

Sunesis Pharmaceuticals Completes Enrollment in Phase 3 VALOR Trial of Vosaroxin in AML

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Unblinding of Largest Company-Sponsored Trial in First Relapsed/Refractory AML Expected First Half 2014

SOUTH SAN FRANCISCO, Calif., Sep 25, 2013 (GLOBE NEWSWIRE via COMTEX) --

Sunesis Pharmaceuticals, Inc. (Nasdaq:SNSS) today announced that enrollment in the company's pivotal, Phase 3 VALOR trial of vosaroxin plus cytarabine in first relapsed or refractory acute myeloid leukemia (AML) is now complete. Enrollment of 712 patients in the randomized, double-blind, placebo-controlled trial was achieved on schedule. Unblinding of the trial is expected in the first half of 2014 after reaching 562 events and locking the final study database.

"Strong investigator support for VALOR from across our more than 100 sites worldwide has allowed us to finish enrolling VALOR, the largest-ever company-sponsored trial in first relapsed/refractory AML, on schedule," said Adam R. Craig, MD, PhD, Executive Vice President, Development and Chief Medical Officer of Sunesis. "With over 700 patients enrolled, VALOR is well powered to demonstrate a clinically meaningful improvement in overall survival, the study's primary endpoint. We look forward to top-line results in the first half of 2014 and, with a positive outcome, to seeing vosaroxin change the global standard of care in this important area of unmet medical need."

The VALOR study was designed around a promising Phase 2 study of vosaroxin in combination with cytarabine in patients with relapsed or refractory AML. The data demonstrated a balance of improved remission rates translating into long leukemia-free survival – including the opportunity to bridge to potentially curative bone marrow transplants – and low induction mortality. Across all past and ongoing studies, more than 700 AML patients have been treated with vosaroxin.

Both the U.S. Food and Drug Administration (FDA) and European Commission have granted orphan drug designation to vosaroxin for the treatment of AML. Additionally, vosaroxin has been granted fast track designation by the FDA for the potential treatment of relapsed or refractory AML in combination with cytarabine.

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 being conducted at more than 100 leading sites in the U.S., Canada, Europe, Australia, New Zealand and South Korea. Patients are randomized in a ratio of 1:1 to receive either vosaroxin on days one and four in combination with cytarabine daily for five days, or placebo in combination with cytarabine. 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. Both the U.S. Food and Drug Administration (FDA) and European Commission have granted orphan drug designation to vosaroxin for the treatment of AML. Additionally, vosaroxin has been granted fast track designation by the FDA for the potential treatment of relapsed or refractory acute myeloid leukemia in combination with cytarabine. At the 2010 American Society of Clinical Oncology Annual Meeting as well as other scientific meetings, Sunesis presented data from a pooled set of 69 patients with first relapsed (n=36) or primary refractory (n=33) AML in which median overall survival was 6.9 months; complete remission, or CR, rate was 26%; the combined complete remission rate, including CR, CR without full platelet recovery and CR with incomplete recovery, was 29%; and leukemia-free survival was 24 months. The combination of vosaroxin with cytarabine was generally well tolerated. All-cause mortality was low, at 3% at 30 days and 9% at 60 days.

About AML

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 estimates there will be approximately 14,590 new cases of AML and approximately

10,370 deaths from AML in the U.S. in 2013. Additionally, it is estimated that the prevalence of AML across major global markets (U.S., France, Germany, Italy, Spain, United Kingdom and Japan) is over 50,000. 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 <http://www.sunesis.com>.

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This press release contains forward-looking statements, including statements related to the design, conduct, progress, timing and results of the VALOR trial. Words such as "believe," "demonstrate," "expect," "look forward to," "improvement," "opportunity," "positive," "potential," "promising," "well powered," 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 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, European Commission 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' Annual Report on Form 10-K for the year ended December 31, 2012, Sunesis' Quarterly Report on Form 10-Q for the quarter ended June 30, 2013 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 Sunesis' expectations with regard thereto or any change in events, conditions or circumstances on which any such statements are based.

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