Sunesis Pharmaceuticals Announces Presentation of Preliminary Data from Phase 1b/2 Trial of Vecabrutinib in Patients with CLL and Other B-Cell Malignancies at ASH Annual Meeting

December 2, 2018

Results to be Further Discussed in Slide Webcast Today at 8:30 p.m. Pacific Time

SOUTH SAN FRANCISCO, Calif., Dec. 02, 2018 (GLOBE NEWSWIRE) -- Sunesis Pharmaceuticals, Inc. (Nasdaq:SNSS) today announced the presentation of results from the Company's Phase 1b/2 clinical trial of its non-covalent BTK inhibitor vecabrutinib in adults with relapsed/refractory chronic lymphocytic leukemia (CLL) and other B-cell malignancies. The results will be presented today, December 2, from 6:00-8:00 p.m. PT in a poster session titled "CLL: Therapy, excluding Transplantation: Poster II" at the 60 thAmerican Society of Hematology (ASH) Annual Meeting in San Diego, California. The poster, titled "Preliminary Safety, Pharmacokinetic, and Pharmacodynamic Results from a Phase 1b/2 Dose-Escalation and Cohort-Expansion Study of the Noncovalent, Reversible Bruton's Tyrosine Kinase Inhibitor, Vecabrutinib, in B-Lymphoid Malignancy Patients with Prior BTKi Therapy," Abstract No. 3141, is available at www.sunesis.com.

"To date, vecabrutinib has demonstrated both an encouraging safety profile and evidence of pharmacodynamic activity in CLL and other B cell cancer patients both with and without the BTK C481 mutation," said Dayton Misfeldt, Sunesis interim Chief Executive Officer. "We believe vecabrutinib has significant potential to be an important new treatment for ibrutinib-resistant B-cell malignancy patients, and its additional activity as an ITK inhibitor suggests further directions for clinical investigation. We look forward to continuing the dose escalation, as we believe that the target dose level is likely to be between 100 mg and 300 mg BID. We are excited to be working with such thoughtful and diligent investigators at eight premier sites across the U.S., and we thank our investigators for their continued support."

Data reported today were available from 11 of 13 treated patients. These included 7 with relapsed/refractory CLL, two with mantle cell lymphoma (MCL), and two with Waldenstrom macroglobulinemia (WM). Patients had received an average of 5 lines of prior therapy, and all had progressed on prior covalent BTK inhibitor treatment. Four of the 7 CLL patients had BTK C481 mutations. Currently, 4 patients are on study: one in Cycle 2, one in Cycle 3, and two new subjects who are in Cycle 1 and are anticipated to complete the 50 mg cohort.

The poster builds vecabrutinib's profile in three key areas:

- **Safety:** data on treatment-emergent adverse events (TEAEs) were available for 10 patients. The most common TEAEs of any grade were anemia (70%) and neutropenia and night sweats (50% each). Grade 3 drug-related AEs were anemia, neutropenia, leukocytosis, and ALT increase (10% each). In the second cohort, one patient experienced a dose-limiting toxicity of an inadequate number of Cycle 1 doses administered due to a drug-related grade 3 ALT elevation, resulting in expansion of the cohort to 6 patients.
- **Pharmacokinetics:** the pharmacokinetic profile of the 50mg dose is approximately dose proportional to the 25 mg dose. The next dose levels are expected to produce plasma concentrations associated with consistently high inhibition of BTK.
- **Pharmacodynamics:** vecabrutinib inhibition of BTK phosphorylation was rapid and sustained in the 5 patients who had adequate baseline signal for analysis. Decreases in serum concentrations of key cytokines associated with B-cell malignancies, CCL2, CCL3, and CCL4, were also observed in 7 patients, consistent with inhibition of BTK signaling.

Webcast Information

The data will be further discussed as part of an analyst and investor event being held in San Diego today, December 2, at 8:00 p.m. PT, with the slide webcast commencing at 8:30 p.m. PT. The event is intended for institutional investors and sell-side analysts only. Please contact maeve@argotpartners.com for more information. The live webcast of the event, with slides, will be available to all on the Investors section of the Sunesis website at www.sunesis.com and will be archived for 90 days.

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 retains its activity in the presence of a BTK C481S mutation, the most common mutation seen in ibrutinib-resistant CLL patients. In preclinical studies, vecabrutinib demonstrated potent activity in both wild-type and C481S-mutant BTK. Vecabrutinib has also been shown to inhibit a select number of other kinases including 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 plans to submit an IND for SNS-510 in 2019. 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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