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Sunesis Announces Publication of Phase 1b Data of Vosaroxin in Relapsed or Refractory Acute Leukemia

SOUTH SAN FRANCISCO, Calif., July 20, 2011 – Sunesis Pharmaceuticals, Inc. (NASDAQ: SNSS) today announced the publication in *Leukemia* of data from a Phase 1b multi-center study of vosaroxin in relapsed or refractory leukemia. The results show that single-agent vosaroxin was well-tolerated, with a potent anti-leukemic effect in patients who had received multiple prior therapies. The Phase 1b data, along with results from Phase 2 studies of vosaroxin used alone and in combination with cytarabine in the treatment of acute myeloid leukemia (AML), support the Company's currently-enrolling VALOR trial, a Phase 3, multinational, randomized, double-blind, placebo-controlled, pivotal clinical trial of vosaroxin in combination with cytarabine in first relapsed or refractory AML.

“Due to the high rate of resistance to available chemotherapy regimens, treatment outcomes for aggressive leukemias such as relapsed or refractory AML remain largely unsatisfactory, underscoring the urgent need for new treatment options,” said Jeffrey E. Lancet, MD, Associate Member and Section Chief of Leukemia/MDS at the H. Lee Moffitt Cancer Center and Research Institute, lead author of the study and a principal investigator in the VALOR trial. “With its unique mechanism of action, good tolerability and strong signals of anti-leukemic activity in both relapsed and refractory disease, vosaroxin warrants aggressive analysis in the treatment of advanced AML. Our center in Tampa, Florida is actively recruiting patients to the pivotal VALOR trial, one of the largest studies undertaken to date in the relapsed/refractory AML population.”

Steven B. Ketchum Ph.D., Senior Vice President, Research and Development, said: “The VALOR study is built on a significant dataset from Phase 1 and 2, including results published in the *Leukemia* article. VALOR's robust, adaptive design factors in these datasets and addresses a range of potential survival outcomes for both the experimental and control arms, enabling the observation of a clinically meaningful and statistically significant survival benefit in the vosaroxin plus cytarabine (experimental) arm relative to the placebo plus cytarabine (control) arm across a range of scenarios. We continue to open study centers around the world and to maintain progress towards an interim analysis of the VALOR trial data by the Data Safety Monitoring Board in mid-2012.”

The Phase 1b clinical trial was designed to evaluate the safety and tolerability of escalating doses of vosaroxin and to establish the maximum-tolerated dose (MTD) in two treatment schedules. A preliminary assessment of vosaroxin's anti-tumor activity as a single agent was a secondary objective of the trial. Overall, vosaroxin was generally well tolerated, with a dose-limiting toxicity of reversible Grade 3 - 4 oral mucositis. Of 73 treated patients with advanced relapsed or refractory leukemia, including AML (85 percent of patients), myelodysplastic syndrome (MDS), acute lymphoblastic leukemia (ALL), or chronic myeloid leukemia (CML) in blast crisis, a morphologic leukemia-free state, defined by bone marrow blasts reduced to less than 5%, was achieved in 16 patients at a median 32.5 days after the first dose of vosaroxin. A combined complete response was achieved in five patients, all of whom presented with AML. The MTD was established at 72 mg/m² weekly and 40 mg/m² twice weekly.

The *Leukemia* article and full, published dataset are available online at <http://www.nature.com/leu/journal/vaop/ncurrent/full/leu2011157a.html>.

Vosaroxin has subsequently been studied in two Phase 2 studies of AML patients to further define doses and regimens suitable for Phase 3 studies, including the ongoing VALOR trial.

About VALOR

VALOR is a Phase 3, randomized, double-blind, placebo-controlled, pivotal trial in patients with first relapsed or refractory AML. The trial is expected to enroll 450 evaluable patients at approximately 100 leading sites in the U.S., Canada, Europe, Australia and New Zealand. The VALOR trial is currently open for enrollment and patients will be randomized one to one to receive either vosaroxin on days one and four in combination with cytarabine daily for five days, or placebo in combination with cytarabine. Additionally, the VALOR trial employs an innovative, adaptive trial design that allows for a one-time sample size adjustment by the DSMB at the interim analysis to maintain adequate power across a broad range of clinically meaningful and statistically significant survival outcomes. The trial's primary endpoint is overall survival. For more information on the VALOR trial, please visit www.valortrial.com.

About Vosaroxin

Vosaroxin 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. Vosaroxin both intercalates DNA and inhibits topoisomerase II, resulting in replication-dependent, site-selective DNA damage, G2 arrest and apoptosis.

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 estimated that 12,330 cases of AML were diagnosed and approximately 9,000 deaths from AML occurred in the U.S. in 2010. Additionally, it is estimated that prevalence of AML is approximately 25,000 in the U.S. 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, vosaroxin, in multiple indications to improve the lives of people with cancer. For additional information on Sunesis, please visit www.sunesis.com.

This press release contains forward-looking statements, including statements related to the design, conduct and results of the VALOR trial, the occurrence and timing of the DSMB interim analysis and vosaroxin's effects, efficacy and safety profile as a single agent and in combination with cytarabine. Words such as "show," "support," "warrants," "enabling," "continue," "progress" 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 substantial additional funding to complete the development and commercialization of vosaroxin, risks related to Sunesis' ability to raise the capital that it believes to be accessible and is required to fully finance the VALOR trial until its planned unblinding in 2013, the risk that Sunesis' development activities for vosaroxin could be otherwise halted or significantly delayed for various reasons, the risk that Sunesis' clinical studies for vosaroxin may not demonstrate safety or efficacy or lead to regulatory approval, the risk that data to date and trends may not be predictive of future data or results, the risk that Sunesis' nonclinical studies and clinical studies 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 vosaroxin and supply of the active pharmaceutical ingredients required for the conduct of the VALOR trial, the risk of third party opposition to granted patents related to vosaroxin, and the risk that Sunesis' proprietary rights may not adequately protect vosaroxin. These and other risk factors are discussed under "Risk Factors" and elsewhere in Sunesis' Quarterly Report on Form 10-Q for the quarter ended March 31, 2011 and Sunesis' other filings with the Securities and Exchange Commission, including Sunesis' Annual Report on Form 10-K for the year ended December 31, 2010. 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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