Sunesis Pharmaceuticals Presents Data from Clinical Trials of Voreloxin (formerly SNS-595) in Patients with Acute Myeloid Leukemia at the 13th Congress of the European Hematology Association

June 16, 2008 1:49 PM ET

Data from Phase 1 Single Agent and Phase 1b Combination Clinical Trials Demonstrate Voreloxin's Anti-Leukemic Activity

SOUTH SAN FRANCISCO, Calif., June 16, 2008 /PRNewswire-FirstCall via COMTEX News Network/ -- Sunesis Pharmaceuticals, Inc. (Nasdaq: SNSS) presented data Saturday from two clinical trials of the company's lead drug candidate, voreloxin (formerly SNS-595), including updated results of a Phase 1 trial of voreloxin when used as a single agent in relapsed or refractory patients with acute myeloid leukemia (AML) and preliminary data from a Phase 1b trial of voreloxin in combination with cytarabine in patients with relapsed/refractory AML.

"Voreloxin has demonstrated anti-leukemic activity as a single agent and is showing encouraging early response data when administered in combination with cytarabine. Importantly, it has also been generally well tolerated, even among patients older than 60 and patients with AML with poor risk features," said Judith E. Karp, M.D., Director, Adult Leukemia Program at The Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins University and an investigator for the Phase 1 and Phase 1b clinical trials of voreloxin in AML. "Voreloxin appears to be a promising new drug for the treatment of AML and I look forward to the results of continued clinical investigation."

Analysis of Safety and Response Data for Older AML Patients Supports Phase 2 REVEAL-1 Trial

Researchers presented an analysis of comparative safety, pharmacokinetic and response data from Sunesis' Phase 1 dose-escalating trial of single-agent voreloxin comparing results from older patients (age >/= 60) with those from younger patients (age < 60). Overall, voreloxin demonstrates a similar safety profile in both older and younger patients. In the Phase 1 trial, voreloxin was administered on a weekly or twice-weekly schedule and patient demographics were similar between the two treatment schedules. Six patients, including four age 60 or older and two younger than age 60, achieved complete remission (CR) or complete remission without platelet recovery (CRp) or complete remission with incomplete recovery of hematopoeitic elements (CRi) when voreloxin was administered at doses of 50 mg/m2 or greater weekly or 40 mg/m2 twice-weekly. Duration of complete remissions (CR or CRp) was reported. Remissions of up to seven months have been observed thus far, with two patients undergoing reinduction with voreloxin following relapse.

Sixty-eight patients were evaluable for safety, with 42 patients ranging in age from 60-85 years old and 26 patients age 21-59 years. Voreloxin was generally well tolerated in both the older and younger patient subgroups with similar incidence of Grade 3-4 adverse events. The dose-limiting toxicity was reversible oral mucositis, and a maximum-tolerated dose of 72 mg/m2 once-weekly and 40 mg/m2 twice-weekly was established. Researchers also reported that voreloxin pharmacokinetics were not influenced by age.

"AML is primarily a disease of the elderly and the medical need for new agents that can be tolerated by older patients remains unmet. Results from our comparative analysis demonstrate that voreloxin is generally well tolerated and achieves anti-leukemic activity among older, advanced AML patients, supporting our strategy for progressing the clinical development of voreloxin in this indication," said Glenn Michelson, M.D., Vice President, Clinical Strategy at Sunesis. "Sunesis recently initiated the Phase 2 REVEAL-1 (Response Evaluation of Voreloxin in Elderly AML) clinical trial to evaluate voreloxin in newly diagnosed AML in elderly patients. We hope to present initial data from the REVEAL-1 trial later this year."

Preliminary Data from Phase 1b Study of Voreloxin and Cytarabine Indicates Activity of Combination Regimen

Preliminary results were also presented today from Sunesis' ongoing dose-escalating Phase 1b clinical trial evaluating voreloxin in combination with cytarabine, the current standard of care in patients with relapsed and/or refractory AML.

The Phase 1b trial is designed to evaluate the safety and tolerability, and to provide a preliminary assessment of 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 twelve evaluable patients in the first three cohorts, three patients have achieved CRs (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 no dose limiting toxicities have been observed thus far at this dose. Patients are now being enrolled in cohort 5 at 70 mg/m2 of voreloxin. Voreloxin pharmacokinetics have so far been unaffected by the combination with cytarabine.

"We are very pleased by the interim results reported today from our Phase 1b combination study of voreloxin with cytarabine. We look forward to reporting results from this study later in the year, including CR rates at 50 mg/m2 and higher dose levels of voreloxin," continued Dr. Michelson.

These data were presented today in a poster titled "Safety and Efficacy Experience of Voreloxin (formerly SNS-595) in Relapsed/Refractory Acute Leukemia Patients >/= 60 Years Old Compared to <60 Years Old: Results of a Phase 1b Study" (Abstract #0515) at the 13th Congress of the European Hematology Association. A copy of the poster will be available on the Sunesis corporate website at http://www.sunesis.com.

About Voreloxin (formerly SNS-595)

Sunesis' lead compound, voreloxin (formerly SNS-595), is a novel naphthyridine analog, structurally related to quinolones, a class of compounds which 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 rapid apoptosis. Voreloxin is currently being evaluated as a single agent in a Phase 2 clinical trial (known as the REVEAL-1 trial) in previously untreated elderly AML patients, in a Phase 1b clinical trial combining voreloxin with cytarabine for the treatment of patients with relapsed/refractory AML, and as a single agent in a Phase 2 clinical 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 Sunesis Pharmaceuticals

Sunesis is a clinical-stage biopharmaceutical company focused on the development 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.

Safe Harbor Statement

This press release contains forward-looking statements including without limitation statements related to the potential safety, efficacy, duration of response 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," "encouraging," "hope," "appears," "demonstrate," "indicates," "supports," and "look forward" 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' 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 including data regarding duration of response, 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; 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, 2007, Sunesis' Quarterly Report on Form 10-Q for the quarter ended March 31, 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.

SOURCE Sunesis Pharmaceuticals, Inc.

http://www.sunesis.com