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Sunesis Pharmaceuticals Receives European Orphan Drug Designation for Vosaroxin to Treat Acute Myeloid Leukemia

SOUTH SAN FRANCISCO, Calif., (May 2, 2012) – Sunesis Pharmaceuticals, Inc. (NASDAQ: SNSS) today announced that the European Commission has granted orphan drug designation to vosaroxin, the Company's lead development candidate, for the treatment of acute myeloid leukemia (AML). The designation provides for 10 years of marketing exclusivity in all EU member countries following product approval. Vosaroxin has previously received orphan drug and fast track designations from the U.S. Food and Drug Administration (FDA).

"The European Commission's decision reinforces the global potential of vosaroxin and recognizes the desperate need for new treatment options in AML, an indication for which treatment standards have not changed appreciably in the past thirty years," said Dr. Adam Craig, EVP Development & CMO of Sunesis. "European orphan drug designation is the latest in a series of regulatory milestones that have strengthened the commercial opportunity for vosaroxin on both sides of the Atlantic. These include the potential for market exclusivity to 2030 and an expedited review process in the U.S., as well as new patents issued in the European Union with exclusivity to 2025."

As established by the European Medicines Agency (EMA), orphan designation is granted to product candidates intended for the treatment of a life-threatening or chronically debilitating condition affecting no more than five in 10,000 persons in the European Union. It also provides for scientific advice and regulatory assistance from the EMA during the product development phase, direct access to centralized marketing authorization, and certain financial incentives for companies developing orphan drug candidates. Orphan drugs are eligible for a reduction of fees associated with pre-authorization inspections, as well as marketing authorization application fees and certain other fees for qualifying companies.

Sunesis is currently enrolling patients in its 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 acute myeloid leukemia.

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 110 leading sites in the U.S., Canada, Europe, Australia and New Zealand. The VALOR trial is currently enrolling patients, who are 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 broader range of 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 anti-cancer quinolone derivative, (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 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 http://www.sunesis.com.

This press release contains forward-looking statements, including statements related to the exclusivity period for vosaroxin in the United States and other geographies and the design, conduct and results of the VALOR trial and the occurrence and timing of the DSMB interim analysis. Words such as "following," "provides," "potential," 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 results 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 development and commercialization of vosaroxin, the risk that raising funds through lending arrangements may restrict our operations or produce other adverse results, 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 September 30, 2011, Sunesis' Annual Report on Form 10-K for the year ended December 31, 2011 and Sunesis' 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.