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

June 15, 2019

SOUTH SAN FRANCISCO, Calif., June 15, 2019 (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 are being presented today, June 15, from 5:30-7:00 p.m. CET in a poster session titled "Chronic lymphocytic leukemia and related disorders – Clinical" at the 24th Congress of the European Hematology Association (EHA) in Amsterdam. The poster, titled "Preliminary Results of a Phase 1b/2 Dose-Escalation and Cohort-Expansion Study of the Noncovalent, Reversible Bruton's Tyrosine Kinase Inhibitor (BTKi) Vecabrutinib in B-Cell Malignancies," Abstract No. PS1148, is available at www.sunesis.com.

"We are encouraged by the data presented today demonstrating vecabrutinib's well-tolerated safety profile and evidence of clinical activity in CLL and other B-cell malignances," said Dayton Misfeldt, Interim Chief Executive Officer of Sunesis. "Importantly, vecabrutinib's median steady-state trough concentrations continue to increase with dose and are approaching levels expected to provide consistent BTK inhibition and greater clinical activity. We are currently dosing patients in the 200mg cohort and momentum in the trial continues as reflected by the robust pace of enrollment we've seen this year. We look forward to sharing data from the additional cohorts as we complete the Phase 1b and proceed to Phase 2 later this year."

Preliminary data reported today were available from 23 patients treated in the trial thus far. These included 19 CLL patients, two mantle cell lymphoma (MCL) patients, and two Waldenstrom Macroglobulinemia (WM) patients. Patients had received an average of 4 lines of prior therapy, and all patients had progressed on prior BTKi therapy. 61% of CLL patients enrolled had a BTK C481 mutation as of the data cutoff for the poster.

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

- **Safety:** Preliminary data on treatment-emergent adverse events (TEAEs) were available for 20 patients. The most common TEAEs of any grade were anemia (40%) and neutropenia and night sweats (30% each), with 5 drug-related Grade 3 adverse events occurring in 3 patients, all in cohort 2 (50mg). In total, there were 8 serious adverse events (SAEs) in six patients, none of which were considered drug-related.

- **Activity:** Stable disease was seen in 4 CLL patients, 3 of whom had BTK C481S mutations. Two of these patients, both with BTK C481S mutations, showed decreases of 16% and 47% in index lesions at first assessment by CT scans. The patient with the 47% decrease was one of two evaluable post-venetoclax patients with the BTK C481S mutation. A patient with WM experienced clinical benefit with improvement in B-symptoms but no impact on immunoglobulin M. One patient in cohort 3 (100mg) continues on treatment in cycle 6 (as of the poster data cutoff, this patient was in cycle 5).

- **Pharmacokinetics:** The pharmacokinetic profile of vecabrutinib showed sustained exposure over the dosing interval, with median steady-state trough concentrations increasing with dose. Preliminary data showed near doubling of trough concentrations between doses of 50 mg (451 ng/mL) and 100 mg (873 ng/mL). Based on the results of the Phase 1A study in healthy subjects, trough levels of >1,000 ng/mL are expected to be required for consistent BTK inhibition and greater clinical activity. This is likely achievable with doses higher than 100 mg BID.

- **Pharmacodynamics:** Vecabrutinib inhibition of BTK phosphorylation was rapid and sustained in 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 observed in most evaluable patients, consistent with inhibition of BTK signaling.

About Sunesis Pharmaceuticals

Sunesis is a biopharmaceutical company developing new targeted 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.

SUNESIS and the logos are trademarks of Sunesis Pharmaceuticals, Inc.

This press release contains forward-looking statements, including statements related to Sunesis' continued development of vecabrutinib (SNS-062), including the timing of the Phase 1b/2 trial of vecabrutinib,the therapeutic potential of vecabrutinib, and the further development and potential of its kinase inhibitor pipeline. Words such as "believe", "expect," "likely," "look forward" 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, 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 March 31, 2019 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.

Investor and Media Inquiries:
Maeve Conneighton
Argot Partners
212-600-1902

Willie Quinn
Sunesis Pharmaceuticals Inc.
650-266-3716

Source: Sunesis Pharmaceuticals, Inc.