Sunesis Pharmaceuticals Announces Presentation of Responder Survival Analysis from Phase 3 VALOR Trial at the 2015 Chemotherapy Foundation Symposium

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SOUTH SAN FRANCISCO, Calif., Nov. 4, 2015 (GLOBE NEWSWIRE) -- Sunesis Pharmaceuticals, Inc. (Nasdaq:SNSS) today announced the presentation of a responder survival analysis from the Phase 3 VALOR trial at the 33rd Annual Chemotherapy Foundation Symposium (CFS) taking place at the Marriott Marquis in New York City. The results are being presented today, Wednesday, November 4th, at 6:00 p.m. as a poster during the general poster session in the Exhibit Hall.

The poster presentation, titled "Impact of Complete Remission on Overall Survival in Patients with Refractory/Relapsed Acute Myeloid Leukemia Treated with Vosaroxin Plus Cytarabine or Placebo Plus Cytarabine: Responder Analysis for the Phase 3 VALOR Trial," will be available on the Sunesis website at www.sunesis.com, following the conclusion of the symposium.

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. The full results from VALOR were recently published in the September 2015 print issue of *The Lancet Oncology*.

A post hoc landmark analysis was performed comparing overall survival (OS) by complete remission (CR) status. To mitigate the potential bias that early death would preclude CR, only patients alive at 60 days were included. Of the 711 patients in the VALOR intent-to-treat population, 570 patients were alive at the 60-day mark, including 285/356 (80%) in the vosaroxin/cytarabine arm and 285/355 (80%) in the placebo/cytarabine arm. At 60 days, the CR rate was 33.0% and 15.4% in the respective treatment arms. The addition of vosaroxin produced the greatest percentage increase in CR rate compared to the control arm in patients ≥ 60 y of age, patients with high blast count, and patients with refractory or early relapsed disease. These same patient groups also show the greatest OS benefit with the addition of vosaroxin. In both treatment arms and all study-strata, achievement of CR was associated with consistently longer median OS; patients with CR at 60 days had a median OS of 20.1 months (21.2 months with vosaroxin/cytarabine and 19.8 months with placebo/cytarabine), and patients without CR had a median OS of 7.1 months (7.3 and 7.1 months, respectively). Irrespective of treatment arm, OS was consistently prolonged in patients with CR. The stratified Chi-square statistical analysis of survival demonstrated a HR for CR of 0.42.

"These data underscore the long-held clinical understanding that CR status is the strongest independent predictor of overall survival in patients with AML, with VALOR demonstrating a two-fold increase in CR with the addition of vosaroxin," said Harry Erba, MD, PhD, Professor of Medicine and Director of the Hematologic Malignancy Program at the University of Alabama at Birmingham. "Importantly, the CR benefit, and thus survival benefit, conveyed by the addition of vosaroxin is most evident in patients over 60 years of age and those with refractory or early relapsed disease. These data further demonstrate the potential of vosaroxin as a much needed new treatment option for patients with relapsed or refractory 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' estimated timelines for regulatory interactions and regulatory progress, including the anticipated submission of the MAA for vosaroxin with the EMA and plans to gain marketing approval of vosaroxin in the U.S., Sunesis' overall strategy, the design, conduct and results of clinical trials, including the expected progress in its kinase inhibitor pipeline, 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 "anticipates," "estimates," "expect," "intends," "plan," "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 submit timely the MAA to the EMA, the risk that Sunesis' clinical studies for vosaroxin may not lead to regulatory approval 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 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 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 September 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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