Sunesis Pharmaceuticals Announces Presentation of Results From Washington University Sponsored Phase 1/2 Trial of Vosaroxin in MDS and VALOR Analysis of Baseline Safety Predictors at ASH Annual Meeting

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SOUTH SAN FRANCISCO, Calif., Dec. 6, 2015 (GLOBE NEWSWIRE) -- Sunesis Pharmaceuticals, Inc. (Nasdaq:SNSS) today announced the presentation of results from a Washington University-sponsored Phase 1 trial of vosaroxin plus azacitidine in patients with myelodysplastic syndrome, and from an analysis of the Company's Phase 3 VALOR trial of vosaroxin and cytarabine in relapsed/refractory acute myeloid leukemia (AML) at the 57th American Society of Hematology Annual Meeting in Orlando, Florida. The posters, titled "A Phase I Study of Vosaroxin plus Azacitidine for Patients with Myelodysplastic Syndrome" (publication number 1686) and "Baseline Predictors of Mortality in Patients with Relapsed or Refractory Acute Myeloid Leukemia Treated with Vosaroxin Plus Cytarabine or Placebo plus Cytarabine in the Phase 3 VALOR Study" (publication number 2560) are available at www.sunesis.com.

A Phase I Study of Vosaroxin Plus Azacitidine for Patients with Myelodysplastic Syndrome

In a Phase 1/2, open label, dose-escalation trial sponsored by the Washington University School of Medicine, patients with MDS who may have received up to three prior cycles of hypomethylating agent-based therapy were given vosaroxin and azacitidine for a maximum of six cycles. The Phase 1 portion of the study was designed to determine the maximum tolerated dose and dose limiting toxicity of the combination. Other endpoints include best response, safety, tolerability, and event-free, progression-free, disease-free and overall survival.

Thirteen patients were enrolled in the dose-escalation phase and five of twenty planned patients have been enrolled in the expansion cohort to date. At the initial dose of 50 mg/m^2/day vosaroxin, 2 of 6 patients experienced a DLT (grade 4 hyperbilirubinemia, and grade 4 neutropenia >42 days). The vosaroxin dose was de-escalated to 34 mg/m^2/day, resulting in 1 of 6 patients with a DLT (grade 4 mucositis). Of the 18 patients enrolled to date, 16 completed ≥1 cycle and are evaluable for response. Best response for each patient was as follows: stable disease, n=3; stable disease with hematologic improvement (HI)-neutrophils, n=2; marrow complete remission (CR), n=4; marrow CR with HI-platelets; n=2; marrow CR with HI-neutrophils, n=1; marrow CR with HI-erythroid, n=1; and marrow CR with HI-platelets and neutrophils, n=1; and CR, n=1. One patient had progressive disease (PD). Of the 16 evaluable patients, 6 have proceeded to allogenic stem cell transplant and 3 are actively undergoing study treatment. The major non-hematologic toxicities of febrile neutropenia, infections, and mucositis were expected based on the disease population and prior experiences with vosaroxin.

"Hypomethlyating agents are the mainstay of treatment for myelodysplastic syndromes, yet these agents alone produce remissions in a minority of patients and are typically not curative," said Meagan A. Jacoby, M.D., Ph.D., Assistant Professor, Division of Oncology, Washington University School of Medicine, and principal investigator of the study. "The combination of vosaroxin and azacitidine show promising activity with response rates comparable or better than those generally observed with azacitidine alone. Additionally, the transplant rate observed is encouraging in this patient population with a median age of 66 years. We look forward to additional patient accrual and follow up from this study."

Baseline Predictors of Mortality in Patients with Relapsed or Refractory Acute Myeloid Leukemia Treated with Vosaroxin Plus Cytarabine or Placebo Plus Cytarabine in the Phase 3 VALOR Study

Treatment-related mortality (TRM) score is a prognostic scoring system to predict risk of 30-day mortality with intensive treatment protocols in patients with newly diagnosed AML (Walter, 2011, J Clin Oncol 29:4417-4424). The "simplified TRM" score includes age, performance status (PS), platelet count, serum albumin, type of AML (secondary vs primary), white blood cell count, blast percentage in the peripheral blood, and serum creatinine. In a retrospective analysis, TRM and other criteria were used to evaluate risk of early mortality in patients with relapsed or refractory acute myeloid leukemia treated with vosaroxin plus cytarabine or placebo plus cytarabine in Sunesis' randomized, double-blind, placebo-controlled Phase 3 VALOR trial.

A total of 705 patients from VALOR were included in the safety population (355 treated with vosaroxin/cytarabine and 350 treated with placebo/cytarabine). Rates of 30-day (7.9% vs 6.6%, respectively) and 60-day (19.7% vs 19.4%, respectively) mortality in VALOR were comparable between vosaroxin plus cytarabine and placebo plus cytarabine arms. Several individual baseline factors independently predicted risk of early mortality, including ECOG performance status, hemoglobin, bilirubin and albumin levels, intermediate or high bone marrow blasts, and prior myelodysplastic syndrome. The previously validated TRM score for predicting early mortality in newly diagnosed AML was also predictive of mortality in this relapsed/refractory population. Vosaroxin/cytarabine treatment and age were not significant predictors of early mortality.

"The rate of early mortality in patients treated for acute myeloid leukemia reflects a balance of efficacy and safety outcomes," said Dr. Jeffrey Lancet, Senior Member and Professor of Oncologic Sciences at the H. Lee Moffitt Cancer Center, Tampa, Florida. "The ability to assess increased risk of early mortality in this disease would provide valuable information in guiding treatment decisions. Based on this analysis, patient selection for future studies of vosaroxin and other intensive regimens in the AML setting may benefit from use of these predictive factors."

About QINPREZO™ (vosaroxin)

QINPREZO™ (vosaroxin) is an anti-cancer quinolone derivative (AQD), a class of compounds that has not been used previously for the treatment of cancer. Preclinical data demonstrate that 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 AML in combination with cytarabine. Vosaroxin is an investigational drug that has not been approved for use in any jurisdiction.

The trademark name QINPREZO is conditionally accepted by the FDA and the EMA as the proprietary name for the vosaroxin drug product candidate.

About Sunesis Pharmaceuticals

Sunesis is a biopharmaceutical company focused on the development and commercialization of new oncology therapeutics for the potential 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 Sunesis' expected progress in its kinase inhibitor pipeline. Words such as "may," "expect," "intends," "plan," "potential," "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, the risk that Sunesis' clinical studies for its product candidates 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, risks related to the conduct of Sunesis' clinical trials, risks related to Sunesis' need for substantial additional funding to complete the development and commercialization of vosaroxin, and 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. 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, 2015. 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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