Sunesis' Voreloxin Receives FDA Orphan Drug Designation for Acute Myeloid Leukemia

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SOUTH SAN FRANCISCO, Calif., Nov 05, 2009 /PRNewswire-FirstCall via COMTEX News Network/ -- Sunesis Pharmaceuticals, Inc. (Nasdaq: SNSS) today announced that the U.S. Food and Drug Administration has granted voreloxin orphan drug designation for the treatment of acute myeloid leukemia (AML). Sunesis is currently conducting two Phase 2 clinical trials of voreloxin in AML: a single-agent study, known as REVEAL-1, of voreloxin in newly diagnosed elderly AML patients unlikely to benefit from standard induction chemotherapy and a study evaluating voreloxin in combination with cytarabine in relapsed/refractory AML.

"This designation recognizes the acute need for more options in treating this poor-prognosis disease," stated Steven B. Ketchum, Ph.D., Senior Vice President of Research and Development at Sunesis. "We believe voreloxin has the potential to impact the standard of care for AML and we continue to be encouraged by our progress. We are finalizing a registration strategy for voreloxin in AML and anticipate launching a pivotal trial in 2010."

Orphan drug designation is granted by the FDA Office of Orphan Drug Products to novel drugs or biologics that treat a rare disease or condition affecting fewer than 200,000 patients in the U.S. The designation provides eligibility for a seven-year period of market exclusivity in the United States after product approval and an exemption from user fees.

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 Phase 2 clinical trial (known as the REVEAL-1 trial) in previously untreated elderly AML patients and in a Phase 1b/2 clinical trial combining voreloxin with cytarabine for the treatment of patients with relapsed/refractory AML, as well as in an ongoing Phase 2 single-agent trial in platinum-resistant ovarian cancer.

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 Leukemia and Lymphoma Society estimates that nearly 13,000 new cases of AML will be diagnosed and approximately 9,000 deaths from AML will occur in the U.S. in 2009. AML is generally a disease of older adults, and the median age of a patient diagnosed with AML is about 67 years. A majority of elderly patients are not considered candidates for standard induction therapy or decline therapy, resulting in an acute need for new treatment options.

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 potential efficacy and commercial potential of voreloxin and Sunesis' plans to launch a pivotal trial of voreloxin including the timing thereof. Words such as "believe," "potential," "anticipate," 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, the risk that Sunesis' drug development activities for voreloxin could be halted significantly or 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 June 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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