Vosaroxin Review Published in Expert Opinion on Pharmacotherapy

May 30, 2013 7:01 AM ET

SOUTH SAN FRANCISCO, Calif., May 30, 2013 (GLOBE NEWSWIRE) -- Sunesis Pharmaceuticals, Inc. (Nasdaq:SNSS) today announced the publication of a peer-reviewed paper in *Expert Opinion on Pharmacotherapy* featuring the Company's lead product candidate, vosaroxin. In addition to an overview of the chemistry, pharmacokinetics and clinical development of vosaroxin, including the ongoing Phase 3 VALOR and Phase 2/3 LI-1 trials, the paper explores the potential advantages of vosaroxin over anthracycline therapy, including overcoming resistance mechanisms, more site-selective DNA damage, and reduced formation of DNA adducts and reactive oxygen species resulting in better tolerability. The paper, entitled "Vosaroxin: a new valuable tool with the potential to replace anthracyclines in the treatment of AML?" is expected to be published in the July 2013 (Volume 14, Number 10) issue of the print publication and is currently available online (click here to link).

"As the authors note, despite new understanding of the biology and genetics of acute myeloid leukemia, outcomes for patients remain poor and the need for new therapies remains urgent," said Adam R. Craig, MD, PhD, Executive Vice President, Development and Chief Medical Officer of Sunesis. "Vosaroxin, as a novel first-in-class anticancer quinolone derivative, has several potential advantages over anthracyclines and target-specific therapies. This paper offers a comprehensive review of these potential advantages in addition to discussing the clinical history and outlook for vosaroxin, including the VALOR trial, which remains on track to complete full enrollment in 2013."

Sunesis is currently evaluating vosaroxin in a pivotal Phase 3, randomized, double-blind, placebo-controlled trial, the VALOR trial, in patients with first relapsed or refractory acute myeloid leukemia (AML). The Company is also participating in a Phase 2/3 randomized, controlled trial evaluating novel treatment regimens, including two treatment arms containing vosaroxin, in newly diagnosed elderly acute myeloid leukemia (AML) and high-risk myelodysplastic syndrome (MDS) patients. The trial, known as the Less Intensive 1 (LI-1) trial, is being sponsored by Cardiff University and conducted by the United Kingdom's National Cancer Research Institute Haematological Oncology Study Group under the direction of Professor Alan K. Burnett.

About VALOR

VALOR is a Phase 3, randomized, double-blind, placebo-controlled, pivotal trial in patients with first relapsed or refractory AML. The trial's target enrollment is approximately 675 patients at more than 100 leading sites in the U.S., Canada, Europe, South Korea, Australia and New Zealand. The VALOR trial is currently enrolling patients, who are randomized in a ratio of 1:1 to receive either vosaroxin on days one and four in combination with cytarabine daily for five days, or placebo in combination with cytarabine. The trial's primary endpoint is overall survival. For more information on the VALOR trial, please visit www.valortrial.com.

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 AML. Additionally, vosaroxin has been granted fast track designation by the FDA for the potential treatment of relapsed or refractory acute myeloid leukemia in combination with cytarabine.

About AML

AML is a rapidly progressing cancer of the blood characterized by the uncontrolled proliferation of immature blast cells in the bone marrow. The American Cancer Society estimates there will be approximately 14,590 new cases of AML and approximately 10,370 deaths from AML in the U.S. in 2013. Additionally, it is estimated that the prevalence of AML across major global markets (U.S., France, Germany, Italy, Spain, United Kingdom and Japan) is over 50,000. AML is generally a disease of older adults, and the median age of a patient diagnosed with AML is about 67 years. AML patients with relapsed or refractory disease and newly diagnosed AML patients over 60 years of age with poor prognostic risk factors typically die within one year, resulting in an acute need for new treatment options for these patients.

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.

SUNESIS and the logos are trademarks of Sunesis Pharmaceuticals, Inc.

This press release contains forward-looking statements, including statements related to the design, conduct, progress, timing and results of the VALOR trial and Sunesis' other clinical programs discussed in this release. Words such as "advantage," "evaluating," "currently," "remains," "on track," "potential," 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 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' Annual Report on Form 10-K for the year ended December 31, 2012 and Sunesis' other filings with the Securities and Exchange Commission, including Sunesis' Quarterly Report on Form 10-Q for the quarter ended March 31, 2013, when available. 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.

CONTACT: Investor and Media Inquiries:
David Pitts
Argot Partners
212-600-1902

Eric Bjerkholt
Sunesis Pharmaceuticals Inc.
650-266-3717

Sunesis Pharmaceuticals, Inc.