Sunesis Pharmaceuticals Announces Advancement into 100mg Cohort of Phase 1b/2 Trial of Vecabrutinib in Patients with CLL and Other B-Cell Malignancies

January 2, 2019

- 50 mg Cohort Completed -

- Clinical Update Expected in the Second Quarter of 2019 -

SOUTH SAN FRANCISCO, Calif., Jan. 02, 2019 (GLOBE NEWSWIRE) -- Sunesis Pharmaceuticals, Inc. (Nasdaq:SNSS) today announced that the Company has opened the 100 mg cohort in the Phase 1b/2 trial of its non-covalent BTK inhibitor vecabrutinib in adults with relapsed/refractory chronic lymphocytic leukemia (CLL) and other B-cell malignancies. Preliminary safety, pharmacokinetic, and pharmacodynamic data from the now completed 50 mg cohort of the study were recently presented at the 60thAmerican Society of Hematology (ASH) Annual Meeting in December 2018.

"We are excited to study the 100 mg dose level as we continue the dose escalation portion of this study," said Dayton Misfeldt, Sunesis interim Chief Executive Officer. "Thus far, we have seen an encouraging safety profile, evidence of pharmacodynamic activity in CLL and other B cell cancer patients both with and without BTK C481 mutations, and some improvements in clinical symptoms. We anticipate that the target dose level for vecabrutinib will likely be between 100 mg and 300 mg BID and look forward to providing a clinical update on potentially active dose levels at a major medical meeting in the second quarter of 2019."

About Vecabrutinib

Vecabrutinib (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. Vecabrutinib has potent activity in vitro against both wild-type and C481S-mutant BTK. BTKC481S is the most common mutation seen in ibrutinib-resistant CLL patients. Vecabrutinib also inhibits IL2-inducible T-cell kinase (ITK), which may improve T cell function. In a Phase 1a randomized, double-blind, placebo-controlled single ascending dose study in healthy volunteers, vecabrutinib demonstrated improved pharmacokinetics over ibrutinib, and sustained inhibition of BTK. Vecabrutinib is now being investigated in a Phase 1b/2 study in patients with relapsed CLL and other B-cell malignancies.

About Sunesis Pharmaceuticals

Sunesis is a biopharmaceutical company developing new therapeutics for the treatment of hematologic and solid cancers. Sunesis has built an experienced 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 its oral non-covalent BTK inhibitor vecabrutinib. Vecabrutinib is currently being evaluated in a Phase 1b/2 study in adults with chronic lymphocytic leukemia and other B-cell malignancies that have progressed after prior therapies. The Company's proprietary PDK1 inhibitor SNS-510 is in preclinical development. PDK1 is a master kinase that activates other kinases important to cell growth and survival including members of the AKT, PKC, RSK, and SGK families. Sunesis is exploring strategic alternatives for vosaroxin, a late-stage investigational product for relapsed or refractory AML. Sunesis also has an interest in the pan-RAF inhibitor TAK-580 which is licensed to Takeda. TAK-580 is in a clinical trial for pediatric low-grade glioma.

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

This press release contains forward-looking statements, including statements related to the continued development of vecabrutinib (SNS-062), including the timing and preliminary results of Phase 1b/2 trial of vecabrutinib and the therapeutic potential of vecabrutinib, further development and potential of its kinase inhibitor pipeline, and planned development of SNS-510 and TAK-580. Words such as "believe," "expect," "future," "look forward," "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 related to the timing or conduct of Sunesis' clinical trials, including the vecabrutinib Phase 1b/2 trial, the risk that Sunesis' clinical or preclinical studies for vecabrutinib, SNS-510 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, risks related to the timing or conduct of Sunesis' clinical trials, that Sunesis' development activities for vecabrutinib or SNS-510 could be otherwise halted or significantly delayed for various reasons, that Sunesis may not be able to receive regulatory approval of vecabrutinib, or SNS-510 in the U.S. or Europe, 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 vecabrutinib, SNS-510 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 September 30, 2018 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 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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