Sunesis Pharmaceuticals Announces Presentation of The Ohio State University-Sponsored Preclinical Study of BTK Inhibitor SNS-062 at AACR Annual Meeting

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SOUTH SAN FRANCISCO, Calif., April 03, 2017 (GLOBE NEWSWIRE) -- Sunesis Pharmaceuticals, Inc. (Nasdaq:SNSS) today announced results from an Ohio State University-sponsored preclinical study evaluating the efficacy of non-covalent BTK inhibitor SNS-062 in chronic lymphocytic leukemia (CLL) proprietary cell lines and patient samples. The study demonstrated that, unlike ibrutinib, SNS-062 inhibition of BTK signaling is unaffected by the presence of the C481S mutation and may address acquired resistance to covalent BTK inhibitors. The results are being presented today in a poster session titled "Reversal of Drug Resistance" on Monday, April 3, 2017 from 8:00 AM to 12:00 PM ET at the American Association for Cancer Research Annual Meeting in Washington, D.C.

"B-cell receptor signaling is exceptionally active in CLL and is vital for the proliferation and survival of CLL cells, making BTK inhibition an effective target. However, a subset of patients acquire resistance to ibrutinib, the current standard of care BTK inhibitor," said Amy Johnson, PhD, Associate Professor, Hematology, The Ohio State University. "A key resistance mechanism to covalent BTK inhibitors is a point mutation in the BTK active site, converting cysteine 481 to serine, or C481S. In this study, we demonstrate that SNS-062, which binds non-covalently to BTK, is a potent inhibitor of BTK unaffected by the presence of the C481S mutation. These findings support clinical investigation of SNS-062 to address acquired resistance to covalent BTK inhibitors in patients."

"Preclinical and healthy volunteer data continue to reveal a unique profile for SNS-062, one distinct from ibrutinib and other covalently binding BTK inhibitors," said Judy Fox, PhD, Chief Scientific Officer of Sunesis. "SNS-062 has the potential to become an important new treatment for CLL, addressing what is an increasingly well-defined and prevalent unmet patient need. With an active IND, we remain on track to dose the first patient in our planned Phase 1B/2 study in patients with advanced B-cell malignancies this quarter."

For the study, primary CLL B-cells were isolated from the whole blood of consenting patients with CLL. In these cells, SNS-062 was found to decrease surface expression of B-cell activation markers and patient CLL cell viability in a dose-dependent manner, with BTK inhibition by SNS-062 comparable to ibrutinib. Further, SNS-062 was found to inhibit BTK wild type (WT) and BTK C481S, while ibrutinib and acalabrutinib show reduced activity toward BTK C481S. SNS-062 has a unique kinase selectivity profile, affecting a limited number of kinases outside the TEC kinase family. SNS-062 was also found to diminish stromal cell protection in patient CLL cells, an important observation given the role of tumor microenvironment in this malignancy.

The poster (Poster Number 22, Abstract Number 1207, Convention Center, Halls A-C, Poster Section 6) titled "SNS-062 demonstrates efficacy in chronic lymphocytic leukemia in vitro and inhibits C481S mutated Bruton tyrosine kinase" is available on the Sunesis website at www.sunesis.com.

About SNS-062

SNS-062 is a novel, second-generation BTK inhibitor, a class of kinase inhibitors that selectively inhibits the enzyme Bruton's tyrosine kinase (BTK). This target mediates signaling through the B-cell receptor, which is critical for adhesion, migration, proliferation and survival of normal and malignant B-lineage lymphoid cells. Unlike other drugs in its class, SNS-062 has a distinct kinase selectivity profile and binds non-covalently to the BTK enzyme. This alternate binding site potentially provides an opportunity to address the leading resistance mechanism, a mutation in the enzyme's binding site required for covalent binding. In preclinical studies, SNS-062 demonstrated potent activity against Cys-481S mutated B-cell malignancies, and has been studied in healthy subjects in a Phase 1A, randomized, double-blind, placebo-controlled dose-ranging study to investigate the drug's safety, pharmacokinetics, and pharmacodynamics. With the reported successful study outcome, SNS-062 is proceeding to a Phase 1B/2 study in patients with B-cell malignancies.

About Sunesis Pharmaceuticals

Sunesis is a biopharmaceutical company focused on the development and commercialization of new oncology therapeutics for the potential treatment of solid and hematologic cancers. Sunesis has built a highly-experienced cancer drug development organization committed to improving the lives of people with cancer. Currently, the company is focused on pursuing regulatory approval in Europe for its lead product candidate, vosaroxin, for the treatment of relapsed or refractory acute myeloid leukemia in patients aged 60 and older, as well as advancing its novel kinase-inhibitor pipeline, which includes its proprietary non-covalent BTK-inhibitor, SNS-062.

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

This press release contains forward-looking statements, including statements related to Sunesis' corporate objectives, the regulatory development, Sunesis' response to Day 180 List of Outstanding Issues and the anticipated timing of a CHMP decision, and potential approval of vosaroxin by the EMA, potential collaborations and ability to commercialize vosaroxin in Europe. Words such as "advancing," "anticipate," "expect," "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 that Sunesis may not be able to receive regulatory approval of vosaroxin in the U.S. or Europe, that Sunesis' development activities for vosaroxin could be otherwise halted or significantly delayed for various reasons, risks related to Sunesis' need for substantial additional funding to complete the development and commercialization of vosaroxin and other product candidates, the risk that Sunesis' clinical studies for vosaroxin or other product candidates, including its pipeline of kinase inhibitors, 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 conduct of Sunesis' clinical trials, 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 vosaroxin and other product candidates. These and other risk factors are discussed under "Risk Factors" and elsewhere in Sunesis' Annual Report on Form 10-K for the year ended December 31, 2016 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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