Sunesis Pharmaceuticals Announces Clinical and Regulatory Updates to SNS-062 and Vosaroxin Programs

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FDA Review of Investigational New Drug Application for SNS-062 Complete; Phase 1B/2 Study in Patients with Advanced B-Cell Malignancies to Begin Dosing in the First Half of 2017

Vosaroxin Day 180 List of Outstanding Issues Received; Company to go Before Scientific Advisory Group in April Prior to CHMP Opinion

SOUTH SAN FRANCISCO, Calif., Jan. 23, 2017 (GLOBE NEWSWIRE) -- Sunesis Pharmaceuticals, Inc. (Nasdaq:SNSS) today announced clinical and regulatory updates to its two lead programs, SNS-062, a second-generation reversible and non-covalent BTK inhibitor, and vosaroxin, an anti-cancer quinolone derivative currently under review for marketing authorization as a treatment for relapsed/refractory acute myeloid leukemia (AML) in Europe.

For SNS-062, the company announced that its Investigational New Drug (IND) application with the U.S. Food and Drug Administration (FDA) is now active, supporting the initiation of a Phase 1B/2 study to assess the candidate's safety and efficacy in patients with advanced B-cell malignancies after prior ibrutinib exposure, including in patients with C481S mutations.

“With a now active IND for SNS-062, another important milestone in the rapid development of this next generation product candidate, we will work toward site activation at our U.S. clinical centers and dosing of the first patients within the first half of 2017,” said Daniel Swisher, President and Chief Executive Officer of Sunesis. “The data presented at ASH from our Phase 1A Healthy Volunteer study were encouraging, and we look forward to understanding the potential for SNS-062 to address the growing unmet needs of patients with B-cell malignancies.”

The company also announced today continued progress with its Marketing Authorization Application (MAA) for vosaroxin. Sunesis recently received the Day 180 List of Outstanding Issues, issued by the Committee for Medicinal Products for Human Use (CHMP) as part of the centralized review process.

Mr. Swisher continued, “We are working diligently to complete a comprehensive and detailed response to the Day 180 List of Outstanding Issues, which we expect to submit by the end of the first quarter. As we enter the final phase of the European approval process for vosaroxin, we are preparing to go before the Scientific Advisory Group’s Oncology Division (SAG-O) in April, which will assist the CHMP in its evaluation of our application. We anticipate a decision from the CHMP by mid-year and continue to advance active dialogues with potential pharma collaborators toward the goal of supporting a market launch of vosaroxin in 2017.”

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 binds non-covalently and reversibly to the BTK enzyme. Its binding profile along with improved PK/PD properties potentially provide SNS-062 an opportunity to address the leading acquired resistance to ibrutinib, a mutation in the enzyme’s binding site required for covalent binding. In preclinical studies, SNS-062 demonstrated potent activity against C481S mutated B-cell malignancies, and has been studied in healthy subjects in a completed 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. 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.

This press release contains forward-looking statements, including statements related to Sunesis' corporate objectives, the regulatory development, timing of SNS-062 clinical development, SNS-062 clinical potential, Sunesis' response to Day 180 List of Outstanding Issues and the timing thereof, and potential approval of vosaroxin by the EMA, potential collaborations and ability to commercialize vosaroxin in Europe. Words such as "advancing," "anticipate," "expect," "goal," "look forward," "potential" "progress," "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 SNS-062 or vosaroxin in the U.S. or Europe, that Sunesis' development activities for SNS-062 or 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 SNS-062, 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 SNS-062, 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 September 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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