Sunesis Announces Anticipated Submission of European Marketing Authorization Application for Vosaroxin in AML Before Year End

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Company Also Announces Executive Management Team Changes

Dr. Adam R. Craig to Step Down as Chief Medical Officer Following Transition Period

Jennifer Smith Appointed Vice President, Biometrics

SOUTH SAN FRANCISCO, Calif., Oct. 7, 2015 (GLOBE NEWSWIRE) -- Sunesis Pharmaceuticals, Inc. (Nasdaq:SNSS) today announced that the company intends to submit a Marketing Authorization Application (MAA) for vosaroxin as a treatment for acute myeloid leukemia (AML) with the European Medicines Agency (EMA) by the end of 2015.

The company recently announced that it met separately with the Rapporteur (United Kingdom) and Co-Rapporteur (Netherlands) assigned to provide advice and guidance to the company through the MAA process. Based on these discussions, the company is proceeding with an MAA filing for the indication of relapsed/refractory AML in patients age 60 years and older, a population with the greatest medical need and for whom the greatest benefit was observed in the vosaroxin/cytarabine treatment arm of VALOR, the company's pivotal Phase 3 study of vosaroxin and cytarabine in adult patients with relapsed or refractory AML.

"The filing of an MAA for vosaroxin in Europe by year end is our top corporate priority. As for the U.S., we are refining a plan to find a timely path towards market," said Daniel Swisher, Chief Executive Officer of Sunesis. "With these efforts underway, we also expect to achieve meaningful progress in our kinase inhibitor pipeline, including data presentations at the upcoming November AACR-NCI-EORTC Conference in Boston. Among those being highlighted at the conference is our second generation, differentiated BTK program, SNS-062."

Sunesis also announced today changes to the executive management team. Chief Medical Officer, Adam R. Craig will step down from his role at the end of the year to pursue other opportunities. Dr. Craig will remain available to the company on an advisory basis throughout the regulatory process with the EMA. Also within the Development group, Jennifer A. Smith has been appointed Vice President of Biometrics, where her responsibilities include the statistical design of the company's clinical trials as well as clinical data analyses and presentations, including those supporting ongoing regulatory filings. Dr. Smith joined Sunesis in 2012 from BiPar Sciences where she was Senior Director of Biometrics. Prior to BiPar, she served in similar roles at Geron, Pharmacyclics and Aviron.

Mr. Swisher added: "We thank Adam for his leadership and significant contributions at Sunesis as Chief Medical Officer and look forward to continuing to work with him as a valued advisor in 2016. We have begun a search to complement our experienced internal team with additional clinical development expertise."

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.

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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Sunesis Pharmaceuticals, Inc.