Sunesis Pharmaceuticals Announces Presentation of Updated Results from Washington University-Sponsored Phase 1/Cohort Expansion Trial of Vosaroxin Plus Azacitidine in Patients with MDS at the EHA Annual Meeting

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Vosaroxin Combination Demonstrates Encouraging Response Rates

SOUTH SAN FRANCISCO, Calif., June 23, 2017 (GLOBE NEWSWIRE) -- Sunesis Pharmaceuticals, Inc. (Nasdaq:SNSS) today announced the presentation of updated results from a Washington University-sponsored Phase 1/Cohort Expansion trial of vosaroxin plus azacitidine in patients with myelodysplastic syndrome (MDS). The results are being presented today from 5:15 to 6:45 P.M. Central European Time in a poster session titled "Myelodysplastic syndromes – Clinical 1" at the 22nd Congress of the European Hematology Association (EHA) being held at the IFEMA - Feria de Madrid in Madrid, Spain. The poster (abstract P319, Hall 7), titled "Vosaroxin Plus Azacitidine Treatment for Patients with Myelodysplastic Syndrome (MDS): A Phase 1/Cohort Expansion Study," will be available following the presentation at www.sunesis.com.

"While hypomethylating agents are a mainstay of treatment for myelodysplastic syndromes, these agents alone produce remissions in a minority of patients and are not curative," said Meagan A. Jacoby, M.D., Ph.D., Assistant Professor, Division of Oncology, Washington University School of Medicine, and principal investigator of the study. "The combination of vosaroxin and azacitidine shows promising activity in this Phase 1/Cohort Expansion study, with response rates and transplant rates in this study that are better than those observed with azacitidine alone, particularly in an older patient population. We look forward to additional follow up from this study."

In this open label, dose-escalation trial sponsored by the Washington University School of Medicine, patients with MDS who may have received up to three prior cycles of hypomethylating agent-based therapy were given vosaroxin and azacitidine for of six cycles. The Phase 1 portion of the study was designed to determine the maximum tolerated dose for use in the expansion portion of the study.

Thirteen patients were enrolled in the dose-escalation phase and 22 patients were enrolled in the expansion cohort. The maximum tolerated dose (MTD) of vosaroxin in patients with MDS was determined to be 34 mg/m2 administered on Days 1 and 4 in combination with 75 mg/m^2 azacitidine on Days 1 through 7; this dose regimen was studied in the Phase 2 cohort.

The major non-hematologic toxicities of febrile neutropenia, infections, and mucositis were expected based on the disease population and prior experiences with vosaroxin. The dose-limiting toxicities at 50 mg/m^2 vosaroxin were hyperbilirubinemia and neutropenia (both Grade 4); at 34 mg/m^2 vosaroxin, 1 of 6 patients experienced a DLT of Grade 4 mucositis. Two deaths were considered possibly treatment-related (sepsis, n=1; diffuse alveolar hemorrhage, n=1). No cardiac toxicity attributable to study treatment was observed, even with prolonged therapy.

Of the 35 patients enrolled to the study, 32 completed ≥1 cycle and were evaluable for response. Among evaluable patients, the median number of total cycles completed was 3 (range: 1-18), with 3 still continuing therapy. Best response was as follows: CR, n=8, marrow complete remission (CR), n=5; marrow CR with HI-platelets; n=3; marrow CR with HI-neutrophil, n=3; marrow CR with HI-erythroid, n=1; marrow CR with HI-platelets and neutrophils, n=1; and stable disease n=10. One patient had progressive disease (PD). Sixteen have proceeded to allogeneic stem cell transplant and 3 are actively undergoing study treatment. Additional data is expected on secondary endpoints and from correlative studies.

About QINPREZO™ (vosaroxin)

QINPREZO™ (vosaroxin) is an anti-cancer quinolone derivative (AQD), a class of compounds that has not been used previously for the treatment of cancer. Preclinical data demonstrate that vosaroxin both intercalates DNA and inhibits

topoisomerase II, resulting in replication-dependent, site-selective DNA damage, G2 arrest and apoptosis. Both the U.S. Food and Drug Administration (FDA) and European Commission have granted orphan drug designation to vosaroxin for the treatment of AML. Additionally, vosaroxin has been granted fast track designation by the FDA for the potential treatment of relapsed/refractory AML in combination with cytarabine. Vosaroxin is an investigational drug that has not been approved for use in any jurisdiction.

The trademark name QINPREZO is conditionally accepted by the FDA and the EMA as the proprietary name for the vosaroxin drug product candidate.

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 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 the continued development and commercialization of vosaroxin, the timing of our Phase 1b/2 trial of SNS-062, and the sufficiency of Sunesis' cash and funding into June 2018. Words such as "advance," "continue," "expect," "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 SNS-062 or 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, including SNS-062, the risk that Sunesis' clinical studies for vosaroxin or other product candidates, including SNS-062 or 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 timing or 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 SNS-062, vosaroxin 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, 2017 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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