Sunesis Reports Data From Nonclinical Studies of Voreloxin at AACR-EORTC-NCI Conference

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SOUTH SAN FRANCISCO, CA, Nov 18, 2009 (MARKETWIRE via COMTEX News Network) -- Sunesis Pharmaceuticals, Inc. (NASDAQ: SNSS) today reported data from two nonclinical studies of voreloxin at the AACR-EORTC-NCI Molecular Targets and Cancer Therapeutics Conference, which is being held in Boston, MA from November 15-19, 2009.

In one study, clinical proof-of-mechanism is established in samples from patients treated with voreloxin in the Company's ongoing Phase 2 clinical study of voreloxin in combination with cytarabine in relapsed or refractory acute myeloid leukemia (AML). In an additional study, voreloxin's synergistic and additive effects are demonstrated in combination with cytarabine, azacitidine, decitabine and clofarabine, agents which are currently used in the treatment of AML. Results from both of these studies support the current combination study and identify potential opportunities for further clinical evaluation.

"The data obtained from patient samples are an important addition to our clinical characterization of voreloxin's pharmacodynamic impact and further confirm our mechanistic understanding," said Judith A. Fox, Ph.D., Vice President of Product and Preclinical Development at Sunesis. "Voreloxin's synergistic activity when combined with cytarabine, a backbone of current AML therapy, and additive affects with other AML agents provides support for our ongoing combination trial and highlights potential future directions for clinical development of this first-in-class agent."

Clinical Evidence of Mechanism-Based Pharmacodynamic Activity in Voreloxin-Treated AML Patients

In a poster presentation titled "Clinical Evidence of Mechanism-Based Activity in Voreloxin-Treated AML Patients" (abstract number C226), Sunesis presented nonclinical data that demonstrated mechanism-based pharmacodynamic activity of voreloxin in patients enrolled in an ongoing phase 1b/2 clinical study of voreloxin in combination with cytarabine in relapsed or refractory AML. The study identified pDNA-PKcs and pCHK2 as mechanism-based pharmacodynamic markers of response to voreloxin. These observations were consistent in cancer cell lines and in peripheral blood mononuclear cells (PBMC) of AML patient donors that were treated ex vivo with voreloxin. Furthermore, the DNA damage response to voreloxin, which was activated in PBMC from AML patients who received voreloxin at doses equal to or greater than 34 mg/m2, was differentiated from that of cytarabine.

Voreloxin is Synergistic in In Vitro Combination with Cytarabine and Additive in Combination with Azacitidine, Decitabine and Clofarabine

In a poster presentation titled "Voreloxin is Synergistic in In Vitro Combination with Cytarabine and Additive in Combination with Azacitidine, Decitabine and Clofarabine" (abstract number C222), Sunesis presented nonclinical data supporting the combination of voreloxin and cytarabine, a regimen currently used in Sunesis' Phase 1b/2 clinical study in patients with relapsed or refractory AML. Voreloxin activity in combination with other agents currently in clinical use as treatments for AML is also reported. The study showed that voreloxin, when combined with cytarabine, demonstrated synergistic activity in two AML cell lines and was additive in an ALL cell line. Voreloxin was found to be additive when combined with nucleoside analogs azacitidine, decitabine and clofarabine, suggesting that combining voreloxin with other DNA damaging agents currently in clinical use for the treatment of AML is feasible.

Clinical Development Updates

The Company will provide voreloxin clinical development updates at the 2009 Annual Meeting of the American Society of Hematology (ASH). Details of the presentations include:

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--  Phase 1b/2 PK/PD Study of Combination Voreloxin and Cytarabine in
Relapsed or Refractory AML Patients. Abstract #635, oral presentation.
Monday, December 7, 4:30PM - 6PM session time, presentation 5:30PM
--  Phase 2 Dose Regimen Optimization Study of Voreloxin as Single
Agent Therapy for Frontline, Elderly AML. Abstract # 1037, poster
presentation. Saturday, December 5, 9AM - 7:30PM viewing, 5:30 - 7:30PM
presentation.
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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. 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 Pharmaceuticals, please visit http://www.sunesis.com.

This press release contains forward-looking statements, including without limitation statements related to voreloxin's mechanism of action, voreloxin's effects in combination with other AML treatments, results from nonclinical studies that support further clinical evaluation and the expectation that voreloxin clinical data will be presented at ASH. Words such as "established," "demonstrated," "suggesting," "will" 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' 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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