Sunesis Pharmaceuticals Announces First Patient Dosed in Phase 1b/2 Study Evaluating Oral Non-Covalent BTK-inhibitor SNS-062 in Adults with Chronic Lymphocytic Leukemia and other B-Cell Malignancies

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SOUTH SAN FRANCISCO, Calif., July 18, 2017 (GLOBE NEWSWIRE) -- Sunesis Pharmaceuticals, Inc. (Nasdaq:SNSS) today announced that the first patient has been dosed at the Dana-Farber Institute in the Phase 1b/2 dose-escalation and cohort-expansion study of its reversible, non-covalent Bruton's Tyrosine Kinase (BTK)-inhibitor, SNS-062, in adults with chronic lymphocytic leukemia (CLL), small lymphocytic leukemia, Waldenstrom's macroglobulinemia and mantle cell lymphoma that have progressed after prior therapies.

"Resistance to ibrutinib, the only FDA approved BTK inhibitor, is a growing area of unmet need in the treatment of relapsed CLL," said Dr. Jennifer Brown, Director of the CLL Center at Dana-Farber Cancer Institute. "SNS-062 is designed to retain its activity in the presence of the C481S mutation, the primary resistance mechanism thus far identified to treatment by covalent-binding BTK inhibitors such as ibrutinib. We look forward to participating in Sunesis' Phase 1b/2 study to explore the therapeutic potential of SNS-062."

"The start of this Phase 1b/2 study marks a significant milestone for the Company," said Daniel Swisher, Chief Executive Officer of Sunesis. "This study is designed to provide initial proof of concept that SNS-062 can become a new treatment option for patients with relapsed CLL. We look forward to progressing this trial to identify a recommended dose and to characterize the profile of SNS-062 across a range of B-cell malignancies."

The Phase 1b/2 trial is an open-label, sequential-group study that will enroll up to 124 subjects and is being conducted at five leading sites in the United States: Dana-Farber Cancer Institute, MD Anderson Cancer Center, The Ohio State University Comprehensive Cancer Center, U.C. Irvine Medical Center, and Weill Cornell Medicine. The target population comprises adult subjects who have advanced B-cell malignancies that have relapsed/progressed after prior

therapy, including a BTK inhibitor. Phase 1b is the dose escalation portion of the study designed to evaluate the safety, pharmacokinetics, pharmacodynamics and antitumor activity of a range of SNS-062 dose levels, to determine the maximum tolerated and/or recommended dose. The Phase 2 portion is the cohort expansion that will further explore the clinical activity and safety of SNS-062 mono-therapy within specific disease cohorts, including relapsed CLL patients with C481S mutations.

About SNS-062

SNS-062 is a selective, oral, reversible, non-covalent inhibitor of Bruton's tyrosine kinase (BTK). BTK is a validated target for the treatment of B-cell malignancies driven by B-cell receptor signaling. SNS-062 is designed to retain its activity in the presence of a C481S mutation in BTK's kinase domain, a leading resistance mechanism of ibrutinib for the treatment of chronic lymphocytic leukemia (CLL). In preclinical studies, SNS-062 demonstrated potent activity in both wild-type and C481S mutant BTK. In a Phase 1A randomized, double-blind, placebo-controlled single ascending dose study in healthy volunteers, SNS-062 demonstrated improved pharmacokinetics over ibrutinib, and sustained inhibition of BTK. SNS-062 is now being investigated in a Phase 1B/2 study in patients with relapsed B-cell malignancies, including CLL.

About Sunesis Pharmaceuticals

Sunesis is a biopharmaceutical company focused on the development and commercialization of new oncology therapeutics for the future treatment of solid and hematologic cancers. Sunesis has built an experienced cancer drug development organization committed to improving the lives of people with cancer. The company is focused on advancing its novel kinase-inhibitor pipeline, with an emphasis on establishing proof of concept that its oral non-covalent BTK-inhibitor, SNS-062, treats ibrutinib-resistant chronic lymphocytic leukemia. Sunesis is also supporting investigator-led studies of vosaroxin in acute myeloid leukemia.

For additional information on Sunesis, please visit http://www.sunesis.com.

This press release contains forward-looking statements, including clinical development and therapeutic potential of SNS-062, including the design and timing of our Phase 1b/2 trial. Words such as "can," "designed," "look forward," "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

risks related to the timing or conduct of Sunesis' clinical trials, including SNS-062 Phase 1b/2 trial, the risk that Sunesis' clinical studies for SNS-062, vosaroxin or other product candidate 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, 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, 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' Quarterly Report on Form 10-Q for the quarter ended March 31, 2017 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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