Sunesis Pharmaceuticals Appoints Steering Committee and Clinical Partners for Vosaroxin Pivotal Phase 3 Trial in AML

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SOUTH SAN FRANCISCO, CA, Aug 04, 2010 (MARKETWIRE via COMTEX News Network) -- Sunesis Pharmaceuticals, Inc. (NASDAQ: SNSS) today announced the Steering Committee and other clinical trial partners for its pivotal Phase 3 trial of vosaroxin in acute myeloid leukemia (AML). Sunesis also announced that it requested, and that the United States Adopted Names (USAN) Council has accepted the new nonproprietary name "vosaroxin" for its lead drug candidate (formerly known as voreloxin). The USAN Council aims for global standardization and unification of drug nomenclature and related rules to ensure that drug information is communicated accurately and unambiguously.

The Phase 3 trial, known as VALOR (Vosaroxin and Ara-C combination evaLuating Overall survival in Relapsed/refractory AML), is a multinational, randomized, double-blind, placebo-controlled, pivotal trial of vosaroxin in combination with cytarabine in 450 patients with first relapsed or primary refractory AML. It is expected to begin enrollment later this year.

"We have made important progress toward ensuring that our pivotal Phase 3 AML trial is a well-executed study, and continue to work diligently toward ensuring its timely launch," said Daniel Swisher, Sunesis' Chief Executive Officer. "Our internal clinical leadership, which includes individuals with extensive late-stage development experience, is now supplemented by clinical partners and a Steering Committee with significant, international hematology experience. We are in the process of compiling and finalizing the documentation needed for local regulatory authority and ethics committee submissions, and we remain on track to initiate the VALOR trial later this year."

"Refractory and relapsed AML are disease settings for which there is an enduring unmet medical need. Currently no Phase 3 trial is enrolling both first relapsed or primary refractory AML patients," said Eric Feldman, MD, Chair of the VALOR Steering Committee and Professor of Medicine and Director of the Leukemia Program and Hematological Malignancies at Weill Cornell Medical College. "The VALOR trial is a rigorously designed study which will provide randomized data assessing the potential incremental contribution of vosaroxin to underlying cytarabine therapy in relapsed or refractory AML, with overall survival serving as the primary endpoint. I look forward to the initiation of this trial and to serving as a member of its Steering Committee."

The Steering Committee will provide scientific oversight for the VALOR trial as well as communicate its recommendations regarding trial conduct with the trial's Data Safety Monitoring Board and Sunesis. Steering Committee members are:

-- Eric Feldman, MD, Chair of Steering Committee, Professor of Medicine and Director of the Leukemia Program and Hematological Malignancies at Weill Cornell Medical College
-- Harry Erba, MD, PhD, Associate Professor, Department of Internal Medicine at the University of Michigan and Executive Officer of the Southwest Oncology Group
-- Gary Schiller, MD, Professor of Medicine, Director of the Hemapherisis Unit and Chairman of the Medical Specialties College of the David Geffen School of Medicine at the University of California, Los Angeles
-- Robert Stuart, MD, founding director of the Aplastic Anemia & Myelodysplastic Syndrome Foundation, Director of the clinical component of the Hollings Cancer Center's Hematological Malignancies Program and Medical Director of the Clinical Trials Office at the University of South Carolina
-- Norbert Vey, MD, Professor of Medicine, Leukemia and MDS Unit, Department of Hematology at the Institut Paoli-Calmettes, Marseille, France

Among the clinical trial partners appointed by Sunesis are (i) ICON, a contract research organization with global capabilities, hematology expertise and extensive Phase 3 experience; (ii) Catalent Pharma Solutions, a leading global provider of advanced technologies, and development, clinical, manufacturing and packaging services, including global comparator procurement, secondary packaging and logistics; and (iii) Cytel, a highly regarded statistical services provider. Sunesis has also retained the Clinical Development Group, LLC to augment Sunesis' Phase 3 strategic development support for the VALOR trial, including clinical site management and patient recruitment. Key individuals from the Clinical Development Group have recent, multinational

Phase 3 AML trial experience, including Ann Cahill, formerly the Vice President of Clinical Development at Vion Pharmaceuticals.

About Vosaroxin (formerly voreloxin)

Vosaroxin, formerly known as 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. 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 second half of this year.

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, vosaroxin, 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 and timing of the VALOR trial, a pivotal Phase 3 clinical trial of vosaroxin (formerly voreloxin). Words such as "expected," "remain on track," "will," "plans" 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 fully finance the planned vosaroxin pivotal trial, the risk that Sunesis' development activities for vosaroxin could be 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. These and other risk factors are discussed under "Risk Factors" and elsewhere in Sunesis' Registration Statement on Form S-3 (File No. 333-168191) and its periodic 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 Sunesis' expectations with regard thereto or any change in events, conditions or circumstances on which any such statements are based.

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