Sunesis Pharmaceuticals Announces Presentation of Results from Completed Phase 1A Healthy Volunteer Study Evaluating Oral Non-Covalent BTK inhibitor SNS-062 at ASH Annual Meeting

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Program On Track to Begin Dosing in Phase 1B/2 Study of Patients with B-Cell Malignancies in the First Half of 2017

SOUTH SAN FRANCISCO, Calif., Dec. 05, 2016 (GLOBE NEWSWIRE) -- Sunesis Pharmaceuticals, Inc. (Nasdaq:SNSS) today announced the presentation of results from the Company's Phase 1A study in healthy volunteers evaluating oral non-covalent reversible BTK inhibitor SNS-062. The results were presented in a poster session titled "CLL: Therapy, excluding Transplantation: Poster I" on Saturday, December 3, at the 58th American Society of Hematology Annual Meeting in San Diego, California. The presentation, titled "First-in-Human Phase 1a Study of the Safety, Pharmacokinetics, and Pharmacodynamics of the Noncovalent Bruton's Tyrosine Kinase (BTK) Inhibitor SNS-062 in Healthy Subjects," is available at www.sunesis.com.

"These final results from the Phase 1A Healthy Volunteer study suggest that SNS-062, with a favorable safety, pharmacokinetic (PK) and pharmacodynamic (PD) profile, and its improved PK properties over ibrutinib and acalabrutinib, has significant potential to become a new treatment option for patients with B-cell malignancies," said Linda Neuman, M.D., Vice President, Clinical Development of Sunesis. "Additionally, as a non-covalent BTK inhibitor with a distinct reversible binding profile, SNS-062 may overcome the acquired resistance to ibrutinib and other covalent clinical-stage BTK inhibitors resulting from a point mutation (C481S) in the active site."

"The safety profile, extent of SNS-062 exposure, and duration of BTK inhibition from these study results are encouraging and support our plans for a Phase 1B/2 study to assess safety and efficacy in patients with advanced B-cell malignancies after prior ibrutinib exposure, both with and without a BTK C481 mutation," said Daniel Swisher, President and Chief Executive Officer of Sunesis. "We are preparing an IND filing for this year as we work closely with our identified clinical sites for this study, and expect to begin dosing patients within the first half of 2017."

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 25, 50, 100, 200, and 300 mg (n=6 per cohort) or placebo (n=2 per cohort).

For the primary endpoint of safety in stage 1, 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. In the unblinded stages 2 and 3 of the trial, a similar pattern and rate of AEs were observed. Overall, 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 6.9 to 17 hours. SNS-062 demonstrated rapid, profound (~100%), and prolonged inhibition of BTK at all dose levels support investigation of a twice-daily dosing regimen in B-cell malignancies with or without an acquired BTK resistance mutation.

Furthermore in stage 2, food had no impact on the extent of absorption or elimination of SNS-062, suggesting that it may be administered to patients without regard to food. In stage 3, SNS-062, similar to ibrutinib, is a sensitive substrate of CYP3A4 and administration with moderate/strong CYP3A4 inhibitors or inducers is not recommended.

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 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 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 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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