Sunesis Poised for Phase 3 Trial of Voreloxin in Acute Myeloid Leukemia After Completing Formal End-of-Phase 2 Meetings With FDA

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Company on Track to Initiate Pivotal Study in Second Half of 2010

SOUTH SAN FRANCISCO, CA, Feb 25, 2010 (MARKETWIRE via COMTEX News Network) -- Sunesis Pharmaceuticals, Inc. (NASDAQ: SNSS) today announced that it has completed formal End-of-Phase 2 meetings with the U.S. Food and Drug Administration (FDA) related to its lead compound, voreloxin, in acute myeloid leukemia (AML). Sunesis has received feedback and guidance from the FDA in response to proposed plans for further development of voreloxin in the treatment of AML. Based on the development clarity achieved as a result of these meetings, Sunesis intends to proceed with its plan to conduct a randomized, double-blind, placebo-controlled, pivotal Phase 3 trial. This trial will evaluate the overall survival of voreloxin in combination with cytarabine, a widely used chemotherapy in AML, compared to cytarabine with placebo, in patients with relapsed or refractory AML. Sunesis anticipates initiating this multi-national, Phase 3 trial in the second half of 2010.

Sunesis also reported today that, as part of its global development strategy, a pre-submission meeting has been scheduled for the current calendar quarter with the European Medicines Agency (EMA) to obtain EMA's scientific advice on the development program for voreloxin, including the proposed Phase 3 trial.

"We are very pleased by the outcomes of these milestone meetings with the FDA and are looking forward to initiating our multi-national Phase 3 trial," stated Daniel Swisher, Chief Executive Officer of Sunesis. "We believe that voreloxin's novel anti-leukemic properties and encouraging Phase 2 clinical data hold significant potential in a patient population with few treatment options. As we evaluate how best to fund our voreloxin development program, including our planned Phase 3 trial, we are continuing discussions with potential pharmaceutical partners."

About Voreloxin

Voreloxin is a first-in-class anticancer quinolone derivative, or AQD, a class of compounds that has not been used previously for the treatment of cancer. Voreloxin both intercalates DNA and inhibits topoisomerase II, resulting in replication-dependent, site-selective DNA damage, G2 arrest and apoptosis. Voreloxin is currently being evaluated in a fully enrolled single agent Phase 2 clinical trial (known as the REVEAL-1 trial) in previously untreated elderly AML patients and in a fully enrolled Phase 1b/2 clinical trial combining voreloxin with cytarabine for the treatment of patients with relapsed/refractory AML. A Phase 2 single agent trial in platinum-resistant ovarian cancer has also completed enrollment. Sunesis anticipates initiating a Phase 3 trial of voreloxin in AML in the second half 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 National Cancer Institute estimated that nearly 13,000 new cases of AML were diagnosed and approximately 9,000 deaths from AML occurred in the U.S. in 2009. 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, voreloxin, to improve the lives of people with cancer. For additional information on Sunesis Pharmaceuticals, please visit http://www.sunesis.com.

This press release contains forward-looking statements, including without limitation statements related to Sunesis' plans to initiate a

Phase 3 trial of voreloxin in AML in the second half of 2010, including the timing and results thereof, the therapeutic potential of voreloxin and the outcome of discussions with potential pharmaceutical partners. Words such as "on track," "intends," "plan," "anticipates," "looking forward," "believe," "potential" 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 additional capital, the risk that Sunesis' drug development activities for voreloxin could be halted or significantly delayed for various reasons, the risk that Sunesis' clinical trials for voreloxin may not demonstrate safety or efficacy or lead to regulatory approval, the risk that preliminary data and trends may not be predictive of future data or results, the risk that Sunesis' nonclinical studies and clinical trials 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 voreloxin, and the risk that Sunesis' proprietary rights may not adequately protect voreloxin. 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, 2009 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.

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