Sunesis Pharmaceuticals Announces First Patient Treated in Vanderbilt University-Sponsored Phase 2 VITAL Study of Vosaroxin in Combination with Infusional Cytarabine in Patients with Previously Untreated AML

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Trial to be Conducted at the Vanderbilt-Ingram Cancer Center

SOUTH SAN FRANCISCO, Calif., March 24, 2016 (GLOBE NEWSWIRE) -- Sunesis Pharmaceuticals, Inc. (Nasdaq:SNSS) today announced that the first patients have been treated in the investigator-sponsored VITAL (**V**osaroxin and **I**nfusional Cytarabine for Frontline **T**reatment of **A**cute Myeloid **L**eukemia) Phase 2 study of vosaroxin in combination with cytarabine in patients with previously untreated acute myeloid leukemia (AML). The trial is being conducted at the Vanderbilt-Ingram Cancer Center at Vanderbilt University under the direction of Michael R. Savona, M.D., FACP, Associate Professor of Medicine and Director of Hematology Early Therapeutics Program, and Stephen A. Strickland, M.D., MSCI, Assistant Professor of Medicine.

"With an alarming rate of mortality in AML and no major change in induction therapy strategy for nearly four decades, there is an urgent need to find novel therapeutic strategies for this disease," said Dr. Strickland. "Given the established, acceptable safety profile of infusional cytarabine given concomitantly with vosaroxin, this combination offers a new approach for achieving remission in this population. It also provides the opportunity to expand upon the previously observed efficacy of vosaroxin in patients with relapsed/refractory AML and has the potential to serve as a foundation for a future randomized Phase 3 trial."

VITAL, a single-arm, open-label Phase 2 trial will enroll up to 61 previously untreated, newly diagnosed adult patients with AML. During stage 1 of the trial, 17 patients will be enrolled. The study design permits one interim look to examine evidence of futility after the first 17 patients are evaluable for response. If ≤ 7 patients achieve complete remission (CR), the VITAL DSMB will review the clinical data to determine the merits of continued enrollment. If > 7 CRs are observed, the second stage will open automatically and increase enrollment to 41 patients. During both stages, Vosaroxin will be administered intravenously at 90 mg/m^2 on days 1 and 4. Cytarabine will be administered in standard fashion as a continuous infusion of 100 mg/m^2 daily on days 1-7.

Patients with evidence of residual leukemia on "Day 14 biopsy" following initial induction will be offered re-induction with intravenous vosaroxin at 70 mg/m2 on days 1 and 4 in combination with continuous infusion cytarabine at 100 mg/m2 daily on days 1-7. The primary endpoint of the study is rate of CR. The secondary endpoints are to determine the safety and tolerability, presence of minimal residual disease, CR (including CR with incomplete blood count recovery), neutrophil and platelet recovery, disease free survival (DFS), overall survival (OS), and the correlation of HSCT comorbidity index and Wheatley index scores with disease response, DFS and OS.

"VITAL is the third investigator-sponsored combination trial of vosaroxin in frontline AML, and an important component of establishing our future development strategy in this setting," said Daniel Swisher, Chief Executive Officer of Sunesis. "We look forward to seeing results from these studies, which include two other leading institutions, MD Anderson and Indiana University, as we make progress on the review of our European Marketing Authorization Application for vosaroxin as a treatment for relapsed/refractory AML."

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 improving the lives of people with cancer and is currently pursuing regulatory approval in Europe for its lead product candidate, vosaroxin, for the treatment of relapsed or refractory acute myeloid leukemia in patients aged 60 and older. In addition, the company is advancing its kinase-inhibitor pipeline of novel targeted therapies into the clinic.

For additional information on Sunesis, please visit http://www.sunesis.com.

This press release contains forward-looking statements, including statements related to Sunesis' estimated timelines for regulatory interactions and regulatory progress, including the anticipated progress and potential approval of vosaroxin by the EMA, clinical development of SNS-062; Sunesis' overall strategy in Europe and other major regions and plans to gain marketing approval of vosaroxin in the U.S., the design, conduct and results of clinical trials, including the expected progress in its kinase inhibitor pipeline, and potential advancements of SNS-229 to an IND, the need for and the role of vosaroxin as a potential new treatment option, and the sufficiency of Sunesis' cash resources. Words such as "expect," "look forward," "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 may not be able to receive regulatory approval of vosaroxin in the U.S. or Europe, that Sunesis' development activities for vosaroxin could be otherwise halted or significantly delayed for various reasons, the risk that Sunesis' clinical studies for vosaroxin or other product candidates, including its pipeline of kinase inhibitors, 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 other product candidates, 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 and other product candidates. 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' Annual Report on Form 10-K for the year ended December 31, 2015, when available, 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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