

## **Preliminary Results from Sunesis Pharmaceuticals' Phase 1 Trial of SNS-595 in Patients with Advanced Leukemias Demonstrate Promising Clinical Activity**

December 10, 2006 12:47 PM ET

### **Data Presented at ASH Annual Meeting Show SNS-595 is Well Tolerated and Decreases Leukemic Blast Cells among Heavily Pre-treated Patients**

South San Francisco, CA, December 10, 2006 – Sunesis Pharmaceuticals, Inc. (Nasdaq: SNSS) presented data on its lead compound, SNS-595, from an ongoing Phase 1 clinical trial and from preclinical studies at The American Society of Hematology (ASH) 48th Annual Meeting and Exposition in Orlando, FL. Interim results from the Phase 1 clinical trial demonstrate that SNS-595 is well tolerated and shows promising signs of clinical activity in patients with advanced acute leukemias. In a second presentation, preclinical data from in vivo mouse studies showed that SNS-595 acts synergistically with cytarabine to reversibly ablate bone marrow. SNS-595 is a naphthyridine analog that selectively targets and kills proliferating cells during the DNA replication phase of the cell cycle.

“SNS-595’s activity among patients with advanced relapsed or refractory acute leukemias is encouraging as there is no standard treatment regimen for such patients, who generally have a very poor prognosis,” said Jeffrey E. Lancet, M.D., Professor, Department of Hematologic Malignancies of the H. Lee Moffitt Cancer Center & Research Institute and a principal investigator for the Phase 1 trial. “To date, we’ve seen significant blast reductions within bone marrow and peripheral blood among patients with leukemias that were refractory to prior regimens. In addition, SNS-595 has been well tolerated, and patient accrual and dose escalation in this trial are ongoing.”

Preliminary results from the trial show that SNS-595 reduces bone marrow blasts among relapsed, refractory acute myeloid leukemia (AML) patients treated with SNS-595 at 50 mg/m<sup>2</sup> weekly for three doses. In particular, three of five evaluable patients treated at this dose level saw reductions in bone marrow blast cells of 95 percent or more after initial treatment with SNS-595; all of these patients had previously failed multiple treatments. SNS-595 was well tolerated, with only one dose-limiting toxicity (prolonged neutropenia) observed to date. All other non-dose-limiting toxicities have been easily manageable. In addition, SNS-595 has demonstrated highly predictable and reproducible pharmacokinetics, consistent with prior clinical trials.

The Phase 1 trial is designed to assess SNS-595’s safety, tolerability and pharmacokinetics and to establish a recommended Phase 2 dose for further studies among patients with acute leukemia. To date, a total of 31 patients with advanced or refractory acute leukemias have been enrolled into one of two study arms in which patients receive escalating doses of SNS-595 weekly or twice weekly.

“We are pleased with these interim results from our Phase 1 trial of SNS-595 among acute leukemia patients. We are seeing promising anticancer activity in our clinical trials and preclinical studies of SNS-595, and we are making excellent progress in defining a dose and schedule for further clinical development of this novel compound,” said Daniel Adelman, M.D., Senior Vice President, Research and Development of Sunesis. “The goal of our program is to advance the 25-year-old standards of care in the treatment of AML. The distinct mechanism and resistance profile of SNS-595, combined with the promising preclinical and clinical data to date, support rapidly moving our drug into mono- and combination-therapy trials in AML in 2007.”

In a poster session at the annual ASH meeting, Sunesis also presented preclinical data demonstrating that SNS-595 acts synergistically with cytarabine, or Ara C, a chemotherapy drug commonly used in the first-line treatment of acute myeloid leukemia. SNS-595 works through the DNA-protein kinase and p73 dependent pathways to induce apoptosis, or programmed cell death. Cytarabine also acts as a DNA-damaging agent, though it relies on a different pathway. Given the potentially complementary mechanisms, Sunesis conducted preclinical studies in a murine model of the two agents when administered alone or in combination to test for activity. Researchers found that low doses of SNS-595 and cytarabine in combination achieved greater reductions in cellularity than either SNS-595 or cytarabine administered alone. Notably, the two agents demonstrated synergy, reducing cellularity by 93 percent. In addition, circulating leukocyte levels were also reduced and complete bone marrow recovery was observed following treatment.

#### **About Sunesis' Oncology Programs**

Sunesis has built a portfolio of preclinical- and development-stage product candidates in oncology focused on novel pathways and

targets, including inhibition of the cell-cycle and survival signaling. Sunesis is currently conducting Phase 2 and Phase 1 clinical trials in lung cancer, and acute myeloid leukemia for its lead compound, SNS-595. A second compound, SNS-032, is in a Phase 1/2 clinical trial to examine the safety and preliminary anti-tumor activity among patients with lung cancer, breast cancer or melanoma. Sunesis is also conducting GLP toxicology studies of a third drug candidate, an Aurora kinase inhibitor known as SNS-314. In addition, in cooperation with Biogen Idec, Sunesis is developing novel small molecule inhibitors of Raf kinase and other oncology kinases.

#### 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>.

#### Forward-Looking Statements

This press release may contain forward-looking statements that involve substantial risks and uncertainties. Sunesis may not actually achieve the plans, intentions or expectations contained in such forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations contained in such forward-looking statements. Sunesis does not assume any obligation to update any such forward-looking statements. For further information on Sunesis Pharmaceuticals, please visit <http://www.sunesis.com>.

#### CONTACTS:

Investors

Eric Bjerkholt, CFO

Sunesis Pharmaceuticals, Inc.,

650-266-3717

Media

Karen L. Bergman or

Michelle Corral

BCC Partners

650-575-1509 or 415-794-8662