Sunesis Pharmaceuticals Announces Initiation of Phase 2 Cohort of MD Anderson Sponsored Study of Vosaroxin in AML and High-Risk MDS

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Phase 1b Cohort Demonstrates Good Tolerability and Objective Responses

SOUTH SAN FRANCISCO, Calif., Oct. 30, 2013 (GLOBE NEWSWIRE) -- Sunesis Pharmaceuticals, Inc. (Nasdaq:SNSS) today announced the initiation of the Phase 2 cohort of the Phase 1b/2, MD Anderson Cancer Center-sponsored study of vosaroxin in combination with decitabine in older patients with previously untreated acute myeloid leukemia (AML) and high-risk myelodysplastic syndrome (MDS). The trial is being conducted under the direction of Naval Daver, M.D., Assistant Professor, Department of Leukemia, and Farhad Ravandi, M.D., Professor of Medicine, Department of Leukemia, both of the MD Anderson Cancer Center at the University of Texas. Dr. Ravandi is also a principal investigator of the Phase 3 VALOR trial, the company's randomized, double-blind, placebo-controlled, pivotal trial of vosaroxin plus cytarabine in patients with first relapsed or refractory AML.

Expansion into the Phase 2 cohort follows the successful completion of a Phase 1b open-label, single-arm dose optimization phase which included six patients with previously untreated AML or high-risk MDS. Patients were treated with vosaroxin (90 mg/m^2) intravenously on days one and four in combination with decitabine (20 mg/m^2) on days one to five. The regimen was found to be well tolerated, with no dose-limiting toxicities, no early mortality and encouraging objective responses. Results, including data from the Phase 2 cohort, are expected to be presented at a medical conference in 2014.

"Older patients with AML or high-risk MDS are often intolerant or unresponsive to standard treatments," said Dr. Ravandi. "We find the tolerability and initial clinical activity in this first cohort of difficult-to-treat patients to be very encouraging and suggest important clinical potential for this combination. Based on these early data, we have designated the conduct of the Phase 2 component of this study a top priority."

Patients in the Phase 2 cohort will be followed for rate of remission, leukemia-free survival, overall survival and safety. The Phase 1b/2 study is expected to enroll up to a combined total of approximately 60 patients.

"We believe vosaroxin will have clinical utility in a number of different patient segments within AML and MDS," said Adam R. Craig, M.D., Ph.D., Executive Vice President, Development and Chief Medical Officer of Sunesis. "The initial data from this study reflects our belief that vosaroxin containing therapies can be used in the treatment of older patients who do not qualify for standard therapy. We are encouraged by these early data, and look forward to enrollment and follow-up in the Phase 2 cohort."

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.

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 MDS

MDS is a hematopoietic stem cell neoplasm that features dysplasia of the myeloid lineage. Hematopoiesis in these patients is disordered and ineffective. As the numbers and quality of blood-forming cells decline irreversibly, blood production is further impaired and patients often develop severe anemia requiring frequent blood transfusions. In most cases, the disease worsens and the patient develops neutropenia and thrombocytopenia caused by progressive bone marrow failure. In about one third of patients with MDS, the disease progresses into AML, usually within months to a few years.

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 design, conduct, progress, timing and results of Sunesis' investigator sponsored trials, including Sunesis' vosaroxin related clinical programs, discussed in this release. Words such as "believe," "belief," "encourage," "estimate," "expect," "look forward to," "potential," "progress," "suggest," "will be," 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 Sunesis' clinical trials, 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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