Sunesis Announces Results From Pivotal Phase 3 VALOR Trial of Vosaroxin and Cytarabine in Patients With First Relapsed or Refractory Acute Myeloid Leukemia

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Trial Does Not Reach Primary Endpoint of Statistically Significant Improvement in Overall Survival

Shows Significant Survival Benefit when Censored for Transplant

Safety Profile Consistent with that Observed in Previous Company Trials

Company Plans to Commence European Filing and Explore U.S. Regulatory Pathway

Sunesis to Host Conference Call and Webcast Today at 8:30 AM Eastern Time

SOUTH SAN FRANCISCO, Calif., Oct. 6, 2014 (GLOBE NEWSWIRE) -- Sunesis Pharmaceuticals, Inc. (Nasdaq:SNSS) today announced results from the pivotal Phase 3 VALOR trial, a randomized, double-blind, placebo-controlled trial of vosaroxin and cytarabine in patients with first relapsed or refractory acute myeloid leukemia (AML). At more than 100 leading international sites, the trial enrolled 711 patients, who were stratified for age, geography and disease status. The trial did not meet its primary endpoint of demonstrating a statistically significant improvement in overall survival, with a median overall survival of 7.5 months for vosaroxin and cytarabine compared to 6.1 months for placebo and cytarabine (HR=0.865, p=0.06). Because transplant may confound the primary analysis, a predefined analysis of overall survival censoring for stem cell transplantation was planned. In this analysis, patients receiving the vosaroxin combination had a median overall survival of 6.7 months versus 5.3 months for placebo and cytarabine (HR=0.809, p=0.02). The trial also demonstrated a clinically significant benefit in complete remission (CR) rate (30.1% vs 16.3%, p=0.0000148), the secondary endpoint.

For age, the trial stratified patient populations into age 60 years and older and younger than 60 years at enrollment. Within a predefined analysis of patients younger than 60 years (n=260), where the rate of stem cell transplant was 45.8%, the vosaroxin combination demonstrated a median overall survival of 9.1 months, versus 7.9 months for placebo and cytarabine (HR=1.079, p=NS), and a CR rate of 26.9% versus 20.8% (p=0.24). In the analysis of patients aged 60 years and older (n=451), where the rate of stem cell transplant was 20.2%, the vosaroxin combination demonstrated a median overall survival of 7.1 months, versus 5.0 months for placebo and cytarabine (HR=0.755, p=0.006), and a CR rate of 31.9% versus 13.8% (p=0.0000048).

In the intent-to-treat population, Grade 3 or higher non-hematologic adverse events that were more common in the vosaroxin combination arm were gastrointestinal and infection-related toxicities, consistent with those observed in previous company trials. The rate of serious adverse events was 55.5% in the vosaroxin combination arm compared to 35.7% in the placebo and cytarabine arm. Thirty-day and 60-day all-cause mortality were comparable between the trial arms (7.9% versus 6.6% and 19.7% versus 19.4%, for the vosaroxin combination versus placebo and cytarabine, respectively).

Based on results of the trial, Sunesis plans to commence a marketing authorization application with the European Medicines Agency (EMA) and to meet with the U.S. Food and Drug Administration to determine the appropriate regulatory path forward.

The results reported above are based upon Sunesis' analysis of the data to date. Detailed results of the VALOR trial will be submitted for presentation at an upcoming medical conference.

"VALOR was a robust, well-conducted trial, among the largest in the relapsed or refractory AML setting. The study outcomes are very encouraging, and I look forward to a full presentation of the data in a peer-reviewed forum," said Robert

Stuart, M.D., Professor of Medicine, Division of Hematology/Oncology, Department of Medicine, Medical University of South Carolina, an investigator in the VALOR study and chairman of the study's steering committee. "The clinical benefit is particularly impressive in patients aged 60 years and older, a population for whom there is no therapeutic standard of care."

"There remains an acute need for new treatment options in AML, particularly relapsed refractory patients, where no therapy has demonstrated a survival benefit in a pivotal Phase 3 trial in more than 40 years," said Adam Craig, M.D., Ph.D., Executive Vice President, Development and Chief Medical Officer of Sunesis. "While we continue to evaluate the findings of VALOR in their totality, we believe the results demonstrate a clinically meaningful and important advancement in the treatment of this disease."

"We are deeply grateful for the support and commitment of the AML investigators, the patients and families who took part in or contributed to VALOR," said Daniel Swisher, Chief Executive Officer of Sunesis. "We look forward to presenting these data in detail to regulators in both Europe and the U.S. and to reporting on our progress and plans as they develop."

Conference Call and Webcast Information

Sunesis will host a conference call today, October 6, 2014, at 8:30 a.m. Eastern Time. The call can be accessed by dialing (866) 953-6856 (U.S. and Canada) or (617) 399-3480 (international), and entering passcode 37368874. To access the live audio, 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 Sunesis' 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 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' regulatory strategy (including plans to commence a marketing authorization filing with the EMA), Sunesis' preliminary analysis, assessment and conclusions of the results of the VALOR trial, and the efficacy and commercial potential of vosaroxin. It is possible that such results or conclusions may change based on further analysis of the VALOR data. Words such as "plans," "intends," "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' preliminary analysis, assessment and conclusions of the results of the VALOR trial set forth in this release may change based on further analysis of such data, the risk that Sunesis' plans to commence a marketing authorization filing with the EMA may change or such filing may be rejected by the EMA, 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 June 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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