Sunesis Pharmaceuticals Announces Initiation of an Investigator-Sponsored Phase I/II Trial Evaluating Vosaroxin in Myelodysplastic Syndrome

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SOUTH SAN FRANCISCO, Calif., Oct. 28, 2013 (GLOBE NEWSWIRE) -- Sunesis Pharmaceuticals, Inc. (Nasdaq:SNSS) today announced the initiation of a Phase I/II investigator-sponsored trial of vosaroxin, the company's lead product candidate, in adult patients with previously treated intermediate-2 or high-risk myelodysplastic syndrome (MDS). The trial is being conducted at Weill Cornell Medical College and New York-Presbyterian Hospital under the direction of Gail J. Roboz, M.D., Associate Professor of Medicine and Director of the Leukemia Program.

"MDS remains a challenging disease in adult patients with few proven effective therapies," said Dr. Roboz. "As a result, there is an urgent need for new treatments for MDS patients who have progressed after front-line treatment. We look forward to studying vosaroxin in this setting."

The Phase I/II, open-label, dose escalating trial is expected to enroll approximately up to 40 patients with MDS who have previously failed treatment with hypomethylating agent-based therapy. Patient cohorts will initially receive escalating doses of vosaroxin over each 28 day treatment cycle. Once the maximum tolerated dose (MTD) is determined, an expanded evaluation of safety and hematologic response or improvement rate at this dose level will be conducted in additional subjects, so that the total number of subjects exposed to this dose level increases to up to 15 subjects. In addition to MTD and dose limiting toxicity, study endpoints include rate of complete remission, partial remission, hematologic improvement and blood transfusion requirements.

"In our early clinical work, single-agent vosaroxin has demonstrated promising anti-leukemic activity and a favorable tolerability profile in elderly patients," said Adam R. Craig, M.D., Ph.D., Executive Vice President, Development and Chief Medical Officer of Sunesis. "Both elements provide a strong rationale for investigating its use as a treatment for MDS. We look forward to seeing the data collected by the team at Weill Cornell Medical College in this important area of unmet medical need, while we focus our internal resources on the completion of our fully-enrolled pivotal Phase 3 VALOR trial of vosaroxin in first relapsed or refractory AML patients."

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 acute myeloid leukemia (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 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.

According to the American Cancer Society, an estimated 12,000 new cases of MDS are diagnosed each year in the United States. MDS is generally a disease of the elderly with about 80-90% of all cases occurring in patients older than 60 years. It is rarely observed in adults under age 40 years and is more common in men than women. The number of new cases diagnosed each year is expected to increase as the average age of the population increases.

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 Sunesis' investigator sponsored trials, including Sunesis' vosaroxin related clinical programs, discussed in this release. Words such as "complete," "expect," "look forward to," "remain," "potential," "progress," "seems," "will," 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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