Sunesis Pharmaceuticals Presents Clinical Trial Data of Voreloxin in Patients with Acute Myeloid Leukemia and Ovarian Cancer at the Chemotherapy Foundation Symposium

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- Voreloxin Demonstrates Promising Clinical Activity in Patients with Difficult-to-Treat Cancers -

SOUTH SAN FRANCISCO, Calif., Nov 06, 2008 /PRNewswire-FirstCall via COMTEX News Network/ -- Sunesis Pharmaceuticals, Inc. (Nasdaq: SNSS) presented data from three clinical trials of the company's lead drug candidate, voreloxin (formerly SNS-595), at the Chemotherapy Foundation Symposium held in New York on November 4-8. Data previously presented from Phase 1 and Phase 1b/2 studies in patients with acute myeloid leukemia (AML) showed that preliminary clinical responses were observed in the relapsed/refractory AML population and the data supports further clinical development for voreloxin both as a single agent and in combination with cytarabine. Preliminary efficacy results previously presented from an ongoing Phase 2 trial demonstrate single agent activity of voreloxin in advanced platinum-resistant ovarian cancer and that the drug is generally well tolerated in this difficult-to-treat patient population.

"We believe that voreloxin has the potential to change the standard of care in AML and platinum-resistant ovarian cancer and look forward to reporting updated results of our AML trials at ASH," said Daniel Swisher, Chief Executive Officer, Sunesis Pharmaceuticals. "Our goal is to advance voreloxin into a pivotal trial in AML by the end of 2009."

Phase 1 and 1b/2 Studies of Voreloxin in AML

Data presented from a completed Phase 1 dose escalation trial of voreloxin as a single agent in acute leukemias (N=73) showed that single agent voreloxin was generally well tolerated, with the most frequently observed dose limited toxicity (DLT) being reversible grade 3/4 oral mucositis. The researchers concluded that single agent activity in the relapsed/refractory AML population supports further clinical development.

Researchers also presented initial data from an ongoing Phase 1b/2 study testing voreloxin in combination with cytarabine. The Phase 1b/2 trial is designed to evaluate safety, pharmacokinetics and anti-leukemic activity of escalating doses of voreloxin when administered on days one and four with a fixed dose of 400 mg/m2/day of cytarabine given as a continuous infusion for five days.

Of 11 evaluable patients in the first three cohorts, 3 patients have achieved a complete remission (one at 20 mg/m2 of voreloxin and two at 34 mg/m2 of voreloxin). Six patients were enrolled in cohort 4 (50 mg/m2 of voreloxin) and one had complete remission and one had a complete remission without full platelet recovery.

A copy of this presentation entitled "Voreloxin (SNS-595): An Active Agent in AML" is available at http://www.sunesis.com.

A Phase 2 Trial of Voreloxin in Platinum-Resistant Ovarian Cancer

In this ongoing Phase 2 study, 65 women with advanced platinum-resistant ovarian cancer were administered voreloxin at a dose of 48 mg/m2 as a single agent once every three weeks. At this dose, two patients have had a complete response, five have had partial responses and 23 achieved stable disease for 90 days or more. This equates to an overall disease control rate of 46%. Thirty-five women in the Phase 2 study were given 60 mg/m2 once every four weeks. Of the 32 patients evaluable for efficacy at this dose, one patient has had a complete response, two have had partial responses and 20 achieved stable disease thus far.

Voreloxin was also generally well tolerated in platinum-resistant ovarian cancer patients. Grade 3/4 non-hematologic adverse events (greater than or equal to 5%) at the 48 mg/m2 dose were low: fatigue (14%), vomiting (6%) and infections (8%). Low rates of febrile neutropenia occurred in 8% of the 65 patients evaluable for safety at 48 mg/m2 dosed every three weeks and 6% of the 35 patients evaluable for safety at 60 mg/m2 dosed every four weeks. Based on this emerging safety profile and low incidence of febrile neutropenia, the dose of voreloxin has been escalated to 75 mg/m2 dosed every four weeks. Sunesis expects to complete enrollment of the 75 mg/m2 cohort by the end of 2008.

A copy of this presentation entitled "Voreloxin (SNS-595) in Platinum-Resistant Ovarian Cancer" is available at http://www.sunesis.com.

About Voreloxin

Voreloxin (formerly SNS-595), is a novel naphthyridine analog, structurally related to quinolones, a class of compounds that has not been used previously for the treatment of cancer. Voreloxin both intercalates DNA and inhibits topoisomerase II, resulting in replication-dependent, site- selective DNA damage, irreversible G2 arrest and apoptosis. Voreloxin is currently being evaluated in a Phase 2 clinical trial (known as the REVEAL-1 trial) in previously untreated elderly AML patients and in a Phase 1b/2 clinical trial combining voreloxin with cytarabine for the treatment of patients with relapsed/refractory AML, as well as in an ongoing Phase 2 single-agent trial in platinum-resistant ovarian cancer. In clinical trials conducted to date, voreloxin has been generally well tolerated and has shown objective responses in both solid and hematologic tumor types.

About Acute Myeloid Leukemia

AML is a rapidly progressing cancer of the blood characterized by the uncontrolled proliferation of immature blast cells in the bone marrow. The Leukemia and Lymphoma Society estimates that over 13,000 new cases of AML were diagnosed and approximately 9,000 deaths from AML occurred in the U.S. during 2007. AML is generally a disease of older adults and the median age of a patient diagnosed with AML is about 67 years. A majority of elderly patients are not considered candidates for standard induction therapy or decline therapy, resulting in an acute need for new treatment options.

About Ovarian Cancer

In the United States, ovarian cancer remains the leading cause of death from gynecologic malignancies and is the fifth leading cause of cancer death overall in women behind lung, breast, colorectal and pancreatic cancers. According to the American Cancer Society, in 2008 there will be an estimated 21,650 new cases and more than 15,000 deaths from ovarian cancer in the U.S. alone. Following frontline treatment, recurrence rates among ovarian cancer patients are high. Treatment options remain limited following relapse and overall long-term survival has not changed significantly over the past 40 years, with five-year survival rates at less than 30 percent.

About Sunesis Pharmaceuticals

Sunesis is a biopharmaceutical company focused on the development and commercialization of new oncology therapeutics for the treatment of solid and hematologic cancers. Sunesis has built a highly experienced cancer drug development organization committed to advancing its lead product candidate, voreloxin, in multiple indications to improve the lives of people with cancer. For additional information on Sunesis Pharmaceuticals, please visit http://www.sunesis.com.

This press release contains forward-looking statements including without limitation statements related to the potential safety, efficacy and commercial potential of voreloxin (formerly SNS-595); planned additional clinical testing and development efforts for voreloxin; the timing of enrollment in the ongoing clinical trials of voreloxin; and the timing of announcements of results of ongoing clinical trials of voreloxin. Words such as "promising," "believe," "potential" "demonstrate" 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, risks related to Sunesis' need for additional funding, the risk that Sunesis' development activities for voreloxin, including enrollment and reporting of results, could be halted significantly or delayed for various reasons; the risk that Sunesis' clinical trials for voreloxin 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; and risks related to the conduct of Sunesis' clinical trials and manufacturing. 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, 2007, Sunesis' Quarterly Report on Form 10-Q for the quarter ended June 30, 2008, 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.

Contacts:
Sunesis Pharmaceuticals, Inc.
Eric Bjerkholt

Media Contact:
Invigorate Communications
Monique Greer

650-266-3717 415-946-1075

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