Sunesis Completes Enrollment of Voreloxin REVEAL-1 Trial in Acute Myeloid Leukemia

October 30, 2009 2:14 PM ET

SOUTH SAN FRANCISCO, Calif., Oct 30, 2009 /PRNewswire-FirstCall via COMTEX News Network/ -- Sunesis Pharmaceuticals, Inc. (Nasdaq: SNSS) today reported that it has completed enrollment in the REVEAL-1 (Response Evaluation of VorEloxin in AmL) trial, a Phase 2 dose regimen optimization trial of single agent voreloxin in newly diagnosed elderly acute myeloid leukemia (AML) patients who are unlikely to benefit from standard induction chemotherapy. A total of 113 patients were enrolled and dosed according to one of three dosing schedules.

"The REVEAL-1 trial's rapid accrual from initiation in May 2008 underscores a strong interest from investigators in voreloxin as a potential new treatment for AML," said Daniel Swisher, Chief Executive Officer of Sunesis. "Previously reported interim data from this and other studies have demonstrated that voreloxin can induce durable complete remissions in a variety of AML patient populations, including highly underserved elderly patients. Results from REVEAL-1 and our ongoing Phase 1b/2 trial of voreloxin in combination with cytarabine in relapsed/refractory AML will contribute greatly to our clinical development strategy as we look to move next year into a pivotal trial of voreloxin."

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 trial will also measure the duration of remission and survival. In order to qualify for the trial, patients had to be at least age 60 with previously untreated AML and satisfy at least one of the following poor prognosis factors: poor performance status (PS 2); intermediate or unfavorable cytogenetics; prior antecedent hematologic disorder; or an age greater than or equal to 70 years. Patients enrolled in the trial were treated with voreloxin according to one of three dosing schedules: 72 mg/m2 of voreloxin dosed weekly for three weeks, 72 mg/m2 of voreloxin dosed weekly for two weeks, or 72 or 90 mg/m2 of voreloxin dosed on days one and four.

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. A majority of elderly patients are not considered candidates for standard induction chemotherapy or decline therapy, resulting in an acute need for new treatment options.

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, please visit *http://www.sunesis.com*.

SUNESIS and the logo are trademarks of Sunesis Pharmaceuticals, Inc.

This press release contains forward-looking statements, including without limitation statements related to the potential efficacy and commercial potential of voreloxin and Sunesis' plans to move into pivotal testing of voreloxin. . Words such as "potential," "can," "will," "look to" 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' drug development activities for voreloxin 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' 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 June 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.


```
Investor and Media Inquiries:
Andrea Rabney                    Eric Bjerkholt
Argot Partners                   Sunesis Pharmaceuticals
212-600-1902                     650-266-3717
```


SOURCE Sunesis Pharmaceuticals, Inc.

`http://www.sunesis.com`