Sunesis Pharmaceuticals Announces First Patient Treated in Indiana University Pilot Study of Vosaroxin and Cytarabine in Adults Age 60 Years and Older With Previously Untreated AML

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Trial to be Conducted at the Melvin and Bren Simon Cancer Center at Indiana University

SOUTH SAN FRANCISCO, Calif., Dec. 1, 2015 (GLOBE NEWSWIRE) -- Sunesis Pharmaceuticals, Inc. (Nasdaq:SNSS) today announced that the first patient has been treated in an investigator-sponsored pilot study of vosaroxin and cytarabine in adult patients age 60 years and older with previously untreated acute myeloid leukemia (AML). The trial is being conducted at the Melvin and Bren Simon Cancer Center at Indiana University under the direction of Seyed Hamid Sayar, M.D., Assistant Professor of Clinical Medicine.

"Achieving a complete remission with induction therapy is directly correlated with prolonged survival in the frontline treatment of AML," said Dr. Sayar. "Yet anthracyclines, a current backbone of induction therapy, are well known to be cardiotoxic, a toxicity that is of particular concern in older patients. New regimens, such as vosaroxin and cytarabine, with potentially less toxicity would be highly appealing not only in daily practice, but also to serve as a backbone for novel combinations."

The pilot efficacy assessment trial is expected to enroll approximately 17 previously untreated patients with AML who are age 60 and older who will receive up to 4 cycles of treatment (2 induction, 2 consolidation). Each 5-day cycle will include 10-minute infusions of vosaroxin (90mg/m2 for induction 1 and 70mg/m2 for subsequent cycles) on days 1 and 4, and 2-hour infusions of cytarabine (1g/m2) on days 1-5, followed by a variable interval required to achieve hematologic recovery (defined as absolute neutrophil count). The primary endpoint of the study is rate of complete remission, including complete remission with incomplete blood count recovery. Secondary objectives are safety of the combination in induction therapy of older patients previously unexposed to intensive chemotherapy, progression-free survival, length of stay in hospital for induction, and 30- and 60-day mortality rate.

"We are encouraged by the initiation of a new vosaroxin study in the frontline induction setting," said Daniel Swisher, Chief Executive Officer of Sunesis. "Vosaroxin is active and well tolerated in this population, both as a single agent, as seen in the REVEAL-1 study, and in combination with decitabine, as seen in our ongoing MD Anderson Cancer Center-sponsored study. We look forward to seeing results from these investigator-led studies, including data from the MD Anderson study later this year, while we continue to focus our internal resources on submitting our European Marketing Authorization Application for vosaroxin as a treatment for relapsed/refractory AML by the end of this year."

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.

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This press release contains forward-looking statements, including statements related to Sunesis' estimated timelines for regulatory interactions and regulatory progress, including the anticipated submission of the MAA for vosaroxin with the EMA and plans to gain marketing approval of vosaroxin in the U.S., Sunesis' overall strategy, the design, conduct and results of clinical trials, including the expected progress in its kinase inhibitor pipeline, estimated new cases of AML, its prevalence across major global markets, prognosis for patients with AML, the need for and the role of vosaroxin as a potential new treatment option, and Sunesis' clinical development of vosaroxin, including the analysis of the results from the VALOR clinical trial. Words such as "anticipates," "estimates," "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 may not be able to submit timely the MAA to the EMA, the risk that Sunesis' clinical studies for vosaroxin may not lead to regulatory approval 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 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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