Sunesis Pharmaceuticals Announces First Subject Dosed in Phase 1A Healthy Volunteer Study Evaluating Oral Non-Covalent BTK-inhibitor SNS-062

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Study Start Marks Sunesis' Second Kinase Inhibitor Program to Enter the Clinic

SOUTH SAN FRANCISCO, Calif., March 23, 2016 (GLOBE NEWSWIRE) -- Sunesis Pharmaceuticals, Inc. (Nasdaq:SNSS) today announced that the first subject has been dosed in a Phase 1A, randomized, double-blind, placebo-controlled dose-ranging study to investigate the safety, pharmacokinetics (PK) and pharmacodynamics (PD) of its oral, next-generation, non-covalently binding BTK-inhibitor, SNS-062, in healthy subjects. The Phase 1A study is being conducted in Belgium, pursuant to a Clinical Trial Application (CTA). With a successful study outcome, SNS-062 is expected to proceed to a Phase 1B/2 study in patients with B-cell malignancies later this year.

"As a non-covalently binding kinase inhibitor with preclinical activity against Cys-481S mutated B-cell malignancies, SNS-062 is an important new drug candidate with the potential to address the emerging resistance to currently marketed and clinical-stage covalent-binding BTK inhibitors," said Daniel Swisher, Chief Executive Officer of Sunesis. "SNS-062's distinct kinase selectivity profile also lends the potential for activity in a broader range of cancers. This is the second of Sunesis' kinase inhibitors, after the Takeda-partnered TAK-580, to enter the clinic. Together with the ongoing review of our vosaroxin marketing authorization application in Europe, these programs provide for a milestone-rich period in the coming quarters."

"BTK inhibitors remain an area of keen interest among investigators and major industry participants, and we believe our clinical strategy will allow us to rapidly differentiate and reach proof-of-concept with SNS-062 in this important field of study," said Deborah Thomas, Ph.D., Senior Vice President, Regulatory Affairs, Quality Assurance, and Non-Clinical Development. "Through the CTA process, Sunesis is able to efficiently understand important aspects of SNS-062's PK/PD profile in humans, identify a pharmacologically active dose and gather initial safety information, allowing us to move into a targeted patient population, including patients with relapsed chronic lymphoid leukemia with acquired mutations in Cys-481S, later this year."

The Phase 1A study will be conducted in three stages and is expected to enroll 52 subjects. In the first stage, the safety, pharmacokinetics, and pharmacodynamics of SNS-062 will be assessed over a range of doses. In the second stage, the effects of food on the pharmacokinetics of the drug will be assessed. In the last stage, a drug-drug interaction assessment will be conducted exploring the effects of CYP3A4 inhibition on the pharmacokinetics of SNS-062. The primary endpoint of the study is safety. The secondary endpoints are pharmacokinetics and pharmacodynamics.

About SNS-062

SNS-062 is a non-covalently binding inhibitor of Bruton's tyrosine kinase (BTK). This target mediates signaling through the B-cell receptor, or BCR, which is critical for adhesion, migration, proliferation and survival of normal and malignant B-lineage lymphoid cells. BTK has been well validated as a target for treatment of B-cell malignancies, with a BTK inhibitor approved for relapsed/refractory mantle cell lymphoma, frontline and relapsed/refractory chronic lymphocytic leukemia, or CLL, CLL with 17p depletion and Waldenström's macroglobulinemia. Because SNS-062 has a distinct binding site and favorable pharmacokinetic profile in preclinical studies, SNS-062 may provide differentiated opportunities for treatment of B-cell malignancies and other blood cancers. The rights to develop SNS-062 for oncology indications were in-licensed from Biogen in December 2013. SNS-062 is currently being evaluated in a Phase 1A Trial in healthy volunteers.

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' estimated timelines for regulatory interactions and regulatory progress, including the anticipated submission of the MAA for vosaroxin with the EMA and plans to gain marketing approval of vosaroxin in the U.S., Sunesis' overall strategy, the design, conduct and results of clinical trials, including the expected progress in its kinase inhibitor pipeline, estimated new cases of AML, its prevalence across major global markets, prognosis for patients with AML, the need for and the role of vosaroxin as a potential new treatment option, and Sunesis' clinical development of vosaroxin, including the analysis of the results from the VALOR clinical trial. Words such as "anticipates," "estimates," "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 may not be able to submit timely the MAA to the EMA, the risk that Sunesis' clinical studies for vosaroxin may not lead to regulatory approval in the U.S. or Europe, that Sunesis' development activities for vosaroxin could be otherwise halted or significantly delayed for various reasons, the risk that Sunesis' clinical studies for vosaroxin or other 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