Sunesis Pharmaceuticals Announces Presentation of VALOR Trial Subgroup Analysis at ASCO 2015 Annual Meeting

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Post Hoc Analysis Shows Promising Outcomes for Vosaroxin/Cytarabine-Treated Patients Age 60 Years and Older Who Received Bone Marrow Transplants

SOUTH SAN FRANCISCO, Calif., May 31, 2015 (GLOBE NEWSWIRE) -- Sunesis Pharmaceuticals, Inc. (Nasdaq:SNSS) today announced results from a post hoc subgroup analysis of patients age 60 years and older who underwent allogeneic hematopoietic cell transplant (HCT) in the VALOR trial, a Phase 3 study of vosaroxin and cytarabine in patients with relapsed or refractory acute myeloid leukemia (AML). The results are being presented today, Sunday, May 31st from 8:00 a.m. to 11:45 a.m. Central Time at the Leukemia, Myelodysplasia, and Transplantation General Poster Session of the American Society of Clinical Oncology (ASCO) Annual Meeting 2015 taking place in Chicago, Illinois.

The poster presentation (Poster #44, S Hall A), titled "Allogeneic hematopoietic cell transplant (HCT) in patients (pts) ≥ 60 years of age with first relapsed or refractory acute myeloid leukemia (R/R AML) after treatment with vosaroxin plus cytarabine (pla/cyt): results from VALOR", will be available on the Sunesis website at www.sunesis.com, following the ASCO presentation.

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.

Of the 711 patients enrolled in VALOR, 451 patients were age 60 years and older. Of these, 226 patients were randomized to the vosaroxin/cytarabine arm and 225 patients to the placebo/cytarabine arm. For the subgroup analysis, complete remission (CR) rates prior to HCT, post-treatment HCT rates, HCT outcomes, and overall survival by treatment arm were assessed. Of the 451 patients, HCTs were performed in 91 patients, including 47 patients in the vosaroxin/cytarabine arm and 44 patients in the placebo/cytarabine arm. Of these patients, 27 (57%) achieved a CR prior to transplant in the vosaroxin/cyrarabine arm versus 16 (36%) in the placebo/cytarabine only arm. An additional 7 and 6 patients on the respective treatment arms received subsequent therapy, and went on to achieve a CR, resulting in a total of 34 patients (72%) in the vosaroxin/cytarabine arm and 22 patients (50%) in the placebo/cytarabine arm achieving CR prior to transplant.

Median overall survival for patients who underwent HCT was 20.2 months for the vosaroxin/cytarabine arm versus 12.2 months on placebo/cytarabine arm (HR 0.699; p=0.18). There were no clinically meaningful differences between treatment arms with respect to transplantation type, complications associated with HCT, 100-day mortality, or achievement of engraftment.

"Due to wider donor availability and improvements in supportive care, increasing numbers of older AML patients undergo allogeneic hematopoietic cell transplants," said Dr. Gary Schiller, Director of Bone Marrow/Stem Cell Transplantation and Professor of Hematology-Oncology at the Oncology Treatment Center at UCLA, and a VALOR study investigator. "The likelihood of a favorable outcome is much greater when patients are transplanted with AML in complete remission and in patients with a good health status going into transplant, underscoring the importance for new therapies that can help realize this clinical objective. The results from this post hoc analysis of VALOR, including a high rate of pre-transplant CR with manageable toxicity and promising survival outcomes for older patients on the vosaroxin/cytarabine arm, are highly encouraging."

"The VALOR data reveal a compelling overall clinical profile of vosaroxin/cytarabine in relapsed and refractory AML, particularly among the most difficult to treat patient populations, including patients age 60 years and older," said Adam R. Craig, M.D., Ph.D, Executive Vice President, Development and Chief Medical Officer of Sunesis. "We remain steadfast in our effort to deliver new treatment options to patients with high unmet medical need, and are engaged with U.S. and European regulators to determine a timely path forward toward registration for vosaroxin in AML."

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 new treatment options, Sunesis' clinical development of vosaroxin, including the analysis of the results from VALOR clinical trial. Words such as "estimate," "potential," "promising," "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' 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.

CONTACT: Investor and Media Inquiries:

David Pitts
Argot Partners
212-600-1902

Eric Bjerkholt
Sunesis Pharmaceuticals Inc.
650-266-3717

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Sunesis Pharmaceuticals, Inc.