Sunesis Pharmaceuticals Initiates Phase 2 Clinical Trial of Voreloxin (SNS-595) in Acute Myeloid Leukemia

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SOUTH SAN FRANCISCO, Calif., May 21, 2008 /PRNewswire-FirstCall via COMTEX News Network/ -- Sunesis Pharmaceuticals, Inc. (Nasdaq: SNSS) today announced the initiation of the REVEAL-1 (Response Evaluation of Voreloxin in Elderly AML) Phase 2 clinical trial of voreloxin (also known as SNS-595), the company's lead anti-cancer therapeutic. The REVEAL-1 trial is being conducted in previously untreated elderly patients with acute myeloid leukemia (AML) who are unlikely to benefit from standard induction therapy. The first patient was enrolled and treated at the Indiana University Melvin and Bren Simon Cancer Center under the care of Larry D. Cripe, M.D., Associate Professor, Department of Medicine, Division of Hematology/Oncology at the Indiana University School of Medicine.

The primary objective of the REVEAL-1 trial is to evaluate voreloxin's anti-leukemic activity as a single agent, measured as either complete remission (CR) or complete remission without full platelet recovery (CRp). The study will also measure the duration of these responses. In order to qualify for the trial, patients must be at least age 60 with previously untreated AML and satisfy at least one of the following factors: poor performance status (PS 2); intermediate or unfavorable cytogenetics; prior antecedent hematologic disorder; or age greater than or equal to 70 years. Patients enrolled in the trial will receive three weekly doses of 72 mg/m2 of voreloxin in a treatment cycle. Approximately 55 patients will be enrolled in the open-label, multi-center REVEAL-1 trial.

"We are pleased to move our voreloxin program forward in AML with this Phase 2 trial. Based on the clinical activity and tolerability profiles observed in our Phase 1 trial of voreloxin in relapsed/refractory AML patients, we see a clear opportunity for this drug in the first-line treatment of older patients who may not benefit from standard induction therapy," said Daniel C. Adelman, M.D., Senior Vice President, Development and Chief Medical Officer of Sunesis. "Treatment options for elderly AML patients are extremely limited. If the data from this trial indicate clear clinical benefit, Sunesis could initiate a pivotal trial in this highly underserved patient population. We expect to present interim data from this trial at a medical conference toward the end of this year."

Sunesis previously reported promising results from its Phase 1 single agent dose-escalation study of voreloxin in relapsed or refractory AML patients. In that trial, 13 of 30 patients (43 percent) who received doses of voreloxin of 50 mg/m2 or greater on a weekly dose schedule achieved bone marrow blast reductions to less than five percent, and five of those 13 achieved either CR, CRp or complete remission with incomplete recovery of normal hematopoietic blood elements. Voreloxin was generally well tolerated, with a dose-limiting toxicity of reversible oral mucositis. A maximum- tolerated weekly dose of 72 mg/m2 was established.

Sunesis also announced today that voreloxin has been accepted as the nonproprietary name for SNS-595 by the United States Adopted Names (USAN) Council, in consultation with the World Health Organization (WHO) International Nonproprietary Names Expert Committee. Although voreloxin has been officially accepted by the USAN Council, the official adoption date has been set for May 28, 2008. The USAN Council serves health professionals in the United States by selecting simple, informative, and unique nonproprietary names for drugs by establishing logical nomenclature classifications based on pharmacological and/or chemical relationships to ensure that drug information is communicated accurately and unambiguously. The USAN Council aims for global standardization and unification of drug nomenclature by working closely with the International Nonproprietary Name Programme of WHO and various national nomenclature groups.

About Voreloxin (SNS-595)

Voreloxin (also known as 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. The topoisomerase II-associated DNA intercalation and DNA damage produced by voreloxin show greater

selectivity for proliferating cells.

In nonclinical evaluations, voreloxin demonstrates broad and potent activity in tumor biopsies and in xenograft, syngeneic and drug-resistant tumor models. In addition to the REVEAL-1 Phase 2 clinical trial in elderly AML patients, voreloxin is being evaluated in combination with cytarabine in a Phase 1b clinical trial 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 American Cancer Society estimates that over 13,000 new cases of AML will be diagnosed and approximately 8,800 deaths from AML will occur in the U.S. during 2008. AML is generally a disease of older adults and the median age of a patient with AML is about 67 years. A majority of elderly patients are not considered candidates for standard 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 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 ongoing clinical testing of voreloxin, potential safety and efficacy and commercial potential of voreloxin, planned additional clinical testing and development efforts, the timing of enrollment of patients in the company's clinical trials, the adoption of voreloxin as a nonproprietary name and the announcement of clinical results. Words such as "expect," "will," "opportunity," "plans," "could," 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, 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, risks related to the conduct of Sunesis' clinical trials and manufacturing of voreloxin 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 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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