Sunesis Announces Publication of REVEAL-1 Trial Results in the British Journal of Haematology

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SOUTH SAN FRANCISCO, Calif., Nov. 24, 2014 (GLOBE NEWSWIRE) -- Sunesis Pharmaceuticals, Inc. (Nasdaq:SNSS) today announced the publication of results from the Company's REVEAL-1 (Response Evaluation of Vosaroxin in Elderly AmL) trial, a Phase 2 trial of single agent vosaroxin in previously untreated, poor-risk elderly acute myeloid leukemia (AML) patients who are unlikely to benefit from standard induction chemotherapy, in the November 17, 2014 Online Version of Record of the *British Journal of Haematology*. The article, titled "REVEAL-1, a phase 2 dose regimen optimization study of vosaroxin in older poor-risk patients with previously untreated acute myeloid leukemia," is available online at http://onlinelibrary.wiley.com/doi/10.1111/bjh.13214/abstract.

"There remains an acute unmet medical need for new treatment options in AML, including patients 60 years of age and older who are unlikely to benefit from standard induction chemotherapy," stated Farhad Ravandi, M.D., Professor of Medicine, Department of Leukemia, University of Texas MD Anderson Cancer Center, and an author of the publication. "Vosaroxin is active and well tolerated in this population, both as a single agent, as seen in the REVEAL-1 study, and in combination with decitabine, as seen in an ongoing MD Anderson Cancer Center-sponsored study. Vosaroxin's activity in AML is further highlighted in the recent outcome of the randomized, double-blind, placebo-controlled Phase 3 VALOR trial, which looks at combination therapy with cytarabine in the relapsed and refractory settings. In their totality, these data suggest an important role for vosaroxin in the treatment of AML."

The REVEAL-1 study evaluated single-agent vosaroxin in patients ≥60 years of age (n=113) with previously untreated unfavorable prognosis AML. Dose regimen optimization was explored in sequential cohorts (A: 72 mg/m^2 on days 1, 8, 15; B: 72 mg/m^2 on days 1, 8; C: 72 mg/m^2 or 90 mg/m^2 on days 1, 4). The primary efficacy endpoint was combined complete remission rate (complete remission [CR] plus CR with incomplete platelet recovery [CRp]). The median age in the study was 75 years and most patients (82%) had 2 or more risk factors (age ≥ 70, antecedent hematologic disease [AHD], ECOG PS=2, or intermediate/unfavorable cytogenetics).

Common (>20%) grade ≥3 adverse events were thrombocytopenia, febrile neutropenia, anemia, neutropenia, sepsis, pneumonia, stomatitis, and hypokalemia. Overall CR and CR/CRp rates were 29% and 32%; median overall survival (OS) was 7.0 months; 1-year OS was 34%. Schedule C (72 mg/m^2) had the most favorable balance of safety and efficacy, with faster hematologic recovery (median 27 days) and lowest incidence of aggregate sepsis (24%) and 30-day (7%) and 60-day (17%) all-cause mortality. At this dose and schedule, CR and CR/CRp rates were 31% and 35%, median OS was 7.7 months, and 1-year OS was 38%.

"Publication of these data in the *British Journal of Haematology* further support our goal of establishing vosaroxin as a new standard of care in AML," said Adam Craig, Chief Medical Officer of Sunesis. "Given ongoing demographic shifts in the U.S. and other major territories, the challenge of treating AML in older adults will continue to grow, underscoring a need for new treatment options. We look forward to building on these data through further investigator-sponsored studies and, with the outcome of VALOR in relapsed or refractory AML, progressing towards initial regulatory approval."

As recently announced, based on results of the VALOR trial, Sunesis has commenced a marketing authorization application (MAA) with the European Medicines Agency (EMA) and plans to meet with the U.S. Food and Drug Administration to determine the appropriate regulatory path forward for vosaroxin in the treatment of 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 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 meet with the US FDA), 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 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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