Sunesis Announces Publication of Vosaroxin Phase 3 VALOR Trial Results in The Lancet Oncology

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SOUTH SAN FRANCISCO, Aug. 4, 2015 (GLOBE NEWSWIRE) -- Sunesis Pharmaceuticals, Inc. (Nasdaq:SNSS) today announced that results from the Company's Phase 3 VALOR trial of vosaroxin and cytarabine in 711 patients with relapsed or refractory acute myeloid leukemia (AML) were published in the *The Lancet Oncology*. The VALOR results were first announced by the company on October 6, 2014. The article, titled "Vosaroxin plus cytarabine versus placebo plus cytarabine in patients with first relapsed or refractory acute myeloid leukaemia (VALOR): a randomised, controlled, double-blind, multinational, phase 3 study" is available online first at http://www.thelancet.com/journals/lanonc/article/PIIS1470-2045(15)00201-6/abstract and will appear in the September 2015 print issue of *The Lancet Oncology*.

The results published in *The Lancet Oncology* describe how vosaroxin plus cytarabine, based on prespecified analyses, is the first regimen to show an overall survival benefit in relapsed/refractory AML, with the greatest benefit observed in patients older than 60 years, a population with limited treatment options.

Although no significant difference was observed in the primary endpoint of overall survival (OS) between groups (unstratified analysis, median 7.5 months for vosaroxin and cytarabine [vos/cyt] vs 6.1 months for placebo and cytarabine [pla/cyt], HR=0.87, p=0.061), OS was significantly prolonged in a predefined analysis that stratified by factors used in randomization (stratified log-rank p=0.024). This was supported by a sensitivity analysis of OS censoring for subsequent transplant (median 6.7 months [vos/cyt] vs 5.3 months [pla/cyt], HR=0.81, p=0.024). Prespecified subgroup analyses according to randomization strata demonstrated that OS benefit with vosaroxin was greatest in patients age ≥60 years (7.1 months [vos/cyt] vs 5.0 months [pla/cyt], HR=0.75; p=0.0030). Median OS was not significantly different between treatment arms in patients age <60 years (HR=1.08; p=0.60).

"The results of VALOR suggest that the combination of vosaroxin and cytarabine could be an important new treatment option for salvage therapy in patients older than 60 years of age," stated Dr. Farhad Ravandi, M.D., Professor of Medicine, Department of Leukemia, University of Texas MD Anderson Cancer Center, and lead author of the publication. "This is particularly meaningful in the context of how little progress has been made in the treatment of this disease in the last forty years. In the last decade alone, no novel agents or regimens studied in randomized trials of relapsed/refractory AML have demonstrated an overall survival benefit. Given the risk-benefit demonstrated in VALOR, and the dire need in AML, I believe this combination represents an important step forward in the treatment of this disease."

The complete remission (CR) rate, the sole secondary efficacy endpoint in the VALOR trial, was significantly greater with vosaroxin (30.1% vs 16.3% with pla/cyt, p<0.0001). Combined complete remission rate was 37.1% and 18.6% for the vos/cyt and pla/cyt treatment arms, respectively (p<0.0001). Prespecified subgroup analyses demonstrated significantly higher response rates for vos/cyt-treated patients across all randomization strata except for those less than 60 years of age, with the most pronounced improvement in patients aged ≥60 years (CR: 31.9% for vos/cyt vs 13.8% for pla/cyt; p<0.0001). A higher proportion of patients in the vos/cyt arm achieved CR with study drug prior to transplant (48% vos/cyt; 32% pla/cyt). In patients with CR, median leukemia-free survival (LFS) was 11.0 months with vos/cyt vs 8.7 months with pla/cyt (HR=0.89; p=0.63). Event-free survival (EFS) was significantly prolonged in vos/cyt-treated patients (HR=0.67; p<0.0001).

Thirty-day and 60-day all-cause mortality was similar in the two treatment arms (30-day: 7.9% vs 6.6%; 60-day: 19.7% vs 19.4% for vos/cyt vs pla/cyt, respectively). Grade 3 and higher adverse events (AEs) were primarily related to myelosuppression, infection, and gastrointestinal events. Serious AEs attributed to study drug were more frequent in the vos/cyt arm, including febrile neutropenia, infections, and gastrointestinal mucosal toxicity. Importantly, there was no increase in the incidence of organ-specific toxicity (cardiac, renal, hepatic, or pulmonary) in the vos/cyt arm compared to the pla/cyt arm.

"Publication of the results from VALOR in *The Lancet Oncology* supports our goal of establishing vosaroxin as the first

meaningful advancement in the standard of care for patients with relapsed and refractory AML," said Adam Craig, Chief Medical Officer of Sunesis. "As we work to determine a path forward toward its registration in Europe and the United States, we also look forward to the continued investigation of vosaroxin in AML, myelodysplastic syndrome and other malignancies through investigator-sponsored studies."

About the VALOR Trial

VALOR is a randomized, double-blind, placebo-controlled Phase 3 trial which enrolled 711 adult patients with first relapsed or refractory acute myeloid leukemia (AML) and was conducted at 124 leading sites in 15 countries. Patients were stratified for age, geographic region and disease status and randomized one-to-one to receive either vosaroxin and cytarabine or placebo and cytarabine.

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 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 that there will be approximately 20,830 new cases of AML and approximately 10,460 deaths from AML in the U.S. in 2015. 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 75,000. 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 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' overall strategy, the design, conduct and results of Sunesis' clinical trials, including the analysis, assessment and conclusions of the results of the VALOR trial, the commercial potential of vosaroxin, estimated new cases of AML, its prevalence across major global markets, prognosis for patients with AML, the need for and the role of vosaroxin as a potential new treatment option, and Sunesis' clinical development of vosaroxin, including the analysis of the results from the VALOR clinical trial. Words such as "suggest," "potential," "supports," "will," "believe" 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' 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, risks related to the conduct of Sunesis' clinical trials, the risk that Sunesis' clinical studies for vosaroxin may not lead to regulatory approval, 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 June 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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