Sunesis Pharmaceuticals Announces Notice of Allowance for U.S. Patent Application Covering Vosaroxin Compositions

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SOUTH SAN FRANCISCO, Calif, Feb. 14, 2012 (GLOBE NEWSWIRE) -- Sunesis Pharmaceuticals, Inc. (Nasdaq:SNSS) today announced that the U.S. Patent and Trademark Office (USPTO) issued a Notice of Allowance for U.S. Patent Application No. 12/982,785 claiming certain compositions related to Sunesis' lead drug candidate, vosaroxin. The patent will grant Sunesis exclusive rights to certain Active Pharmaceutical Ingredient compositions of vosaroxin, as well as the final product related to such compositions, and provides patent exclusivity to mid 2030 in the United States. A family of corresponding patent applications are pending in the U.S. and internationally.

Image: Sunesis Pharmaceuticals, Inc. Logo

Image: VALOR Logo

"The '785 patent is an important aspect of our intellectual property estate. Once granted, the patent will provide significant additional patent protection and support market exclusivity for vosaroxin out nearly two decades to 2030," stated Daniel Swisher, Chief Executive Officer of Sunesis. "The successful pursuit of this patent is another step in our intellectual property strategy, a strategy which provides Sunesis with greater certainty in pursuing the full clinical and commercial potential of vosaroxin. We look forward to additional important milestones for vosaroxin this year, including an interim analysis of the Phase 3 VALOR trial."

Sunesis is currently enrolling patients with more than 110 active sites open in 14 countries in the VALOR trial, a Phase 3, multinational, randomized, double-blind, placebo-controlled, pivotal clinical trial of vosaroxin in combination with cytarabine in first relapsed or refractory acute myeloid leukemia.

About VALOR

VALOR is a Phase 3, randomized, double-blind, placebo-controlled, pivotal trial in patients with first relapsed or refractory AML. The trial is expected to enroll 450 evaluable patients at approximately 110 leading sites in the U.S., Canada, Europe, Australia and New Zealand. The VALOR trial is currently enrolling patients, who are randomized one to one to receive either vosaroxin on days one and four in combination with cytarabine daily for five days, or placebo in combination with cytarabine. Additionally, the VALOR trial employs an innovative, adaptive trial design that allows for a one-time sample size adjustment by the DSMB at the interim analysis to maintain adequate power across a broader range of survival outcomes. The trial's primary endpoint is overall survival. For more information on the VALOR trial, please visit www.valortrial.com.

The VALOR logo is available at http://www.globenewswire.com/newsroom/prs/?pkgid=8774.

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.

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.

The Sunesis Pharmaceuticals, Inc. logo is available at http://www.globenewswire.com/newsroom/prs/?pkgid=8773

This press release contains forward-looking statements, including statements related to the exclusivity period for vosaroxin in the United States and other geographies and the design, conduct and results of the VALOR trial and the occurrence and timing of the DSMB interim analysis. Words such as "will," "provides," "pending," "expected" 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 results 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 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 the VALOR trial, 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' Quarterly Report on Form 10-Q for the quarter ended September 30, 2011, Sunesis' Annual Report on Form 10-K for the year ended December 31, 2010 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 the company's expectations with regard thereto or any change in events, conditions or circumstances on which any such statements are based.

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