



Sunesis Pharmaceuticals Announces Data from Ongoing Phase 1b/2 Trial of Vecabrutinib in Patients with CLL and Other B-Cell Malignancies

December 5, 2019

Poster to be Presented at Upcoming ASH Annual Meeting

SOUTH SAN FRANCISCO, Calif., Dec. 05, 2019 (GLOBE NEWSWIRE) -- Sunesis Pharmaceuticals, Inc. (Nasdaq: SNSS) today announced data 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 on Sunday, December 8, from 6:00-8:00 p.m. ET in a poster session titled "CLL: Therapy, excluding Transplantation: Poster II" at the 60th American Society of Hematology (ASH) Annual Meeting in Orlando, Florida. The poster, titled "Ongoing Results of a Phase 1b/2 Dose Escalation and Cohort-Expansion Study of the Selective, Noncovalent, Reversible Bruton's Tyrosine Kinase Inhibitor, Vecabrutinib, in B-Cell Malignancies," Abstract No. 3041, will be available at www.sunesis.com on Sunday.

The data are being disclosed in advance of the ASH meeting due to an unauthorized disclosure of the poster on social media this morning.

"The data are encouraging, with vecabrutinib showing evidence of clinical activity in high-risk patients resistant to covalent BTK inhibitors, in both wild-type and C481-mutated BTK disease," said Dayton Misfeldt, Interim Chief Executive Officer of Sunesis. "Vecabrutinib is very well tolerated at the dose levels studied thus far, with patients now being treated in the 400 mg cohort. We are prepared for Phase 2 expansion, which will focus on BTK inhibitor-resistant CLL/SLL patients and those with prior intolerance to other BTK inhibitors."

Data reported today were from 29 relapsed/refractory patients treated in Cohorts 1 to 5 (25 mg to 300 mg). These included 23 patients with CLL, three with Waldenstrom macroglobulinemia (WM), two with mantle cell lymphoma (MCL), and one with marginal zone lymphoma (MZL). Patients had received an average of 4 lines of prior therapy, and all had progressed on prior BTK inhibitor therapy; 61% of the CLL patients had a BTK C481 mutation.

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

- **Safety:** The most common treatment-emergent adverse events (TEAEs) of any grade were anemia (35%), headache (28%), and night sweats (24%). Headache and nausea (both 10%) were the two most common drug-related TEAEs. To date, no drug-related Grade 3 or Grade 4 TEAEs have been observed at dose levels higher than 50 mg.
- **Activity:** Clinical benefit has been observed in covalent BTK inhibitor-resistant patients with poor prognostic features and in both wild-type and C481-mutated BTK disease. In the 300mg dose group (Cohort 5), stable disease was observed in 3 of 5 patients, and two remain on treatment in Cycle 5 and Cycle 6, including a wild-type BTK CLL patient with -40% change in tumor burden at first scan. In addition, one patient from Cohort 3 remains on study in Cycle 12, having been dose escalated twice from their initial dose of 100 mg to their current dose of 300 mg.
- **Pharmacokinetics:** Vecabrutinib showed sustained exposure over the dosing interval with both exposure and median steady-state minimum blood plasma concentration (C_{min}) increasing with dose. On Day 8, steady-state median C_{min} values were 75 ng/mL (Cohort 1, n=3), 451 ng/mL (Cohort 2, n=10), 873 ng/mL (Cohort 3, n=4), 1124 ng/mL (Cohort 4, n=4), and 1950 ng/mL (Cohort 5, n=5).
- **Pharmacodynamics:** Vecabrutinib's pharmacodynamic effects (reductions in chemokines CCL3 and CCL4) increased with dose in CLL patients and indicate increased impact on BTK signaling as dose is escalated.

About Sunesis Pharmaceuticals

Sunesis is a biopharmaceutical company developing novel targeted inhibitors 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.

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

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

Forward-Looking Statements

This press release contains forward-looking statements, including statements related to Sunesis' continued development of vecabrutinib, including the timing of Phase 1b/2 trial of vecabrutinib and the therapeutic potential of vecabrutinib, further development and potential of its kinase inhibitor pipeline, and sufficiency of its cash resources and financial position. Words such as "expect," "will," "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. These and other risk factors are discussed under "Risk Factors" in Sunesis' Quarterly Report on Form 10-Q for the quarter ended September 30, 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 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.

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

Willie Quinn
Sunesis Pharmaceuticals Inc.
650-266-3716



Source: Sunesis Pharmaceuticals, Inc.