Sunesis Presents Positive Phase 2 Clinical Data of Voreloxin in Acute Myeloid Leukemia at the American Society of Hematology 2009 Annual Meeting

December 7, 2009 2:19 PM ET

Conference Call Scheduled for December 8 at 2:00 PM EST to Discuss ASH Data Presentations

SOUTH SAN FRANCISCO, CA, Dec 07, 2009 (MARKETWIRE via COMTEX News Network) -- Sunesis Pharmaceuticals, Inc. (NASDAQ: SNSS) today announced positive data from two Phase 2 clinical trials of the Company's lead drug candidate, voreloxin. The results highlight voreloxin's strong efficacy and safety profile when used as a single agent or in combination with chemotherapy in patients with difficult to treat acute myeloid leukemia (AML). The trial results were presented at the 51st American Society Hematology (ASH) Annual Meeting in New Orleans, LA. The presentations are available on the Sunesis website at www.sunesis.com.

"These results provide us with the efficacy and safety data to move voreloxin forward into pivotal testing," said Steven Ketchum, Ph.D., Senior Vice President of Research and Development at Sunesis. "Trial results show that the high rates of remission observed in both trials have translated into durable effects with meaningful preliminary overall survival results. With an anticipated median survival of three and a half to six months on currently available therapies, primary refractory and first relapse AML patients are particularly in desperate need of more effective treatment options. We look forward to discussing these data with the FDA in our End-of-Phase 2 meeting scheduled for the first quarter of 2010."

Phase 1b/2 Clinical Trial of Voreloxin in Combination with Cytarabine in Relapsed/Refractory (Abstract No. 645)

In an oral presentation, Jeffrey Lancet, M.D., Associate Member, Section Chief - Leukemia, Department of Hematologic Malignancies, at the H. Lee Moffitt Cancer Center & Research Institute and a clinical trial investigator, presented data from a Phase 1b/2 clinical trial testing voreloxin in combination with cytarabine, a widely used chemotherapy, in patients with relapsed or refractory AML. The trial is designed to evaluate the safety, pharmacokinetics and anti-leukemic activity of escalating doses of voreloxin when administered in combination with cytarabine given either as continuous infusion or as a two hour IV infusion. To date, 66 patients have been treated in the expansion Phase 2 populations of the trial, which includes primary refractory and first relapse AML patients. Of these, 64 patients were evaluable for efficacy outcomes.

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--  Among evaluable first relapse (n=36) and primary refractory patients
(n=28), preliminary median overall survival is 7.8 months and the remission
rate is 31% (complete remission [CR] 27%, complete remission without full
platelet recovery [CRp] 2% and complete remission with incomplete recovery
[CRi] 2%).  Historical median overall survival data in primary refractory
and first relapse patients on currently available chemotherapies range from
3.4 to 5.9 months(1) (2).
--  Voreloxin in combination with either bolus or continuous infusion
cytarabine was generally well-tolerated.  Infection-related toxicities were
the most common Grade 3 or higher non-hematologic adverse events.  In
addition, Grade 3 or higher oral mucositis was observed.
--  All-cause mortality among these patients was 1% at 30 days and 8% at 60
days.
--  A recommended pivotal dose-regimen of voreloxin used in combination
with cytarabine has been identified.
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"Voreloxin has induced remissions in difficult to treat relapsed, primary refractory and relapsed/refractory AML patients," said Dr. Lancet. "Voreloxin used in combination with cytarabine has demonstrated meaningful anti-leukemic activity with an acceptable tolerability profile in these difficult-to-treat patients."

Phase 2 Clinical Trial of Single Agent Voreloxin in Newly Diagnosed Elderly AML (REVEAL-1 Trial) (Abstract No. 1037)

In a poster presentation, investigators presented data from the fully enrolled REVEAL-1 (Response Evaluation of VorEloxin in AmL) trial, a Phase 2 dose optimization trial of single agent voreloxin in previously untreated, elderly AML patients who are unlikely to benefit from standard induction chemotherapy. 113 AML patients have been treated in the trial, all of whom had at

least one additional adverse risk factor at enrollment, including intermediate or unfavorable cytogenetics in the majority of patients. Median age for patients in the trial was 74 years. The trial includes three dosing schedules: Schedule A, once weekly for three weeks (n=29); Schedule B, once weekly for two weeks (n=35); and Schedule C, on days one and four at either 72 mg/m2 (n=29) or 90 mg/m2 (n=20).

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--  Median survival was 8.7 months in Schedule A; 5.8 months in Schedule B;
and 7.3 months (preliminary) in Schedule C (72 mg/m2 on days one and four).
--  Median duration of remission was 10.7 months and one year survival was
38% for Schedule A.   For the other schedules, median duration of remission
has not been reached and one year survival is too early to evaluate.
--  Patients age 75 or older (N=49) with at least 1 additional risk factor
at diagnosis, a population identified by the National Comprehensive Cancer
Network (2010) AML Guidelines as having poor outcome to standard treatment,
experienced a CR rate of 30% and a 30-day all-cause mortality of 5%.
Survival in these patients was too early to evaluate.
--  Based on trial results, Schedule C has been determined to be the
recommended pivotal dose regimen.  For Schedule C, response rates (CR and
CRp) are 38%; 30- and 60-day all-cause mortality are 7% and 17% with
improved tolerability over Schedule A.
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"Voreloxin has demonstrated a unique combination of anti-leukemic activity and tolerability, important for patients who are unlikely to benefit from standard induction therapy," said Robert K. Stuart, M.D., Professor of Medicine, Division of Hematology/Oncology, Department of Medicine, Medical University of South Carolina, and an investigator in the Phase 2 clinical trial. "Particularly encouraging are the durable response, tolerability and promising survival results in the Schedule C group. I look forward to seeing further data from this trial as it matures, particularly voreloxin's durability and overall survival in Schedule C."

Conference Call and Slide Presentation Information

The company will host a conference call and webcast slide presentation tomorrow, December 8, 2009 at 2:00 PM EST to discuss the Company's new clinical data. Robert K. Stuart, M.D., Professor of Medicine, Division of Hematology/Oncology, Department of Medicine, Medical University of South Carolina, will join the Sunesis senior management team to review the updated data from the Company's Phase 2 studies of voreloxin. The call can be accessed by dialing 888-726-2443 (U.S. and Canada) or 913-312-1516 (international). To access the live audio webcast and accompanying slide presentation, or the subsequent archived recording, visit the "Investors and Media - Calendar of Events" section of the Sunesis website at www.sunesis.com. The webcast will be recorded and available for replay on the company's website until December 22, 2009.

About Voreloxin

Voreloxin is a first-in-class anticancer quinolone derivative, or AQD, 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, 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.

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 nearly 13,000 new cases of AML will be diagnosed and approximately 9,000 deaths from AML will occur in the U.S. in 2009. AML is generally a disease of older adults, and the median age of a patient diagnosed with AML is about 67 years. AML patients with relapsed or refractory disease and newly diagnosed AML patients over 60 years of age with poor prognostic risk factors typically die within one year, resulting in an acute need for new treatment options for these patients.

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.

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This press release contains forward-looking statements, including without limitation statements related to voreloxin's efficacy, safety profile and effects as a single agent and in combination with other AML treatments, the timing and outcome of the End-of-Phase 2 meeting with the FDA, voreloxin's mechanism of action and results that may warrant further clinical evaluation of voreloxin. Words such as "highlight," "look forward to," "show," "demonstrated," "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, the risk that Sunesis' drug development activities for voreloxin could be halted or significantly 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' nonclinical 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, risks related to the manufacturing of voreloxin, and the risk that Sunesis' proprietary rights may not adequately protect voreloxin. These and other risk factors are discussed under "Risk Factors" and elsewhere in Sunesis' Quarterly Report on Form 10-Q for the quarter ended September 30, 2009 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.

(1) Giles et al. (2009) Blood.

(2) Litzow et al. (2009) Br J Haematol.

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