Sunesis Pharmaceuticals Announces European Medicines Agency Acceptance of Pediatric Investigation Plan for QINPREZO™ (Vosaroxin) for AML

July 9, 2014 7:01 AM ET

SOUTH SAN FRANCISCO, Calif., July 9, 2014 (GLOBE NEWSWIRE) -- Sunesis Pharmaceuticals, Inc. (Nasdaq:SNSS) today announced that the Pediatric Committee of the European Medicines Agency (EMA) has issued a positive opinion on the Company's Pediatric Investigation Plan (PIP) for QINPREZO™ (vosaroxin), Sunesis' lead drug candidate. Sunesis is currently conducting the VALOR trial, a pivotal Phase 3, randomized, double-blind, placebo-controlled clinical trial in patients with first relapsed or refractory acute myeloid leukemia (AML).

A PIP is part of the EMA approval process and must be accepted prior to submission of a Marketing Authorization Application (MAA) for the drug in the European Union. A PIP describes how a company intends to evaluate the use of a given drug in children. Completion of studies outlined in the PIP prior to European Union approval is not a requirement for MAA submission if deferral for completion has been received.

"We are pleased with the acceptance of our PIP by the EMA, an important step leading into a potential filing of our Marketing Authorization Application for QINPREZO in Europe," said Daniel Swisher, Chief Executive Officer of Sunesis. "AML remains a significant unmet medical need, one which has seen little innovation in the last 40 years. We look forward to understanding QINPREZO's potential within first relapsed or refractory AML with the unblinding of VALOR expected in the third or fourth quarter of 2014."

About QINPREZO™ (vosaroxin)

QINPREZO™ (vosaroxin) is a first-in-class anti-cancer quinolone derivative (AQD), a class of compounds that has not been used previously for the treatment of cancer. Preclinical data demonstrate that QINPREZO 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 QINPREZO for the treatment of AML. Additionally, QINPREZO has been granted fast track designation by the FDA for the potential treatment of relapsed or refractory AML in combination with cytarabine. QINPREZO 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 there will be approximately 18,860 new cases of AML and approximately 10,460 deaths from AML in the U.S. in 2014. 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 50,000. 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 treatment of solid and hematologic cancers. Sunesis has built a highly experienced cancer drug development organization committed to advancing its lead product candidate, QINPREZO, 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' overall strategy, the design, conduct, progress, timing and results of the VALOR trial and Sunesis' other clinical trials and the commercial potential for QINPREZOâ„¢ (vosaroxin). Words such as "anticipate," "approximately," "believe," "could," "estimate," "expect," "potential," "remain," "transform," 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, risks related to Sunesis' need for substantial additional funding to complete the development and commercialization of QINPREZO, risks related to whether outstanding warrants will be exercised in the future, 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 QINPREZO, the risk that raising funds through lending arrangements may restrict our operations or produce other adverse results, the risk that Sunesis' development activities for QINPREZO could be otherwise halted or significantly delayed for various reasons, the risk that Sunesis' clinical studies for QINPREZO 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, the risk that Sunesis' nonclinical studies and clinical studies may not satisfy the requirements of the FDA, European Commission or other regulatory agencies, risks related to the conduct of Sunesis' clinical trials, risks related to the manufacturing of QINPREZO and supply of the active pharmaceutical ingredients required for the conduct of Sunesis' clinical trials, the risk of third party opposition to granted patents related to QINPREZO, and the risk that Sunesis' proprietary rights may not adequately protect QINPREZO. 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, 2013, Sunesis' Quarterly Report on Form 10-Q for the quarter ended March 31, 2014, 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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