Sunesis Completes Consultative Review Process With EMA for Voreloxin in AML

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SOUTH SAN FRANCISCO, CA, Jun 02, 2010 (MARKETWIRE via COMTEX News Network) -- Sunesis Pharmaceuticals, Inc. (NASDAQ: SNSS) today announced that it has received written, scientific advice from the European Medicines Agency (EMA) on the Company's proposed plans for further development of voreloxin in acute myeloid leukemia (AML), including the Company's plans for a pivotal trial in patients with first relapsed or primary refractory AML. The EMA's written advice, similar to guidance previously received from the U.S. Food and Drug Administration (FDA) in February following formal End-of-Phase 2 meetings, is consistent with and supportive of Sunesis' proposed plans, and provides development clarity toward a potential regulatory submission for marketing approval. The EMA issued its advice following its established consultative review process.

The Company continues to anticipate a launch of its multi-national, randomized, double-blind, placebo-controlled Phase 3 trial in the second half of 2010. Based on feedback and guidance received from the FDA and EMA, the Company expects that future results demonstrating a convincing magnitude of improvement in overall survival, the study's primary endpoint, along with a favorable benefit-risk ratio in the planned Phase 3 trial, would be sufficient as the primary basis for registration of voreloxin in both the U.S. and Europe.

"With the EMA's scientific advice, we have successfully completed an important step in our global development strategy for voreloxin in relapsed and refractory AML," stated Daniel Swisher, Chief Executive Officer of Sunesis. "The Company, its advisors and clinical service providers continue to collaborate toward the successful initiation of our multi-national Phase 3 trial in the second half of this year."

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 the Pivotal Phase 3 Trial Sunesis anticipates initiating a Phase 3, randomized, double-blind, placebo-controlled, pivotal trial in patients with first relapsed or primary refractory AML in the second half of 2010. The trial is designed to evaluate approximately 450 patients, multi-nationally, including leading sites in the U.S. and Europe. Patients are expected to be randomized one to one to receive either voreloxin (90 mg/m2) on days one and four in combination with cytarabine (1 g/m2) daily for five days, or placebo in combination with cytarabine. The study's primary endpoint is overall survival.

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, 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 without limitation statements related to the planned commencement of a pivotal trial of voreloxin and its timing. Words such as "anticipates," "upcoming" 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 funding to finance the voreloxin pivotal trial and to continue as a going concern, 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' Annual Report on Form 10-K for the year ended December 31, 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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