Sunesis Pharmaceuticals Announces Regulatory Update

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Company to Proceed Expeditiously With Marketing Authorization Application in Europe and Will Evaluate Regulatory and Clinical Strategies to Gain Marketing Approval in the U.S.

Sunesis to Host Conference Call Today at 5:00 PM Eastern Time

SOUTH SAN FRANCISCO, Calif., July 23, 2015 (GLOBE NEWSWIRE) -- Sunesis Pharmaceuticals, Inc. (Nasdaq:SNSS) today announced regulatory updates from its interactions with the European Medicines Agency (EMA) and U.S. Food and Drug Administration (FDA) regarding a potential path toward marketing authorization for vosaroxin as a treatment for acute myeloid leukemia (AML) in Europe and the United States.

With respect to Europe, the company recently met separately with the Rapporteur (United Kingdom) and Co-Rapporteur (Netherlands) assigned to provide advice and guide the company through the Marketing Authorization Application (MAA) process. Based on these substantive discussions, the company was encouraged to proceed 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.

With respect to the United States, after conducting additional safety and efficacy analyses, the company recently met with the FDA. In light of not reaching statistical significance on the protocol-defined primary analysis of overall survival, Sunesis was informed that the Agency did not support a filing and encouraged the company to provide additional clinical evidence to support a future NDA submission.

Based on feedback from European and U.S. regulators, the company will place near-term focus on the MAA filing, which it will work to complete as expeditiously as possible, and will evaluate and refine its plan to gain marketing approval in the U.S.

"We are at once encouraged by our interactions with European regulators and disappointed with the outcome of our meeting with their U.S. counterparts," said Daniel Swisher, Chief Executive Officer of Sunesis. "Our belief, supported by many in the medical community, is that the VALOR outcomes for patients with high unmet needs were both compelling and an important step forward in addressing the enduring challenges of treating AML. We look forward to moving ahead with the submission of an MAA filing in Europe."

Mr. Swisher added: "Our confidence in vosaroxin stems not only from the outcomes seen in VALOR, but our ongoing investigator sponsored studies. It is our goal to leverage this body of data to determine a clinical and regulatory path forward for vosaroxin that is time and resource efficient, addresses the needs of patients with AML and maximizes our likelihood of regulatory and commercial success."

Conference Call Information

Sunesis will host an update conference call today, July 23rd at 5:00 p.m. Eastern Time. The call can be accessed by dialing (866) 953-6856 (U.S. and Canada) or (617) 399-3480 (international), and entering passcode 68399706. To access the live audio webcast, or the subsequent archived recording, visit the "Investors and Media - Calendar of Events" section of the Sunesis website at www.sunesis.com. The webcast will be recorded and available for replay on the company's website for two weeks.

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' overall strategy, including regulatory plans to file a marketing authorization application with the European Medicines Agency, our goal of gaining marketing approval in the U.S., our ability to gain approval to market vosaroxin in the U.S., the design, conduct and results of Sunesis' clinical trials, including the analysis, assessment and conclusions of the results of the VALOR trial, the commercial potential of vosaroxin, estimated new cases of AML, its prevalence across major global markets, prognosis for patients with AML, and the need for and the role of vosaroxin as a new treatment options, Sunesis' clinical development of vosaroxin, including the analysis of the results from VALOR clinical trial. Words such as "belief," "estimate," "goal," "hope," "intend," "look forward," "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' 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 in Europe or the U.S., 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 March 31, 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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