Sunesis Presents Dose Escalation Results from the Phase 1A Healthy Volunteer Study Evaluating Oral Non-Covalent BTK inhibitor SNS-062

September 12, 2016 6:01 AM ET

Sunesis to Host Conference Call and Slide Webcast Today at 8:00 AM Eastern Time

SOUTH SAN FRANCISCO, Calif., Sept. 12, 2016 (GLOBE NEWSWIRE) -- Sunesis Pharmaceuticals, Inc. (Nasdaq:SNSS) today announced results from the Company's Phase 1A study in healthy volunteers evaluating oral non-covalent BTK inhibitor SNS-062. The study demonstrated a favorable safety, pharmacokinetic (PK) and pharmacodynamic (PD) profile for SNS-062 in healthy subjects. The results were presented on Saturday, September 10th at the European School of Haematology's (ESH) 2nd International Conference on New Concepts in B-Cell Malignancies at the Estoril Congress Centre in Estoril, Portugal.

"Our first-in-human clinical results are encouraging and reinforce our belief that SNS-062 has the potential to become an important new treatment option for patients with B-cell malignancies," said Linda Neuman, M.D., Vice President, Clinical Development of Sunesis. "Notably, SNS-062 exposure, even at the lowest dose of 50 mg, exceeded those reported for both ibrutinib and acalabrutinib at their respective recommended dose levels, suggesting that SNS-062 has improved PK properties. Furthermore, as a non-covalent BTK inhibitor with a distinct binding profile, SNS-062 may overcome the acquired resistance to ibrutinib and other covalent clinical-stage inhibitors resulting from a point mutation (C481S) in the BTK active site."

"The safety profile and the extent and duration of BTK inhibition by SNS-062 support the timely advancement of this program into cancer-directed studies," said Daniel Swisher, President and Chief Executive Officer of Sunesis. "We look forward to moving SNS-062 into a planned Phase 1B/2 study of patients with advanced B-cell malignancies."

The reported data from this Phase 1A randomized, double-blind, placebo-controlled, single-dose study are from four sequential cohorts of 8 subjects each who were randomly assigned to receive progressively higher single oral administrations of SNS-062 at doses of 50, 100, 200, and 300 mg (n=6 per cohort) or placebo (n=2 per cohort). An evaluation of the effects of food and CYP3A4 inhibition on the PK of SNS-062 is ongoing.

For the primary endpoint of safety, investigators were blinded to treatment arm for assessment of relatedness. Overall, AEs were reported for 8 (33%) subjects who received SNS-062 and for 3 (38%) subjects who received placebo. Treatment-related AEs were reported in 6/24 (25%) subjects who received SNS-062 compared with 3/8 (38%) subjects who received placebo. For patients who received SNS-062, treatment-related AEs included headache, nausea, and supraventricular tachycardia. In the placebo group, treatment-related AEs included headache, nausea, and diarrhea. No obvious pattern of dose-dependent toxicity was observed. All AEs were transient and low grade. None of the AEs, laboratory abnormalities, or ECG or telemetry findings were considered clinically meaningful. No SAEs were reported.

SNS-062 was rapidly absorbed and had mean plasma half-life values across all dose cohorts of 7.4 to 17 hours. SNS-062 concentrations declined in a multiphasic manner. Total exposure (AUC and Cmax) increased proportionally with dose. SNS-062 demonstrated rapid, profound (~100%), and prolonged inhibition of BTK at all dose levels supporting a future twice-daily dosing regimen.

The poster, titled "A Phase 1A Study to Investigate the Safety, Pharmacokinetics, and Pharmacodynamics of the Noncovalent Bruton Tyrosine Kinase (BTK) Inhibitor SNS-062 in Healthy Subjects: Preliminary Results" is available on the Sunesis website at www.sunesis.com.

Conference Call and Webcast Information

Sunesis will host a conference call and slide webcast today, Monday, September 12 at 8:00 a.m. Eastern Time. The call can be accessed by dialing (844) 296-7720 (U.S. and Canada) or (574) 990-1148 (international), and entering passcode 70718677. To access the live audio webcast, or the subsequent archived recording, visit the "Investors and Media -

Calendar of Events" section of the Sunesis website at www.sunesis.com. The webcast will be recorded and available for replay on the company's website for two weeks.

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. SNS-062's favorable safety, pharmacokinetics, potency, kinase selectivity and non-covalent binding profile support the advancement to a Phase 1B/2 study in patients with B-cell malignancies. This study will include patients with an acquired resistance from a C481S mutation at the point in the enzyme's binding site required for covalent binding of ibrutinib and other covalent inhibitors.

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, including the clinical development of SNS-062 and potential approval of vosaroxin by the EMA. Words such as "belief," "look forward," "may," "planned," "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 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, 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, 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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