Sunesis Pharmaceuticals Announces Initiation of an Investigator-Sponsored Trial Evaluating Vosaroxin in Combination With Azacitidine in MDS

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Cardiff University-Sponsored LI-1 Trial Combination Arm Evaluated by DMEC

SOUTH SAN FRANCISCO, Calif., Dec. 10, 2013 (GLOBE NEWSWIRE) -- Sunesis Pharmaceuticals, Inc. (Nasdaq:SNSS) today announced the initiation of an investigator-sponsored trial of vosaroxin in combination with azacitidine in patients with myelodysplastic syndrome (MDS). The trial is being conducted at the Washington University School of Medicine under the direction of Meagan A. Jacoby, M.D., Ph.D., Instructor of Medicine, Division of Oncology.

"Additional therapeutic options are needed for patients with MDS," said Dr. Jacoby. "While azacitidine has been shown to improve survival in patients with high-risk MDS, existing therapies do not produce a remission in the majority of patients and are not curative. Given its clinical profile, we believe that investigation of vosaroxin's activity in high-risk MDS is warranted."

The Phase 1/2, open label, dose-escalation trial will enroll up to approximately 40 patients with MDS who may have received up to three prior cycles of hypomethylating agent-based therapy. Patients will receive vosaroxin (days one and four) and azacitidine (days one through seven) for a maximum of six cycles. This dose escalation study is designed to enroll six patients per cohort in order to determine the maximum tolerated dose (MTD) and dose limiting toxicity of the combination. Other endpoints include best response, safety, tolerability, and event-free, progression-free, disease-free and overall survival. Once the MTD is determined, up to an additional 20 patients will be enrolled, treated and evaluated at that dose level.

"We are pleased that vosaroxin continues to receive a great deal of interest from the oncology community. With the initiation of this trial, vosaroxin is now being studied in three investigator-sponsored trials at leading U.S. medical research centers," said Adam R. Craig, M.D., Ph.D., Executive Vice President, Development and Chief Medical Officer of Sunesis. "We recently highlighted encouraging data in difficult-to-treat AML and high-risk MDS patients from a study at the MD Anderson Cancer Center and now look forward to learning more about the use of vosoraxin in MDS in this new study. Overall, the results of our IST studies will provide us with valuable clinical data and a greater understanding of vosaroxin's potential as a new treatment option in MDS, as our pivotal Phase 3 VALOR trial in acute myeloid leukemia reaches completion in 2014."

Sunesis also announced today that it has been informed that the Cardiff University-sponsored LI-1 trial's Data Monitoring and Ethics Committee (DMEC) will recommend discontinuing the combination arm of vosaroxin and low dose cytarabine (LoDAC). The LI-1 trial is being conducted under the direction of Professor Alan K. Burnett, Head of Haematology at Cardiff University.

Dr. Craig added: "While not unexpected, we are disappointed by outcomes in the LI-1 trial and, as with the single agent vosaroxin arm in this study, believe that investigator familiarity and adequate supportive care are critical factors in achieving positive clinical benefit in a frail, elderly population. We remain confident in vosaroxin's potential in the elderly AML population, which we continue to explore through investigator-sponsored studies at leading institutions."

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 MDS 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 of initial diagnosis.

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.

This press release contains forward-looking statements, including statements related to the design, conduct, progress, timing and results of the VALOR trial and Sunesis' investigator sponsored trials, including Sunesis' vosaroxin related clinical programs, discussed in this release. Words such as "continues," "expect," "look forward," "need," "potential," "provide," "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 September 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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