Sunesis Pharmaceuticals Announces Presentation of Positive Results From MD Anderson Sponsored Trial in AML at ASH Annual Meeting

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SOUTH SAN FRANCISCO, Calif., Dec. 7, 2015 (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 myelodyplastic syndrome (MDS). The results are being presented today at 8:00 AM in an oral session titled "Acute Myeloid Leukemia: Novel Therapy, excluding Transplantation: New Epigenetic Approaches" taking place from 7:00 AM to 8:30 AM ET at the 56th American Society of Hematology Annual Meeting in Orlando, Florida. The presentation (abstract 461, Orange County Convention Center, W109), titled "Phase I/II Study of Vosaroxin and Decitabine in Newly Diagnosed Older Patients (pts) with Acute Myeloid Leukemia (AML) and High Risk Myelodyplastic Syndrome (MDS)," is available at www.sunesis.com.

"Inability to tolerate frontline chemotherapy greatly limits treatment options and worsens prognoses among older patients with newly diagnosed AML and MDS," said Naval Daver, M.D., Assistant Professor, Department of Leukemia, University of Texas MD Anderson Cancer Center, and a study investigator. "This study demonstrates compelling outcomes both for the high rate of complete remission seen with vosaroxin and decitabine, historically the best predictor or overall survival, and the tolerability of the combination. Particularly noteworthy are outcomes in patients who received the 70 mg/m^2 induction dose of vosaroxin, where early mortality is low and overall survival is very promising."

To date, 61 patients (54 AML, 7 high-risk MDS) with a median age of 69 years (range, 60-78) have been enrolled in the Phase 1b/2 trial. All 61 patients have completed at least 2 cycles of therapy and were evaluable for response: 32 patients (52%) achieved complete response (CR), 9 patients (15%) achieved CR with incomplete platelet recovery (CRp), and 4 patients (7%) achieved CR with incomplete peripheral blood count recovery (CRi) for an overall response rate of 74%. Minimal residual disease (MRD) by 19 color flow-cytometry was evaluable in 33 of the 45 responders. MRD was not detectable in 22 of 33 (67%) evaluable responders. The median number of cycles to response was 1; 15 patients have required >1 cycle to achieve response. Eleven (19%) patients have proceeded to allogeneic stem cell transplant. The median follow-up is 7.7 months (2.2 – 24.5). The regimen was well tolerated with the main therapy related grade 3 or higher non-infectious toxicities being mucositis in 11 (18%) patients and elevated bilirubin in 8 (13%) patients.

Median overall survival (OS) for all patients is 8.8 months. Four-week and 8-week mortality for all patients were 0 and 13%, respectively. The induction dose of vosaroxin was 90 mg/m2 in 22 patients and 70 mg/m2 in 39 patients. The lower induction dose of vosaroxin was associated with a reduced early mortality and an improved overall response rate and OS, as follows:

Induction dose (vosaroxin)	**N**	**Med OS**	**8-week mortality**	**Overall Response**	**CR**	**Need >1 cycle to response**
90 mg/m^2	22	5.5 mos	27%	73%	41%	19%
70 mg/m^2	39	10.9 mos	5%	77%	62%	40%

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

Parameter	**Category**	**N**	**Overall response**	**CR**

Age	60-69	29	78%	57%
	>/=70	17	71%	42%
Cytogenetics	Diploid	19	83%	57%
	Miscellaneous	13	76%	63%
	-5/-7/other adverse	14	67%	42%
Mutation	*IDH2*	10	91%	73%
Status	*TP53*	9	75%	55%
	RAS	6	67%	28%
	IDHT	3	33%	43%

"This trial continues to reinforce observations from VALOR and other studies of vosaroxin, in the front-line and relapsed refractory AML settings, demonstrating that vosaroxin can become a new backbone of treatment and in combination with other important therapeutic candidates can increase the rates of complete response, translating to promising overall survival," said Daniel Swisher, Chief Executive Officer of Sunesis. "We look forward to exploring vosaroxin's treatment potential within other segments of the AML and MDS disease spectrum through a comprehensive program of investigator-led and Sunesis-led 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 or 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 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' expected progress in its kinase inhibitor pipeline. Words such as "may," "expect," "intends," "plan," "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' clinical studies for its product candidates 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, risks related to Sunesis' need for substantial

additional funding to complete the development and commercialization of vosaroxin, 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. These and other risk factors are discussed under "Risk Factors" and elsewhere in Sunesis' Quarterly Report on Form 10-Q for the quarter ended September 30, 2015. 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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