Sunesis Announces Positive Phase 2 Data for Vosaroxin in AML

November 10, 2010 2:38 PM ET

SOUTH SAN FRANCISCO, CA -- (MARKET WIRE) -- 11/10/10 -- Sunesis Pharmaceuticals, Inc. (NASDAQ: SNSS) today announced updated data from Phase 2 clinical trials of the Company's lead drug candidate, vosaroxin, in combination with cytarabine, a widely used chemotherapy, in relapsed/refractory acute myeloid leukemia (AML) and as a single agent in frontline elderly AML. The data were presented today by Robert Stuart, M.D., Professor of Medicine, Division of Hematology/Oncology, Department of Medicine, Medical University of South Carolina, at the Chemotherapy Foundation Symposium XXVIII in New York City. The presentation is available on the Sunesis website at www.sunesis.com.

For the fully enrolled relapsed/refractory AML study, a total of 69 patients with first relapse or primary refractory AML have been treated at doses of 80 to 90 mg/m(2) of vosaroxin, in combination with bolus or continuous infusion cytarabine. Consistent with results presented at the American Society of Clinical Oncology (ASCO) Annual Meeting, vosaroxin achieved clinically meaningful complete remission rates balanced with low all-cause early mortality. Preliminary leukemia free survival, measured as time from complete remission to relapse or death, is now 14.4 months (440 days). Median overall survival was 7.1 months, with 14 patients continuing in survival follow up well beyond this median.

These updated clinical findings continue to support Sunesis' plan to initiate the VALOR trial, a multinational, randomized, double-blind, placebo-controlled, pivotal Phase 3 clinical trial of vosaroxin in combination with cytarabine in a relapsed/refractory AML patient population expected to begin in the fourth quarter of this year.

"The successful treatment of relapsed or refractory AML requires a durable complete remission and low all-cause early mortality with the ultimate goal of getting the patient to transplant, a combination of outcomes observed in this study," said Dr. Stuart, a clinical study investigator for the trial and member of the VALOR trial steering committee. "Particularly noteworthy is the long leukemia free survival seen among patients who had a complete remission. These mature data provide encouraging evidence of clinically meaningful benefit for this novel combination in patients with limited treatment options. I hope this benefit will be confirmed in the upcoming VALOR trial which is rigorously designed to demonstrate a clinically meaningful survival advantage over a current standard of care."

About VALOR

Sunesis anticipates initiating VALOR, a Phase 3, randomized, double-blind, placebo-controlled, pivotal trial in patients with first relapsed or refractory AML, in the fourth quarter of 2010. The trial is designed to evaluate approximately 450 patients, multi-nationally, including leading sites in the U.S. and Europe. Patients will be randomized one to one to receive either vosaroxin on days one and four in combination with cytarabine daily for five days, or placebo in combination with cytarabine. Additionally, the VALOR trial employs an innovative, adaptive trial design that allows for a one-time sample size adjustment by the Data Safety Monitoring Board at the interim analysis to ensure adequate power across a broader range of clinically meaningful and statistically significant survival outcomes. The study's primary endpoint is overall survival.

About Vosaroxin (formerly voreloxin)

Vosaroxin, formerly known as voreloxin, is a first-in-class anticancer quinolone derivative (AQD), a class of compounds that has not been used previously for the treatment of cancer. Vosaroxin both intercalates DNA and inhibits topoisomerase II, resulting in replication dependent, site-selective DNA damage, G2 arrest and apoptosis. Sunesis plans to initiate the VALOR trial, a multinational, randomized, double-blind, placebo-controlled, pivotal Phase 3 clinical trial of vosaroxin in combination with cytarabine in a relapsed/refractory AML patient population, in the fourth quarter of 2010.

About Acute Myeloid Leukemia

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 12,330 new cases of AML will be diagnosed and approximately 9,000 deaths from AML will occur in the U.S. in 2010. Additionally, it is estimated that prevalence of AML is approximately 25,000 in the U.S. 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.

SUNESIS and the logo are trademarks of Sunesis Pharmaceuticals, Inc.

This press release contains forward-looking statements, including statements related to vosaroxin's efficacy, safety profile and effects as a single agent and in combination with other AML treatments, the planned commencement and timing of the VALOR trial, and results that may warrant further clinical evaluation of vosaroxin. Words such as "achieved," "support," "will," "designed" 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, risks related to Sunesis' need for substantial additional funding to complete the development and commercialization of vosaroxin, the risk that unfavorable economic and market conditions may make it more difficult and costly to raise additional capital, the risk that the VALOR trial may not be initiated on the anticipated timeline and 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, the risk that Sunesis' nonclinical studies and clinical studies may not satisfy the requirements of the FDA or other regulatory agencies, risks related to the conduct of Sunesis' clinical trials, risks related to the manufacturing of vosaroxin, and the risk that Sunesis' proprietary rights may not adequately protect vosaroxin. Risk factors related to Sunesis and its business are discussed under "Risk Factors" and elsewhere in Sunesis' Quarterly Report on Form 10-Q for the quarter ended September 30, 2010 and other filings with the Securities and Exchange Commission. 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 the company's expectations with regard thereto or any change in events, conditions or circumstances on which any such statements are based.

Investor and Media Inquiries:

David Pitts

Argot Partners

212-600-1902

Eric Bjerkholt

Sunesis Pharmaceuticals Inc.

650-266-3717

Source: Sunesis Pharmaceuticals

News Provided by Acquire Media