Sunesis Announces Presentation of Positive Results From Ongoing MD Anderson-Sponsored Trial of Vosaroxin in AML and High-Risk MDS

April 8, 2014 8:00 AM ET

Data Presented at AACR 2014 Annual Meeting

Company to Host Conference Call Today at 8:00 AM Pacific Time

SOUTH SAN FRANCISCO, Calif., April 8, 2014 (GLOBE NEWSWIRE) -- Sunesis Pharmaceuticals, Inc. (Nasdaq:SNSS) today announced the presentation of results from an ongoing Phase 1b/2 University of Texas MD Anderson Cancer Center-sponsored trial of 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 Phase II/III Clinical Trials Poster Session of the American Association for Cancer Research Annual Meeting 2014 (AACR) in San Diego, California. The poster (Poster #7, Hall A-E, Poster Section 38) 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 of the Phase 1b/2 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 rate of response, leukemia-free survival, overall survival and safety. To date, the combination of vosaroxin and decitabine has been found to be effective and well tolerated in older patients with AML and high-risk MDS. Twenty four patients are evaluable for response; 9 (38%) achieved complete response (CR), 5 (21%) achieved CR with incomplete platelet recovery (CRp), and 2 (8%) achieved CR with incomplete peripheral blood count recovery (CRi), for an overall response rate of 67%. The main grade ≥ 3 toxicity was mucositis in 6 (6/29, 21%) patients. No patients died during the initial 30-day induction period. Enrollment in the trial is ongoing.

"The treatment of older patients with AML or high-risk MDS presents particular challenges, including many patients not tolerating or responding to existing therapies," said Farhad Ravandi, M.D., Professor of Medicine, Department of Leukemia, University of Texas MD Anderson Cancer Center, and a study investigator. "Emerging outcomes from this trial suggest that vosaroxin and decitabine hold meaningful promise as a potential new combination treatment option for this population. The high number of complete remissions with good tolerability are highly encouraging and make this trial a designated priority for our center."

"Vosaroxin's activity against genetically heterogeneous diseases like AML and high-risk MDS is driven by its unique characteristics as a first-in-class, anti-cancer quinolone derivative – properties that appear to combine well with the anti-leukemic activity of decitabine, a hypomethylating agent, to provide a much higher rate of remission than would be expected from decitabine alone," said Adam R. Craig, M.D., Ph.D., Executive Vice President, Development and Chief Medical Officer of Sunesis. "These encouraging results support our goal of elucidating vosaroxin's full clinical benefit in different patient segments as well as in new treatment combinations. We look forward to additional progress in this study and to working closely with MD Anderson and our growing list of experienced investigators to explore vosaroxin's value within AML and MDS."

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 vosaroxin plus cytarabine in patients with first relapsed or refractory AML.

Results in Detail

For the trial, patients were treated with vosaroxin (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 was reduced to 70 mg/m^2 in consolidation cycles, which were 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 were allowed based on toxicity. Patients were eligible if they had AML or high-risk MDS (defined as having $\geq 10\%$ blasts in the bone marrow), were 60 years of age or older, and had adequate performance status (ECOG ≤ 2) and organ function. Patients younger than 60 who were unsuited for standard chemotherapy were also eligible. The primary endpoint of the study is to determine the CR rate. Secondary endpoints include CR duration, disease-free survival, overall survival, safety and early mortality.

To date, 29 patients (25 AML, 4 high-risk MDS) with a median age of 73 years (range, 41-78) have been enrolled; 97% were older than 60 years and 59% were older than 70 years. Of these, 24 patients were evaluable for response; 9 (38%) achieved CR, 5 (21%) achieved CRp, and 2 (8%) achieved CRi, for an overall response rate of 67%. One patient without a response after cycle one is currently undergoing re-induction. Five 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 regimen was found to be well tolerated. The main grade ≥ 3 toxicity was mucositis in 6 (6/29, 21%) patients. No patients died during the initial 30-day induction period.

Conference Call Information

Sunesis will host a conference call today, April 8th at 8:00 a.m. Pacific Time. Dr. Farhad Ravandi will join the Sunesis senior management team in a discussion of the poster. The call can be accessed by dialing (866) 700-6067 (U.S. and Canada) or (617) 213-8834 (international), and entering passcode 34122691. To access the live audio webcast, or the subsequent archived recording, visit the "Investors and Media - Calendar of Events" section of the Sunesis website at www.sunesis.com. The webcast will be recorded and available for replay on the company's website for two weeks.

About Vosaroxin

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. 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 or refractory AML in combination with cytarabine.

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, vosaroxin, 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's overall strategy, the design, conduct, progress, timing and results of Sunesis' clinical trials and the commercial potential for vosaroxin. Words such

as "approximately," "believe," "effective," "encouraging," "expected," "explore," "look forward," "meaningful," "potential," "promise," "responding," "well tolerated" 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 vosaroxin, 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 vosaroxin, the risk that raising funds through lending arrangements may restrict our operations or produce other adverse results, the risk that Sunesis' development activities for vosaroxin could be otherwise halted or significantly delayed for various reasons, the risk that Sunesis' clinical studies for vosaroxin 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 vosaroxin 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 vosaroxin, and the risk that Sunesis' proprietary rights may not adequately protect vosaroxin. 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 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.

CONTACT: Investor and Media Inquiries:
David Pitts
Argot Partners
212-600-1902

Eric Bjerkholt
Sunesis Pharmaceuticals Inc.
650-266-3717

Sunesis Pharmaceuticals, Inc.