Sunesis Announces Publication of Vosaroxin Phase 1b/2 AML Trial Results in Haematologica

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SOUTH SAN FRANCISCO, Calif., Nov. 19, 2014 (GLOBE NEWSWIRE) -- Sunesis Pharmaceuticals, Inc. (Nasdaq:SNSS) today announced the online publication of results from the Company's Phase 1b/2 study of vosaroxin in combination with cytarabine in patients with relapsed or refractory acute myeloid leukemia (AML) in the November 7, 2014 Ahead of Print issue of *Haematologica*. The article, titled "A Phase 1b/2 study of combination vosaroxin and cytarabine in patients with relapsed or refractory acute myeloid leukemia," is available online at http://www.haematologica.org/content/early/recent.

"Acute myeloid leukemia is a complex, genetically heterogeneous cancer for which there has been no advancement in drug treatment in over 40 years," stated Dr. Jeffrey Lancet, Senior Member and Professor of Oncologic Sciences at the H. Lee Moffitt Cancer Center, Tampa, Florida and lead author of the publication. "In this study, we see that vosaroxin, in combination with cytarabine, is active and well tolerated. These results were mirrored in the Phase 3 VALOR trial, which demonstrated clinically meaningful outcomes supported by encouraging response rates and a manageable safety profile.

The Phase 1b/2 study assessed the safety and tolerability of vosaroxin plus cytarabine in patients with relapsed or refractory acute myeloid leukemia. Escalating vosaroxin doses (10-minute infusion; 10-90 mg/m^2 on days 1, 4) were given in combination with cytarabine on 1 of 2 schedules: schedule A (24-hour continuous intravenous infusion, 400 mg/m^2 per day on days 1-5) or schedule B (2-hour intravenous infusion, 1 g/m^2 per day on days 1-5). Following dose escalation, enrollment was expanded at the maximum tolerated dose. The maximum tolerated dose for schedule A was vosaroxin 80 mg/m^2 (dose-limiting toxicities: grade 3 bowel obstruction and stomatitis); the maximum tolerated dose was not reached for schedule B (recommended phase 2 dose: 90 mg/m^2).

The median age in the study was 60 years, and patients had received as many as 6 prior cycles of therapy. Furthermore, most patients (89%) had intermediate or unfavorable cytogenetic risk status. The most common treatment-emergent nonhematologic adverse events of any grade were diarrhea, hypokalemia, nausea, and stomatitis. In the efficacy population, (all first relapsed or primary refractory patients treated with vosaroxin 80-90 mg/m^2; n=69), the complete remission (CR) and combined CR rates (CR or CR with incomplete blood count recovery) were 25% and 28%, respectively. Thirty-day all-cause mortality was 2.5% among all patients treated at 80-90 mg/m^2. Based upon these results, the phase 3 VALOR trial of vosaroxin plus cytarabine was initiated in patients with first relapsed or refractory acute myeloid leukemia.

"The results published in *Haematologica* online were the foundation for the VALOR trial, among the largest studies ever conducted in the relapsed or refractory AML setting," said Adam Craig, Chief Medical Officer of Sunesis. "Based on the outcome of VALOR, we plan to submit a Marketing Authorization Application for vosaroxin and look forward to discussing the data with the U.S. Food and Drug Administration. We also look forward to building upon these and other data for vosaroxin in AML through investigator-sponsored studies."

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.

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," "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 September 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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