Sunesis Pharmaceuticals Announces Clinical Update on Vecabrutinib Program

June 23, 2020

Company Shifting Resources from Vecabrutinib to Development of PDK-1 Inhibitor SNS-510

SOUTH SAN FRANCISCO, Calif., June 23, 2020 (GLOBE NEWSWIRE) -- Sunesis Pharmaceuticals, Inc. (Nasdaq: SNSS) today announced that the Company will not advance its non-covalent BTK inhibitor vecabrutinib into the planned Phase 2 portion of the Phase 1b/2 trial in adults with relapsed/refractory chronic lymphocytic leukemia (CLL) and other B-cell malignancies. The decision was made after assessing the totality of the data including the 500 mg cohort, the highest dose studied in the trial.

“Although vecabrutinib continues to exhibit an excellent safety profile, there is insufficient evidence of activity in BTK-inhibitor resistant B-cell malignancies to advance the drug into the planned Phase 2 portion of the trial. One partial remission was observed after 11 treatment cycles in a CLL patient treated in Cohort 5 (300 mg BID) and a number of patients treated across the dose range explored (25 mg to 500 mg BID) saw stable disease; however, no other remissions have been observed,” said Dayton Misfeldt, Interim Chief Executive Officer of Sunesis. “We will complete the Phase 1b and evaluate the best path forward for vecabrutinib. We are grateful for the patients and their families who participated in this trial, as well as the investigators and research staff at our trial sites.”

Mr. Misfeldt continued: “We are shifting our resources and development focus to our first-in-class PDK1 inhibitor SNS-510. SNS-510 inhibits PI3K-dependent and PIP3-independent pathways important in both solid and hematologic malignancies. We remain on track to file an IND by the end of 2020 and expect to present additional preclinical findings at a medical meeting in the second half of the year. We expect that our current cash resources are sufficient to fund the company into 2021.”

Vecabrutinib Phase 1b/2 Clinical update. Currently, five patients enrolled in cohorts 5-7 remain on treatment and continue to be followed. Vecabrutinib is very well tolerated across the dose range investigated.

- Cohort 7 (500mg BID): Three (2 CLL, 1 MCL) of six treated patients had stable disease at first response assessment (beginning of cycle 4). One of the CLL patients is in Cycle 7, the MCL patient is in cycle 6 and one CLL patient was determined to have progressive disease after 6 cycles. We did not see a reduction in tumor burden in any of the patients with stable disease.

- Cohort 6 (400mg BID): Of 6 patients treated, 2 CLL patients remain on study in cycle 9, one with stable disease and the other who had progressive disease at first assessment but continues to derive clinical benefit. One CLL patient who had stable disease with a 48% reduction in tumor burden at first assessment progressed in cycle 7.

- Cohort 5 (300mg BID): One CLL patient remains on treatment in cycle 12 with a partial response observed at third response assessment done at the start of cycle 12.

About SNS-510

SNS-510 is a PDK1 inhibitor licensed from Millennium Pharmaceuticals, Inc. (“Takeda Oncology”), a wholly-owned subsidiary of Takeda Pharmaceutical Company Limited. SNS-510 interaction with PDK1 inhibits both PI3K signaling and PIP3-independent pathways integral to many malignancies, and PDK1 can also be overexpressed in breast, lung, prostate, hematologic and other cancers. Evaluation of SNS-510 in the Eurofins Oncopanel™, a panel of >300 genomically profiled cancer cell lines from diverse tissue origins, indicated that CDKN2A-mutated tumors are particularly sensitive to SNS-510. CDKN2A alterations are common in human cancers and may prove to be useful biomarkers for broad investigation of SNS-510 as a monotherapy and in combination with other anticancer agents. Sunesis is conducting an Investigational New Drug (“IND”)-enabling program for SNS-510 and plan to file an IND by the end of 2020.

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, including first-in-class PDK1 inhibitor SNS-510 and its oral non-covalent BTK inhibitor vecabrutinib. SNS-510 is in IND-enabling studies and vecabrutinib is completing a Phase 1b trial in patients with advanced B cell malignancies.

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

Forward-Looking Statements

This press release contains forward-looking statements, including statements related to Sunesis’ continued development and potential of its kinase inhibitor pipeline, including the timing of the additional preclinical findings related to SNS-510; the timing of the potential IND filing for SNS-510; completion of the Phase 1b trial of vecabrutinib and the therapeutic potential of vecabrutinib; and the sufficiency of Sunesis’ 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 March

31, 2020 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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