Sunesis Announces Presentation of Positive Updated Results From Ongoing MD Anderson-Sponsored Trial of Vosaroxin in AML and High-Risk MDS at ASCO 2014 Annual Meeting

June 2, 2014 7:01 AM ET

SOUTH SAN FRANCISCO, Calif., June 2, 2014 (GLOBE NEWSWIRE) -- Sunesis Pharmaceuticals, Inc. (Nasdaq:SNSS) today announced the presentation of updated results from an ongoing Phase 1b/2 University of Texas MD Anderson Cancer Center-sponsored trial of Qinprezo™ (vosaroxin) in combination with decitabine in older patients with previously untreated acute myeloid leukemia (AML) and high-risk myelodysplastic syndrome (MDS). The results will be presented today at the Leukemia, Myelodysplasia, and Transplantation General Poster Session of the American Society of Clinical Oncology Annual Meeting 2014 (ASCO) in Chicago, Illinois. The poster (Poster #383, S Hall A2) is titled "Phase I/II study of vosaroxin and decitabine in older patients with acute myeloid leukemia (AML) and high risk myelodysplastic syndrome (MDS)."

The Phase 1b/2 trial is expected to enroll up to a combined total of approximately 70 patients. As previously announced, the Phase 2 cohort was initiated in October 2013, following successful completion of a Phase 1b open-label, single-arm dose optimization phase. Patients in the ongoing trial are being followed for response, leukemia-free survival, overall survival and safety. Enrollment in the trial is ongoing.

To date, 34 patients (31 AML, 3 high-risk MDS) with a median age of 70 years (range, 41-78) have been enrolled; 97% were older than 60 years and 50% were older than 70 years. Of these, 30 patients were evaluable for response; 13 patients (43%) achieved complete response (CR), 6 patients (20%) achieved CR with incomplete platelet recovery (CRp), and 3 patients (10%) achieved CR with incomplete peripheral blood count recovery (CRi), for an overall response rate of 73%. Four patients are too early for response assessment. Patients have received a median of 2 (1 - 6) treatment cycles with median number of cycles to response being 1 (1 - 4). The main grade ≥ 3 toxicity was mucositis in 8 patients (24%). No patients died during the initial 30-day induction period.

Patients were also assessed for response by baseline characteristics, including mutation status. Among them, 6 patients had a documented mutation in isocitrate dehydrogenase-2 (IDH2) and 8 patients in tumor protein 53 (TP53, or mutational p53). The overall response rate among evaluable patients with IDH2 and TP53 mutations was 100% (6/6) and 63% (5/8), respectively.

"We remain encouraged by this study's high response rates in older patients with AML and high-risk MDS, a population frequently resistant to or intolerant of therapy," said Farhad Ravandi, M.D., Professor of Medicine, Department of Leukemia, University of Texas MD Anderson Cancer Center, and a study investigator. "In particular, the broad activity of Qinprezo and decitabine across AML mutational types is compelling. This unique breadth of activity, along with good tolerability, suggests the potential for a new treatment option for this underserved patient population."

"This study, which explores a novel combination with the hypomethylating agent decitabine, further supports the encouraging clinical profile of Qinprezo, a first-in-class, anti-cancer quinolone derivative," said Adam R. Craig, M.D., Ph.D., Executive Vice President, Development and Chief Medical Officer of Sunesis. "As we prepare for unblinding of the pivotal Phase 3 VALOR trial in first relapsed or refractory AML, expected in the third or fourth quarter of 2014, we will continue to work closely with experienced investigators to explore Qinprezo's value within other segments of the AML and MDS disease spectrum."

For the trial, patients are treated with Qinprezo (70 or 90 mg/m^2) intravenously on days one and four in combination with decitabine (20 mg/m^2) on days one to five. Vosaroxin dose is 70 mg/m^2 in consolidation cycles, which are repeated in approximately four to five week intervals for a total of up to seven cycles. Dose adjustments and dose delays of one or both agents are allowed based on toxicity. Patients are eligible if they had AML or high-risk MDS (defined as having $\geq 10\%$ blasts in the bone marrow), are 60 years of age or older, and have adequate performance status (ECOG ≤ 2) and organ function. Patients younger than 60 who are unsuited for standard chemotherapy are also eligible. The primary endpoint of the study is to determine the overall combined complete response rate. Secondary endpoints include CR duration, disease-free survival, overall survival, safety and early mortality.

The MD Anderson Cancer Center-sponsored trial is being conducted under the direction of Naval Daver, M.D., Assistant Professor, Department of Leukemia, University of Texas MD Anderson Cancer Center, and Dr. Ravandi. Dr. Ravandi is also a principal investigator of the Phase 3 VALOR trial, the company's randomized, double-blind, placebo-controlled, pivotal trial of Qinprezo plus cytarabine in patients with first relapsed or refractory AML.

About Qinprezo™ (vosaroxin)

Qinprezo™ (vosaroxin) is a first-in-class anti-cancer quinolone derivative (AQD), a class of compounds that has not been used previously for the treatment of cancer. Qinprezo 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, Qinprezo has been granted fast track designation by the FDA for the potential treatment of relapsed or refractory AML in combination with cytarabine. Qinprezo is an investigational drug that has not been approved for use in any jurisdiction.

About AML

AML is a rapidly progressing cancer of the blood characterized by the uncontrolled proliferation of immature blast cells in the bone marrow. The American Cancer Society estimates there will be approximately 18,860 new cases of AML and approximately 10,460 deaths from AML in the U.S. in 2014. Additionally, it is estimated that the prevalence of AML across major global markets (U.S., France, Germany, Italy, Spain, United Kingdom and Japan) is over 50,000. AML is generally a disease of older adults, and the median age of a patient diagnosed with AML is about 67 years. AML patients with relapsed or refractory disease and newly diagnosed AML patients over 60 years of age with poor prognostic risk factors typically die within one year, resulting in an acute need for new treatment options for these patients.

About MDS

MDS is a hematopoietic stem cell neoplasm that features dysplasia of the myeloid lineage. Hematopoiesis in these patients is disordered and ineffective. As the number and quality of blood-forming cells decline irreversibly, blood production is further impaired and patients often develop severe anemia requiring frequent blood transfusions. In most cases, the disease worsens and the patient develops neutropenia and thrombocytopenia caused by progressive bone marrow failure. In about one third of patients with MDS, the disease progresses into AML, usually within months to a few years.

About Sunesis Pharmaceuticals

Sunesis is a biopharmaceutical company focused on the development and commercialization of new oncology therapeutics for the treatment of solid and hematologic cancers. Sunesis has built a highly experienced cancer drug development organization committed to advancing its lead product candidate, Qinprezo, in multiple indications to improve the lives of people with cancer. For additional information on Sunesis, please visit http://www.sunesis.com.

This press release contains forward-looking statements, including statements related to Sunesis' overall strategy, the design, conduct, progress, timing and results of the VALOR trial and Sunesis' other clinical trials, the sufficiency of Sunesis' financial resources and the commercial potential for Qinprezo™ (vosaroxin). Words such as "anticipate," "approximately," "believe," "compelling," "continue," "could," "estimate," "expect," "explore," "potential," "remain," "suggest," "support," 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, risks related to Sunesis' need for substantial additional funding to complete the development and commercialization of Qinprezo, risks related to whether outstanding warrants will be exercised in the future, 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 Qinprezo, the risk that raising funds through lending arrangements may restrict our operations or produce other adverse results, the risk that Sunesis' development activities for Qinprezo could be otherwise halted or significantly delayed for various reasons, the risk that Sunesis' clinical studies for Qinprezo 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, the risk that Sunesis' nonclinical studies and clinical studies may not satisfy the requirements of the FDA, European Commission or other regulatory agencies, risks related to the conduct of Sunesis' clinical trials, risks related to the manufacturing of Qinprezo and supply of the active pharmaceutical ingredients required for the conduct of Sunesis' clinical trials, the risk of third party opposition to granted patents related to Qinprezo, and the risk that Sunesis' proprietary rights may not adequately protect Qinprezo. 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, 2013, Sunesis' Quarterly Report on Form 10-Q for the quarter ended March 31, 2014, 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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