

Sunesis Announces Submission of Responses to the EMA Day 120 List of Questions for Marketing Authorization Application for Vosaroxin

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SOUTH SAN FRANCISCO, Calif., Oct. 13, 2016 (GLOBE NEWSWIRE) -- Sunesis Pharmaceuticals, Inc. (Nasdaq:SNSS) today announced that it has submitted its responses to European Medicines Agency (EMA) Day 120 List of Questions issued by the Committee for Medicinal Products for Human Use (CHMP) as part of the centralized review process of the Marketing Authorization Application (MAA) for vosaroxin as a treatment for relapsed/refractory acute myeloid leukemia (AML) in patients aged 60 years and older. Sunesis expects to receive the EMA Day 180 List of Outstanding Issues before year-end.

“We are pleased with the comprehensive set of answers and additional analyses that our team has provided in response to the EMA’s Day 120 list of questions,” said Daniel Swisher, President and Chief Executive Officer of Sunesis. “As our regulatory efforts progress to bring vosaroxin to market in Europe as a treatment for relapsed/refractory AML, we are advancing active dialogues with potential pharma collaborators toward the goal of supporting a market launch in 2017. With the clock now restarting, we anticipate being one step closer to that goal.”

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. Vosaroxin is an investigational drug that has not been approved for use in any jurisdiction.

Vosaroxin’s Marketing Authorization Application for relapsed refractory AML is currently under review by the European Medicines Agency, and a regulatory decision regarding approval is expected in 2017.

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 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, as well as 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>.

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This press release contains forward-looking statements, including statements related to Sunesis' corporate objectives, including the regulatory development and potential approval of vosaroxin by the EMA, potential collaborations and ability to commercialize vosaroxin in Europe. Words such as “expect,” “goal,” “may,” “potential” “advancing,” “anticipate,” “progress” 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 SNS-062, 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, 2015, Sunesis' Quarterly Report on Form 10-Q for the quarter ended June 30, 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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