Sunesis Pharmaceuticals' SNS-595 Shows Clinical Activity in Patients With Relapsed or Refractory Acute Leukemias; Data Presented in Oral Session at 49th Annual Meeting of the American Society of Hematology

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Conference Call Scheduled for 4:00 p.m. Eastern Time to Review Clinical Trial Results for SNS-595 and Non-clinical Data for SNS-032 Presented at the ASH Meeting

ATLANTA, Dec 10, 2007 /PRNewswire-FirstCall via COMTEX News Network/ -- Sunesis Pharmaceuticals, Inc. (Nasdaq: SNSS), a clinical-stage biopharmaceutical company developing novel anticancer therapeutics, presented positive results for SNS-595 in relapsed or refractory acute leukemia patients in an oral session by Jeffrey Lancet, M.D, Assistant Professor, Division of Hematologic Malignancies at the H. Lee Moffitt Cancer Center & Research Institute, at the 49th Annual Meeting of the American Society of Hematology (ASH) in Atlanta, Georgia. In a Phase 1 clinical trial, SNS-595 was generally well tolerated with anti-leukemic clinical activity when administered either once- or twice-weekly at biologically active doses.

In addition, non-clinical data showing that SNS-032 induces apoptosis in chronic lymphocytic leukemia (CLL) cells are being presented by William Plunkett, Ph.D., Professor and Chief, Section of Molecular and Cellular Oncology at the University of Texas M. D. Anderson, in a poster session. SNS-032 is currently in a Phase 1 clinical trial in patients with CLL or multiple myeloma.

Sunesis management will host a conference call today at 4:00 p.m. Eastern time to review the SNS-595 and SNS-032 data presented at the ASH meeting. Drs. Lancet and Plunkett will join management on the call.

Oral Presentation: A Phase 1b Open-Label Study of the Novel DNA Replication Inhibitor SNS-595 in Refractory Acute Leukemia (Abstract #442)

SNS-595, a first-in-class naphthyridine analog that intercalates DNA and poisons topoisomerase II causing selective DNA damage, was administered on a weekly or twice weekly schedule to patients with relapsed or refractory acute leukemias. Twelve of thirty patients (40 percent) who received doses of SNS-595 of 50 mg/m2 or greater on a weekly dose schedule achieved bone marrow blast reductions to less than five percent, and four of these twelve patients achieved either complete remission (CR), complete remission without platelet recovery (CRp) or complete remission with incomplete recovery of normal hematopoietic blood elements (CRi). In the twice-weekly dosing cohort, anti-leukemic activity was observed among two out of fourteen patients (14 percent) who received doses of 40 mg/m2 or greater, including one complete remission. In both arms of the study, SNS-595's anticancer activity correlated with sustained exposure to drug above a threshold plasma concentration for at least 20 hours per week of active treatment. At the maximum-tolerated-dose, this threshold was exceeded on average in both dosing schedules.

"SNS-595 is a novel chemotherapeutic agent with a distinct mechanism of action that is demonstrating both good tolerability and early signals of promising clinical activity in a group of patients with very advanced acute leukemias," said Dr. Lancet, a principal investigator for the Phase 1 trial. "I look forward to its continued clinical development in AML, both as a single agent and in combination with other cytotoxics."

The Phase 1 clinical trial was designed to evaluate the safety and tolerability of escalating doses of SNS-595 and to establish the maximum-tolerated dose in both treatment schedules. A preliminary assessment of SNS-595's anti-tumor activity as a single agent was a secondary objective of the trial. Overall, SNS-595 was generally well tolerated, with a dose-limiting toxicity of reversible Grade 3 - 4 oral mucositis. A maximum-tolerated dose of 72 mg/m2 once-weekly and 40 mg/m2 twice-weekly was established. SNS-595 exhibited consistent and predictable pharmacokinetics. These data were presented today by Dr. Lancet in the "Acute Myeloid Leukemias: Therapy, excluding Transplantation-Novel Therapies" oral session.

"We are pleased to report these promising results from our Phase 1 trial of SNS-595 in advanced leukemia patients. We believe three significant observations have emerged from this study: SNS-595 demonstrates anticancer activity among patients with advanced disease; SNS-595 is generally well tolerated -- even among elderly patients; and SNS-595 may be administered on either a once- or twice-weekly schedule," said Daniel C. Adelman, M.D., Sunesis' Senior Vice President, Development and Chief Medical Officer. "Data from our Phase 1 clinical trial provide strong support for our development plans for SNS-595 as a single agent and in combination with other anti-leukemic agents, such as cytarabine."

Poster Presentation: Mechanism of Action of SNS-032, a Novel Cyclin-Dependent Kinase Inhibitor, in Chronic Lymphocytic Leukemia: Comparison with Flavopiridol (Abstract # 3112)

Results from a non-clinical study of SNS-032, a potent and selective inhibitor of CDKs 2, 7 and 9, further characterized SNS-032's potential mechanism of action and favorably compared SNS-032's in vitro activity with flavopiridol in CLL cells obtained from patients.

SNS-032 acts by inhibiting the activity of CDKs 7 and 9 and reducing RNA synthesis, as well as down-regulating the expression of anti-apoptotic proteins, such as myeloid cell leukemia sequence 1, or MCL-1, and X-linked Inhibitor of Apoptosis Protein, or XIAP, both of which are associated with CLL-cell survival and proliferation. SNS-032 induces apoptosis in CLL cells, and its activity appears to be independent of p53 activity. This profile is significant as loss of p53 function has been implicated in the development of drug resistance with other agents. In a direct comparison, SNS-032 was more potent than flavopiridol in CLL cells. In addition, SNS-032 demonstrated 10- to 30-fold greater activity than that of flavopiridol in inhibiting transcription. Flavopiridol is a non-selective pan-CDK inhibitor currently in late-stage evaluation for the treatment of CLL.

Dr. Plunkett will present these data during this evening's poster session "CLL: Salvage Therapies and New Agents" from 5:00 p.m. to 7:00 p.m.

"SNS-032 demonstrates potent and selective induction of apoptosis in primary CLL cells at concentrations that we believe are achievable clinically. Data from these non-clinical studies of SNS-032 provide solid support and in vitro validation for our ongoing clinical trial of SNS-032 in patients with advanced CLL or multiple myeloma," said Dr. Adelman.

Conference Call Information

Sunesis management will host a conference call with clinical investigators discussing data presented today at the ASH meeting at 4:00 p.m. Eastern Time/1:00 p.m. Pacific Time.

Individual and institutional investors can access the call via 877-723-9519 (U.S. and Canada) or 719-325-4841 (international). To access the live audio webcast and subsequent archived recording, visit the "Investors and Media - Calendar of Events" section of the Sunesis website at http://www.sunesis.com. Please log on to Sunesis' website several minutes prior to the start of the presentation to ensure adequate time for any software download that may be necessary. A replay of the conference call will be archived on the Sunesis website for two weeks until December 24, 2007.

About Sunesis' Oncology Programs

Sunesis has built a rich portfolio of product candidates in oncology focused on novel pathways and targets, including inhibition of the cell-cycle and survival signaling. SNS-595, a first-in-class naphthyridine analog that intercalates DNA and poisons topoisomerase II causing selective DNA damage, is currently in a Phase 1b clinical trial in patients with acute leukemia and a Phase 2 clinical trial in patients with ovarian cancer. SNS-032, Sunesis' potent and selective inhibitor of CDKs 2, 7 and 9, is being evaluated in a Phase 1 clinical trial in chronic lymphocytic leukemia and multiple myeloma. SNS-314, a potent and selective pan-Aurora kinase inhibitor, is being studied in a Phase 1 dose-escalating clinical trial in patients with advanced solid tumors. In addition, Sunesis is developing novel small molecule inhibitors of Raf kinase and receptor tyrosine kinases in collaboration with Biogen Idec.

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.

Safe Harbor Statement

This press release contains forward-looking statements including without limitation statements related to the potential safety and efficacy of SNS-595 and SNS-032 and planned additional clinical testing and development efforts. Words such as "look forward," "designed," "believe," "appears" 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, the risk that Sunesis' drug discovery and development activities could be halted significantly or delayed for various reasons, the risk that Sunesis' clinical trials for SNS-595 and/or SNS-032 may not demonstrate safety or efficacy or lead to regulatory approval, the risk that preliminary data and trends may not be predictive of future data or results, the risk that Sunesis' preclinical studies and clinical trials may not satisfy the requirements of the FDA or other regulatory agencies, risks related to the conduct of Sunesis' clinical trials and manufacturing of SNS-595 and SNS-032 and risks related to Sunesis' need for additional funding. 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 to reflect any change in the company's expectations with regard thereto or any change in events, conditions or circumstances on which any such statements are based.

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