Sunesis Pharmaceuticals Announces Presentation of Positive Results from MD Anderson Sponsored Trial in Frontline Elderly AML and MDS at the EHA Annual Meeting

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SOUTH SAN FRANCISCO, Calif., June 13, 2016 (GLOBE NEWSWIRE) -- Sunesis Pharmaceuticals (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 were presented Saturday in an oral session titled "New Compounds in AML Treatment" at the 21st Congress of the European Hematology Association (EHA) in Copenhagen, Denmark. The presentation (abstract S505, Bella Center, Hall A3), titled "Phase I/ll study of vosaroxin and decitabine in newly diagnosed older patients with acute myeloid leukemia and high-risk myelodysplastic syndrome," is available at www.sunesis.com.

"Older patients diagnosed with AML and MDS have limited treatment options and exceedingly poor outcomes," said Naval Daver, M.D., Assistant Professor, Department of Leukemia, University of Texas MD Anderson Cancer Center, and a study investigator. "At the optimized induction dose of 70 mg/m^2 of vosaroxin, the combination of vosaroxin and decitabine demonstrates a compelling CR/CRp/CRi rate of 76% and a median overall survival of 16.1 months. This response rate and survival are significantly better than seen with single-agent decitabine among similar patients at our institution. This outcome was achieved with <5% induction mortality and good tolerability. In this vosaroxin-decitabine cohort, 23 of 41 patients remain alive."

Daniel Swisher, CEO of Sunesis, added: "We believe these results warrant further exploration in a larger outcome study, with plans currently under review to conduct a multicenter clinical trial comparing vosaroxin plus decitabine and vosaroxin plus cytarabine to the 7+3 regimen in patients with AML."

To date, 63 patients (56 AML, 7 high-risk MDS) with a median age of 69 years (range 60-78) have been enrolled in the trial. All 63 patients have completed at least 2 treatment rounds, rendering them evaluable for response; with a 75% overall response rate, 49% (31 patients) achieved complete remission (CR), 17% (11 patients) achieved CR with incomplete platelet recovery (CRp), and 8% (5 patients) achieved CR with incomplete peripheral blood count recovery (CRi). The therapy was well-tolerated, with the main therapy related grade 3 or higher toxicities being mucositis in 11 (17%) patients.

Initially for the first 22 patients in the study, the selected induction dose of vosaroxin was 90 mg/m^2. Thereafter to reduce the incidence of mucositis, the induction dose was reduced to 70 mg/m^2 for the next 41 patients. The lower dose of vosaroxin in combination with decitabine was associated with reduced early mortality and an improved overall response rate and OS, as follows:

Induction Dose (vosaroxin)	**N**	**Median OS**	**8-week Mortality**	**Overall Response**	**Need >1 Cycle to Response**
90 mg/m^2	22	5.5	27 %	73 %	19 %
70 mg/m^2	41	16.1	5 %	76 %	42 %

Sunesis also announced that follow-up data from the company's VALOR trial was presented as an e-poster during the EHA meeting. The poster (abstract E930, Bella Center, E-Poster Screens), titled "Characterization of patients with relapsed or refractory AML in continued follow-up after treatment with vosaroxin/cytarabine vs placebo/cytarabine in the VALOR trial," shows that, as of January 22, 2016, 83 of 711 patients enrolled in VALOR remain alive (46/356 in the vosaroxin/cytarabine arm, 37/355 in the placebo/cytarabine arm) and in follow up, which has reached a median of 40

months. In patients ≥60 years, more than twice as many patients were alive in the vosaroxin/cytarabine arm (23 vs. 10 patients).

All but seven patients in this follow up underwent allogeneic hematopoietic stem cell transplant (HCT). Of note, the non-HCT survivors were all in the vosaroxin/cytarabine treatment arm (68-71 years old, 2 primary refractory and 5 early relapsed).

Mr. Swisher added: "We are encouraged by the long-term benefit seen in the VALOR follow-up and also the potential for vosaroxin and cytarabine to provide long-term benefit in older patients who need more options."

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 improving the lives of people with cancer and is currently pursuing regulatory approval in Europe for its lead product candidate, vosaroxin, for the treatment of relapsed or refractory acute myeloid leukemia in patients aged 60 and older. In addition, the company is advancing its kinase-inhibitor pipeline of novel targeted therapies into the clinic.

For additional information on Sunesis, please visit http://www.sunesis.com.

This press release contains forward-looking statements, including statements related to Sunesis' corporate objectives, including the anticipated progress and potential approval of vosaroxin by the EMA, and further clinical development of vosaroxin,. Words such as "believe," "look forward," "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 may not be able to receive regulatory approval of vosaroxin in the U.S. or Europe, that Sunesis' development activities for vosaroxin could be otherwise halted or significantly delayed for various reasons, the risk that Sunesis' clinical studies for vosaroxin or other product candidates, including 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 conduct of Sunesis' clinical trials, risks related to Sunesis' need for substantial additional funding to complete the development and commercialization of vosaroxin and other product candidates, 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 and other product candidates. 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, 2015, Sunesis' Quarterly Report on Form 10-Q for the quarter ended March 31, 2016, when available, 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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