Sunesis Pharmaceuticals Announces Oral Presentation of VALOR Analysis at the 77th Annual Meeting of the Japanese Society of Hematology

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SOUTH SAN FRANCISCO, Calif., Oct. 15, 2015 (GLOBE NEWSWIRE) -- Sunesis Pharmaceuticals, Inc. (Nasdaq:SNSS) today announced that data from the company's VALOR trial evaluating vosaroxin in older patients with acute myeloid leukemia (AML) will be presented at the AML Clinical Trial Oral Session of the 77th Annual Meeting of the Japanese Society of Hematology (JSH), taking place in Kanazawa, Japan. The results are being presented Friday, October 16th at 8:30 a.m. Japanese Standard Time by Robert Stuart, M.D., Professor of Medicine, Division of Hematology/Oncology, Department of Medicine, Medical University of South Carolina.

The presentation (Abstract OS-1-82), titled "Patients Age ≥60 Yrs With First Relapsed/Refractory AML Treated With Vosaroxin/Cytarabine vs Placebo/Cytarabine," will be the first presentation in the session, which will take place in Session Room 15 (Emerald A) in Hotel Kanazawa 4F. Detailed results of the VALOR trial were presented in the "Late Breaking Abstracts" session of the American Society of Hematology (ASH) Annual Meeting in December 2014. The data presented today at the JSH Annual Meeting were first presented at the European Hematology Association Congress in June 2015.

"Globally, patients with relapsed or refractory AML are highly underserved, particularly older patients whose prognoses are far poorer," said Shuichi Miyawaki, MD, PhD., Division of Hematology, Tokyo Metropolitan Ohtsuka Hospital, and former vice-president of the Japan Adult Leukemia Study Group. "As in the U.S. and Europe, treatment standards in Japan have not changed significantly in the past several decades. The data from VALOR in patients age 60 years and older show a compelling survival benefit, durable responses and tolerability profile that strongly support the potential for the vosaroxin/cytarabine combination as an important new treatment option for this highly underserved population."

Sunesis recently announced that the company intends to submit a Marketing Authorization Application (MAA) for vosaroxin as a treatment for patients age 60 years and older with relapsed/refractory AML with the European Medicine Agency (EMA) by the end of 2015.

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 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 that there will be approximately 20,830 new cases of AML and approximately 10,460 deaths from AML in the U.S. in 2015. 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 75,000. 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 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 June 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.

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

Eric Bjerkholt
Sunesis Pharmaceuticals Inc.
650-266-3717

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