Sunesis Pharmaceuticals Announces European Medicines Agency Validates Marketing Authorization Application for Vosaroxin in AML

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SOUTH SAN FRANCISCO, Calif., Jan. 04, 2016 (GLOBE NEWSWIRE) -- Sunesis Pharmaceuticals, Inc. (Nasdaq:SNSS) today announced that the European Medicines Agency (EMA) has validated the Marketing Authorization Application (MAA) for vosaroxin as a treatment for relapsed refractory acute myeloid leukemia (AML) in patients aged 60 years and older. Validation confirms that the submission is complete and initiates the Centralized Review process by the EMA's Committee for Medicinal Products for Human Use (CHMP). Under Centralized Review, the CHMP review period is 210 days, excluding question or opinion response periods, after which the CHMP opinion is reviewed by the European Commission, which usually issues a final decision on EU approval within three months. The MAA submission will be reviewed in the Centralized Procedure, which if authorized, provides a marketing license valid in all 28 EU member states.

"Validation of our vosaroxin MAA begins the EMA review process and brings us another step closer to delivering a new treatment option to patients with relapsed refractory AML," said Deborah Thomas, Ph.D., Vice President, Regulatory Affairs and Medical Writing. "Following encouraging interactions with the agency last summer, we look forward to progressing to the next stage of the review process, which includes the 120-day questions following the assessment report by the CHMP."

"We believe European marketing authorization would represent a significant opportunity both commercially and in providing regulatory validation for other geographies around the world," said Daniel Swisher, Chief Executive Officer of Sunesis. "We look forward to providing more updates in 2016 as we move forward with this regulatory process."

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. 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 improving the lives of people with cancer and is currently pursuing regulatory

approval in Europe for its lead product candidate, vosaroxin, for the treatment of relapsed or refractory acute myeloid leukemia in patients aged 60 and older. In addition, the company is advancing its kinase-inhibitor pipeline of novel targeted therapies into the clinic.

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' expected progress in its kinase inhibitor pipeline. Words such as "may," "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' clinical studies for its 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 September 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.

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

Eric Bjerkholt
Sunesis Pharmaceuticals Inc.
650-266-3717

Sunesis Pharmaceuticals Inc