Sunesis Pharmaceuticals Presents New Data From VALOR Evaluating Vosaroxin in Older Patients With Acute Myeloid Leukemia at the 20th Congress of the European Hematology Association

June 12, 2015 7:00 AM ET

Sunesis to Host Conference Call and Webcast Today at 10:00 AM Eastern Time

SOUTH SAN FRANCISCO, Calif., June 12, 2015 (GLOBE NEWSWIRE) -- Sunesis Pharmaceuticals, Inc. (Nasdaq:SNSS) announced today additional results of the VALOR trial, a Phase 3 study of vosaroxin and cytarabine in adult patients with relapsed or refractory acute myeloid leukemia (AML). The results are being presented today, Friday, June 12th from 5:15 p.m. to 6:45 p.m. Central European Time at the acute myeloid leukemia (AML) poster session of the 20th Congress of the European Hematology Association (EHA) taking place in Vienna, Austria.

VALOR is a randomized, double-blind, placebo-controlled Phase 3 trial which enrolled 711 adult patients with first relapsed or refractory AML 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. Detailed results of the VALOR trial were presented in the "Late Breaking Abstracts" session of the American Society of Hematology (ASH) Annual Meeting in December 2014. Data from the post-hoc analysis of VALOR patients age 60 years and older who received allogeneic transplant after treatment with vosaroxin or placebo plus cytarabine were presented at the American Society of Clinical Oncology Annual Meeting in May 2015 and now at the EHA Congress.

Among the new data presented today are detailed results from the subgroups of patients age 60 years and older (451 out of 711 enrolled in VALOR) with late relapse (n=87) and refractory and early relapse disease (combined n=364).

Among patients with late relapse disease, overall survival (OS) and leukemia-free survival (LFS) were comparable between treatment arms. The complete remission (CR) rate was 57% and 28% (p=0.0064) and event-free survival (EFS) was 5.5 months versus 2.3 months (HR=0.65, p=0.0852) for vosaroxin/cytarabine and placebo/cytarabine, respectively. Thirty- and 60-day all-cause mortality among these patients was 11% and 18% versus 2% and 14% for vosaroxin/cytarabine and placebo/cytarabine, respectively.

Among patients with refractory and early relapse disease (combined n=364), a population known to have poorer outcomes, OS was 6.5 months versus 3.9 months for vosaroxin/cytarabine and placebo/cytarabine, respectively (HR=0.69, p=0.0008). CR rates in this population were 26% and 10% (p=0.0001) for vosaroxin/cytarabine and placebo/cytarabine, respectively. Among these patients, LFS was 9.7 months versus 5.5 months (HR=0.50, p=0.0424) and EFS was 1.7 months versus 1.3 months (HR=0.59, p<0.0001) for vosaroxin/cytarabine and placebo/cytarabine, respectively. Thirty- and 60-day all-cause mortality among these patients was comparable, at 10% and 21% versus 11% and 25% for vosaroxin/cytarabine and placebo/cytarabine, respectively.

In all patients age 60 years and older, Grade 3 or higher non-hematologic adverse events that were more common in the vosaroxin combination arm were gastrointestinal and myelosuppression-related toxicities, consistent with those observed in previous company trials. The rate of serious adverse events related to treatment was 74% and 60% for vosaroxin/cytarabine and placebo/cytarabine, respectively.

"AML is a disease that primarily affects older patients, and clinical outcomes among these patients is abysmal," said Farhad Ravandi, M.D., Professor of Medicine, Department of Leukemia, University of Texas MD Anderson Cancer Center, and a principal investigator of the VALOR study. "These patients have had few options outside of clinical trial enrollment. Results from the analyses presented today show compelling survival and durable responses with comparable early mortality for the vosaroxin and cytarabine treatment arm in the older refractory and early relapse patients. Given these results, I believe vosaroxin represents an important new treatment option."

"In over four decades of research, there has been far too little progress in the treatment of AML," said Patricia J.

Goldsmith, CEO of CancerCare®. "This need is particularly pronounced in those patients age 60 and older with the fewest options. Progress for these patients cannot wait."

The two poster presentations (Abstracts #4192 and #4693, Hall C), titled "Improved survival in patients ≥60 with first relapsed/refractory acute myeloid leukemia treated with vosaroxin plus cytarabine vs placebo plus cytarabine: results from the Phase 3 VALOR study" and "Allogeneic transplant in patients ≥60 years of age with first relapsed or refractory acute myeloid leukemia after treatment with vosaroxin or placebo plus cytarabine: results from VALOR," will be available on the Sunesis website at www.sunesis.com. In addition, an E-poster, titled "Impact of cytogenetics on clinical outcomes in patients with first relapsed or refractory acute myeloid leukemia treated with vosaroxin plus cytarabine: results from VALOR," is on display at EHA through tomorrow, Saturday, June 13th at 6:45 p.m. Central European Time.

Conference Call and Webcast Information

Sunesis will host a conference call and slide webcast today, June 12th at 10:00 a.m. Eastern Time. The call can be accessed by dialing (866) 515-2908 (U.S. and Canada) or (617) 399-5122 (international), and entering passcode 93595855. 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 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, and the need for and the role of vosaroxin as a new treatment options, Sunesis' clinical development of vosaroxin, including the analysis of the results from VALOR clinical trial. Words such as "estimate," "potential," "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 March 31, 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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