Sunesis Announces Data From Phase 2 Clinical Program of Voreloxin in Acute Myeloid Leukemia Support Phase 3 Trial in Relapsed or Refractory Patients

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Updated, Positive Phase 2 Data in AML and Ovarian Cancer Presented at the ASCO 2010 Annual Meeting; Sunesis to Host Conference Call Tuesday, June 8th at 9:00 AM Eastern Time

SOUTH SAN FRANCISCO, CA, Jun 07, 2010 (MARKETWIRE via COMTEX News Network) -- Sunesis Pharmaceuticals, Inc. (NASDAQ: SNSS) today announced updated clinical data from Phase 2 clinical studies of the Company's lead drug candidate, voreloxin, in acute myeloid leukemia (AML) and platinum-resistant ovarian cancer. The results were presented today at the 2010 American Society of Clinical Oncology (ASCO) Annual Meeting in Chicago, Illinois. The presentations are available on the Sunesis website at www.sunesis.com.

Clinical data from the Sunesis' Phase 2 clinical trial of voreloxin in combination with cytarabine in first relapsed or primary refractory AML exhibit a meaningful improvement in overall survival relative to literature-based values reported for current treatment standards of care, including cytarabine-based regimens. These positive clinical findings, along with formal feedback from both U.S. and EU regulatory agencies, support Sunesis' plan to initiate a multinational, randomized, double-blind, placebo-controlled, pivotal Phase 3 clinical trial of voreloxin in combination with cytarabine in a relapsed/refractory AML patient population in the second half of this year.

"Across both AML studies, either as a single agent in frontline elderly AML or in combination with cytarabine in relapsed/refractory AML, voreloxin has consistently achieved clinically meaningful remission rates balanced with impressively low all-cause early mortality," said Robert K. Stuart, M.D., Professor of Medicine, Division of Hematology/Oncology, Department of Medicine, Medical University of South Carolina and a clinical study investigator for both Phase 2 AML clinical trials. "There remains a significant and enduring unmet need for new therapies among patients with this disease. These results merit investigation in a larger outcome study in AML and I look forward to actively participating in Sunesis' planned Phase 3 clinical trial in relapsed/refractory AML."

"Data from these Phase 2 trials underscore voreloxin's potential as a treatment for both hematologic cancers and solid tumors," said Steven Ketchum, Ph.D., Senior Vice President of Research and Development at Sunesis. "In particular, in our Phase 2 trial of relapsed/refractory AML, voreloxin in combination with cytarabine has demonstrated impressive survival outcomes, leading us to focus our initial development and registration efforts on this patient population. Based on our substantial Phase 2 dataset, combined with our careful review of literature and input from clinical advisors and regulatory agencies, we are confident that our planned Phase 3 trial is rigorously designed to detect a significant difference in overall survival."

With 450 evaluable patients, the Phase 3 clinical trial will have 90% power to detect a 40% difference in overall survival. In this trial, there will be a single prespecified interim analysis by an independent Data Safety Monitoring Board (DSMB) which will enable the DSMB to implement a one-time sample size adjustment of 225 additional evaluable patients to maintain adequate power across a broader range of potential survival outcomes. Sunesis' ongoing focus is directed toward the initiation of this multinational pivotal Phase 3 trial later this year.

Phase 2 Clinical Trial of Voreloxin in Combination with Cytarabine in Relapsed/Refractory AML - Abstract #6526

In a poster presentation and poster discussion session, investigators presented data from a Phase 2 clinical trial testing voreloxin in combination with cytarabine, a widely used chemotherapy, in patients with relapsed or refractory AML. In this trial, a total of 69 patients with first relapse or primary refractory AML have been treated at doses of 80 to 90 mg/m2 of voreloxin, in addition to either bolus or continuous infusion cytarabine.

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--  Among evaluable first relapse (n=36) and primary refractory patients
    (n=33), median overall survival is 7.1 months. Of these patients, over
    80% were either primary refractory or had an initial first remission
    (CR1) of less than 12 months. 20 patients are still in survival
    follow-up and are beyond the current median; 12 of these patients have
    survived out to one year or more as of the most recent evaluation.
--  Preliminary median leukemia-free survival (LFS) is 10.8 months.
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-- The overall remission rate was 29% with the vast majority being complete remissions (17 of 20).
-- Infection-related toxicities were the most common Grade 3 or higher non-hematologic adverse events, all of which were expected. In addition, Grade 3 or higher oral mucositis was observed. The combination of voreloxin and cytarabine, regardless of cytarabine schedule, did not appear to exacerbate mucositis.
-- All-cause mortality among these patients was 3% at 30 days and 9% at 60 days.
-- The dose regimen to be used in the pivotal Phase 3 trial is 90 mg/m2 of voreloxin given as a 10 minute infusion on days one and four and 1 g/m2 of bolus cytarabine given as a two hour infusion on days one through five.

Phase 2 Clinical Trial of Single Agent Voreloxin in Newly Diagnosed Elderly AML (REVEAL-1 Trial) - Abstract #6525

In a poster presentation and poster discussion session, investigators presented data from the REVEAL-1 (Response Evaluation of VorEloxin in AmL) trial, a Phase 2 dose optimization trial of single agent voreloxin in previously untreated, elderly AML patients who are unlikely to benefit from standard induction chemotherapy. 113 AML patients have been treated in the trial, 82 percent of whom had two or more adverse risk factors, including age greater than 70 and intermediate or unfavorable cytogenetics. Median age for patients in the trial was 74 years. The REVEAL-1 trial includes three dosing schedules. As previously reported, Schedule C (72 mg/m2 of voreloxin on days one and four) is the recommended dose regimen for further study.

-- For Schedule C (72 mg/m2, n=30), median overall survival was 7.7 months and one year survival is approximately 38%, with 33% of patients remaining in follow-up. Response rate (CR and CRp) was 38%; 30- and 60-day all-cause mortality were 7% and 17%, respectively.
-- The most common grade 3 or higher non-hematologic adverse events included upper GI mucosal inflammation and infection.

"For elderly AML patients that present with additional risk factors, options are often limited due to the patients' intolerance to standard treatment," said Farhad Ravandi, M.D., Associate Professor, Department of Leukemia, Division of Cancer Medicine, The University of Texas M. D. Anderson Cancer Center, and an investigator in the Phase 2 clinical trial. "Voreloxin has demonstrated both strong anti-leukemic activity and adequate tolerability in this population, a balance which has yielded encouraging survival outcomes. I look forward to seeing voreloxin developed further in this and other AML settings."

Phase 2 Clinical Trial of Single Agent Voreloxin in Women with Platinum-Resistant Ovarian Cancer - Abstract #5002

Final clinical data from the Phase 2 trial of single agent voreloxin in women with platinum-resistant ovarian cancer were also presented during an oral presentation at the ASCO 2010 Annual Meeting. Platinum resistance is defined as progression within six months of completing platinum-based chemotherapy or progression while on platinum-based chemotherapy. Patients may have received up to three prior platinum regimens plus one additional non-platinum cytotoxic regimen. For approximately one third of the patients studied, prior treatment with Doxil(R) had failed. A total of 143 patients were enrolled in the trial, and enrollment was completed in December of 2008. Three dose cohorts of voreloxin were studied, and the 60 mg/m2 of voreloxin given every four weeks used in Cohort B is the recommended dose regimen for further study.

-- Data from this Phase 2 trial demonstrated encouraging, durable anti-tumor activity across all three dose cohorts, with the majority of patients achieving stable disease or an objective response.
-- For Cohort B (n=37), 54% of patients achieved disease control including 11% objective response rate (ORR, 2 CRs and 2 PRs), low incidence of grade 3 or higher febrile neutropenia (16%) and a long progression-free survival, with one patient remaining on study after 26 cycles of voreloxin. Median progression-free survival (PFS) was 85 days.
-- Four PRs were achieved in the 44 women who were Doxil(R) failures for an ORR of 9%. 66% of these patients achieved disease control, and median PFS in Doxil(R) failure patients was 91 days.
-- Overall, the adverse event profile was similar across cohorts and

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voreloxin was generally well-tolerated. Grade 3 or higher adverse
events occurring in more than 10% of patients included neutropenia,
febrile neutropenia, and anemia, all of which were expected and
reversible with standard care.
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"Responses to single agent voreloxin observed in women with ovarian cancer for whom multiple prior therapies have failed, including some for whom both platinum-based chemotherapy and Doxil(R) had failed, are promising," said Hal Hirte, M.D., Associate Professor, McMaster University, Department of Oncology and Chief of Oncology, Juravinski Cancer Centre at Hamilton Health Sciences and an investigator for the Phase 2 clinical trial. "These data warrant further investigation of voreloxin in this vastly underserved patient population, both in this later stage, salvage setting and in earlier lines of therapy."

Conference Call Information

Sunesis will host a conference call and webcast slide presentation Tuesday, June 8th at 9:00 a.m. Eastern time. Robert K. Stuart, M.D., Professor of Medicine, Division of Hematology/Oncology, Department of Medicine, Medical University of South Carolina, will join the Sunesis senior management team in a discussion of the new Phase 2 data presented at ASCO and review the plans for the upcoming randomized, pivotal Phase 3 clinical trial evaluating the effect on overall survival of voreloxin in combination with cytarabine for the treatment of first relapsed or refractory AML. The call can be accessed by dialing (877) 303-9029 (U.S. and Canada) or (914) 495-8584 (international). To access the live audio webcast, or the subsequent archived recording, visit the "Investors and Media - Calendar of Events" section of the Sunesis website at www.sunesis.com. The webcast will be recorded and available for replay on Sunesis' website for two weeks.

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 2 clinical trial combining voreloxin with cytarabine for the treatment of patients with relapsed/refractory AML. A Phase 2 single agent clinical 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 Ovarian Cancer

In the United States, ovarian cancer remains the leading cause of death from gynecologic malignancies and is the fifth leading cause of cancer death overall in women behind lung, breast, colorectal and pancreatic cancers. According to the American Cancer Society, in 2009 there were an estimated 21,550 new cases and more than 14,000 deaths from ovarian cancer in the U.S. alone. Following frontline treatment, recurrence rates among ovarian cancer patients are high. Treatment options remain limited following relapse, and overall long-term survival has not changed significantly over the past 40 years in women with recurrent disease, with less than 30 percent of patients surviving for more than five years.

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 efficacy, safety profile and effects as a single agent and in combination with other AML treatments, the planned commencement and timing of a pivotal Phase 3 clinical trial of voreloxin, and voreloxin's mechanism of action and results that may warrant further clinical evaluation of voreloxin. Words such as "support," "plan," "merit," "demonstrated," "designed," "will," "look forward to," "warrant," "potential," "leading," "confident," 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 studies 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 studies may not satisfy the requirements of the FDA or other regulatory agencies, risks related to the conduct of Sunesis' clinical studies, 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 March 31, 2010 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.

Investor and Media Inquiries:
David Pitts
Argot Partners
212-600-1902

Eric Bjerkholt
Sunesis Pharmaceuticals Inc.
650-266-3717

SOURCE: Sunesis Pharmaceuticals, Inc.