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

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SOUTH SAN FRANCISCO, Calif., Dec. 8, 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 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 in an oral session titled "Acute Myeloid Leukemia: Novel Therapy, excluding Transplantation: New Drugs II" taking place from 10:30 AM to 12:00 PM PT at the 56th American Society of Hematology Annual Meeting in San Francisco, California. The presentation (abstract 385, Gateway Ballroom 103), titled "Phase I/II Study of Vosaroxin and Decitabine in Newly Diagnosed Older Patients (pts) with Acute Myeloid Leukemia (AML) and High Risk Myelodysplastic Syndrome (MDS)," is available at www.sunesis.com.

The Phase 1b/2 trial is expected to enroll up to a total of approximately 70 patients. Patients in the ongoing trial are being followed for response, leukemia-free survival, overall survival and safety. To date, 41 patients (38 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 51% were older than 70 years. Of the 37 patients evaluable for response, 22 patients (59%) achieved complete response (CR), 5 patients (14%) achieved CR with incomplete platelet recovery (CRp), and 1 patient (3%) achieved CR with incomplete peripheral blood count recovery (CRi), for an overall response rate of 76%. Preliminary median overall survival was 8.3 months. Median duration of response for patients achieving CR/CRp/CRi has not been reached. Patients have received a median of 2 (1 - 7) treatment cycles with median number of cycles to response being 1 (1 - 4). Six patients (16%) have proceeded to allogeneic stem cell transplant (ASCT) and 6 patients have relapsed.

Four-week and 8-week mortality were 0% and 14%, respectively. Infection related toxicities were the most common Grade ≥3 adverse events. Grade ≥3 toxicity was mucositis was observed in 11 patients (30%).

Patients were also assessed for response by baseline characteristics, including mutation status. Responses among these patients were as follows:

Parameter	Category	Overall response
Age*	60-69	14/17 (82%)
	>70	13/19 (68%)
Cytogenetics	Diploid	11/15 (73%)
	-5/-7/other adverse	9/13 (69%)
	Miscellaneous	7/8 (88%)
	Insufficient metaphases	1/1
Mutation Status	IDH2	7/7 (100%)
	IDH1	2/5 (45%)
	TP53	7/10 (70%)
	RAS	4/9 (44%)

*1 patient below the age of 60 years was unsuitable for standard chemotherapy and was enrolled on study.

"As with virtually all patient populations with this disease, older patients who are not candidates for standard frontline chemotherapy have few treatment options and poor prognoses," said Naval Daver, M.D., Assistant Professor, Department of Leukemia, University of Texas MD Anderson Cancer Center, and a study investigator. "In this study, we

continue to see good tolerability and a high, durable response rate in the overall population, and among patients with both different baseline characteristics and various mutational statuses. In diseases as genetically heterogeneous as AML and MDS, these results suggest the potential for an important new treatment option across this underserved patient population."

"As we see in our Phase 3 VALOR study, the high response rates observed with vosaroxin used in various treatment combinations suggests clinical benefit in the context of a manageable safety profile," said Adam R. Craig, M.D., Ph.D., Executive Vice President, Development and Chief Medical Officer of Sunesis. "We look forward to continuing to work closely with experienced investigators to explore vosaroxin's value within other segments of the AML and MDS disease spectrum."

For the trial, patients are treated with vosaroxin (70 or 90 mg/m2) intravenously on days one and four in combination with decitabine (20 mg/m2) on days one to five. Vosaroxin dose is 70 mg/m2 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 ≥ 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.

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 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 QINPREZO 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.

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

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 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.

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This press release contains forward-looking statements, including statements related to Sunesis' overall strategy, the design, conduct, progress, timing and results of Sunesis' clinical trials, the preliminary analysis, assessment and conclusions of the results of the VALOR trial and Sunesis' other clinical trials, and the efficacy and commercial potential of vosaroxin. Words such as "believe," "expect," "explore," "look forward," "potential," "suggest," "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, risks related to Sunesis' need for substantial additional funding to complete the development and commercialization of QINPREZO*, 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 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, risks related to the conduct of Sunesis' clinical trials, and the risk that Sunesis' clinical studies for vosaroxin may not lead to regulatory approval. 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, including Sunesis' Quarterly Report on Form 10-Q for the quarter ended September 30, 2014. 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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