Chief Medical Officer at Sunesis.

"We're also excited to be treating patients for the first time with SNS-314, our internally discovered Aurora kinase inhibitor. SNS-314 has shown broad anti-tumor activity across a number of tumor models, and selective and specific activity against Aurora kinases in non-clinical studies," Dr. Adelman continued.

About SNS-595

SNS-595 is currently in Phase 1 and Phase 1b acute leukemia clinical trials and a Phase 2 ovarian cancer clinical trial. SNS-595 is a replication- dependent DNA damaging agent that causes irreversible growth arrest of proliferating cells and rapid apoptosis. In clinical trials conducted to date, SNS-595 has been well tolerated and has shown promising signs of clinical activity in both solid and hematological tumor types. In non- clinical evaluations, SNS-595 demonstrates broad and potent activity in xenograft, syngeneic and drug-resistant models.

About SNS-314

Discovered by Sunesis using the company's discovery platform, SNS-314 is a potent and selective inhibitor of Aurora kinases A, B and C. SNS-314 targets the uncontrolled cellular proliferation associated with cancer by halting cell division at the mitotic phase of the cell cycle. Aurora kinases are key enzymes involved in cancer cell division and have a central role in the abnormal proliferation of tumors.

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. For additional information on Sunesis Pharmaceuticals, please visit http://www.sunesis.com.

Other Information

In August, Ms. Karen Terrick joined Sunesis as a Director, Regulatory Affairs. In conjunction with her joining, the Compensation Committee of the company's Board of Directors approved an employment commencement grant to Ms. Terrick of a non-qualified stock option to purchase 25,000 shares of Sunesis common stock, effective August 31, 2007. This option award was granted without shareholder approval pursuant to Nasdaq Marketplace Rule 4350 (i)(1)(A)(iv) and with the following material terms: (a) an exercise price equal to the fair market value of the company's common stock on the grant date, (b) a term of ten years, and (c) a vesting schedule providing that the option is exercisable as to one-quarter of the total grant on the first anniversary of Ms. Terrick's hire, and one-forty-eighth of the total grant each month thereafter until the grant is fully vested.

Safe Harbor Statement

This press release contains forward-looking statements, including without limitation statements related to the safety, tolerability and potential efficacy of SNS-595 (alone and in combination with cytarabine) and SNS-314, planned clinical testing and development efforts and the anticipated clinical sites and timing of clinical trials. Words such as "will" and similar expressions are intended to identify forward-looking statements. These forward-looking statements are based upon Sunesis' current expectations. Forward-looking statements involve risks and uncertainties. Sunesis' actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of these risks and uncertainties, which include, without limitation, Sunesis' drug discovery, development and clinical manufacturing activities could be halted or significantly delayed, Sunesis' clinical trials for SNS-595 and SNS-314 may not demonstrate safety or efficacy or lead to regulatory approval, Sunesis' preclinical studies and clinical trials may not satisfy the requirements of the FDA or other regulatory agencies and Sunesis may require substantial additional funding, which may not be available to us on acceptable terms, or at all. These and other risk factors are discussed under "Risk Factors" and elsewhere in Sunesis' annual report on Form 10-K for the year ended December 31, 2006 and other filings with the Securities and Exchange Commission. Sunesis expressly disclaims any obligation or undertaking to release publicly any updates or revisions to any forward-looking statements contained herein.

SOURCE Sunesis Pharmaceuticals, Inc.

http://www.sunesis.com