Sunesis Pharmaceuticals Announces Withdrawal of European Marketing Authorization Application (MAA) for Vosaroxin as a Treatment for Relapsed/Refractory AML

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Company's Primary Development Focus is Non-Covalent Reversible BTK-Inhibitor SNS-062

Sunesis to Host Conference Call and Webcast in Conjunction with First Quarter 2017 Financial Results on Monday, May 8th at 11:00 AM ET

SOUTH SAN FRANCISCO, Calif., May 01, 2017 (GLOBE NEWSWIRE) -- Sunesis Pharmaceuticals, Inc. (Nasdaq:SNSS) announced today that the Company will withdraw its European Marketing Authorization Application (MAA) for vosaroxin as a treatment for relapsed/refractory acute myeloid leukemia (AML) in patients aged 60 years and older. The decision follows recent interactions with the European Medicine Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP), during which the Company learned that the committee was likely to formally adopt a negative opinion in its evaluation of the application.

"We are disappointed to not achieve approval for vosaroxin's MAA given its reported efficacy in a patient population with such poor outcomes. Although we did not receive a definitive CHMP opinion, we believed that a positive opinion was unlikely," said Daniel Swisher, President and Chief Executive Officer of Sunesis. "Following our appearances before the committee's Scientific Advisory Group Oncology and CHMP, we carefully considered feedback from our rapporteurs and input from retained regulatory experts to make our decision to notify EMA to withdraw vosaroxin's MAA as our assessment concluded it was unlikely we could achieve a majority vote of CHMP members at this time or upon an immediate re-examination for our proposed indication based on VALOR data from a sub-group of a single pivotal trial that had missed reaching full statistical significance in its primary analysis."

Mr. Swisher added: "In light of this, we are significantly reducing our investment in the AML program and shifting an increasing portion of resources to our kinase inhibitor pipeline, including lead asset SNS-062, our non-covalent reversible BTK-inhibitor, which will begin dosing this quarter in a Phase 1b/2 trial in cancer patients with B-cell malignancies. We expect to continue to advance the development of vosaroxin through a modest investment in investigator-sponsored group trials, and will carefully assess business development alternatives to support the conduct of another pivotal trial to achieve future regulatory approval of vosaroxin. We expect that our current cash resources are sufficient to fund the company beyond Q1 2018."

Conference Call Information

Sunesis will host a conference call in conjunction with first quarter 2017 financial results on Monday, May 8th at 11:00 a.m. Eastern Time. The call can be accessed by dialing (844) 296-7720 (U.S. and Canada) or (574) 990-1148 (international) and entering passcode 13018661. 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 SNS-062

SNS-062 is a novel, second-generation BTK inhibitor, a class of kinase inhibitors that selectively inhibits the enzyme Bruton's tyrosine kinase (BTK). This target mediates signaling through the B-cell receptor, which is critical for adhesion, migration, proliferation and survival of normal and malignant B-lineage lymphoid cells. Unlike other drugs in its class, SNS-062 has a distinct kinase selectivity profile and binds non-covalently to the BTK enzyme. This alternate binding site potentially provides an opportunity to address the leading resistance mechanism, a mutation in the enzyme's binding site required for covalent binding. In preclinical studies, SNS-062 demonstrated potent activity against Cys-481S mutated B-cell malignancies, and has been studied in healthy subjects in a Phase 1A, randomized, double-blind, placebo-

controlled dose-ranging study to investigate the drug's safety, pharmacokinetics, and pharmacodynamics. With the reported successful study outcome, SNS-062 is proceeding to a Phase 1b/2 study in patients with B-cell malignancies.

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/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 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 improving the lives of people with cancer. Currently, the company is focused on advancing its novel kinase-inhibitor pipeline, which includes its proprietary non-covalent BTK-inhibitor, SNS-062.

For additional information on Sunesis, please visit http://www.sunesis.com.

This press release contains forward-looking statements, including statements related to the continued development and commercialization of vosaroxin, the timing of our Phase 1b/2 trial of SNS-062, and the sufficiency of Sunesis' cash and funding through Q1 2018. Words such as "advance," "continue," "expect," "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 receive regulatory approval of vosaroxin in the U.S. or Europe, that Sunesis' development activities for vosaroxin could be otherwise halted or significantly delayed for various reasons, risks related to Sunesis' need for substantial additional funding to complete the development and commercialization of vosaroxin and other product candidates, the risk that Sunesis' clinical studies for vosaroxin or other product candidates, including its pipeline of kinase inhibitors, 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, 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 and other product candidates. 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, 2016 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 Sunesis' expectations with regard thereto or any change in events, conditions or circumstances on which any such statements are based.

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