

## Sunesis Pharmaceuticals Presents Voreloxin Clinical Data at the American Society of Clinical Oncology 2009 Annual Meeting

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### -- Conference Call Scheduled for Today, Monday June 1, at 1:00 PM ET to Discuss ASCO Data Presentations --

SOUTH SAN FRANCISCO, Calif., June 1, 2009 /PRNewswire-FirstCall via COMTEX News Network/ -- Sunesis Pharmaceuticals, Inc. (Nasdaq: SNSS), announced today new data from three ongoing clinical trials demonstrating that Sunesis' lead drug candidate, voreloxin, shows promising safety and efficacy in acute myeloid leukemia (AML) and in platinum-resistant ovarian cancer. These data were presented today and this past weekend at the American Society of Clinical Oncology 2009 Annual Meeting in Orlando. The presentations are available on the Sunesis website at [www.sunesis.com](http://www.sunesis.com).

"We have made significant progress with our voreloxin program," said Daniel Swisher, Chief Executive Officer of Sunesis. "Over 190 patients were enrolled across the voreloxin trials in 2008. In AML, voreloxin, as a single agent or when combined with cytarabine, has induced over 50 patients into a complete remission to date. This positive momentum has carried into 2009 as we complete our current studies, prepare for our End-of-Phase 2 meeting with the FDA and complete our plans for entering into pivotal studies in AML."

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

REVEAL-1 (Response Evaluation of VorEloxin in AmL) is a Phase 2 dose regimen optimization study of single agent voreloxin in newly diagnosed elderly AML patients who are unlikely to benefit from standard induction chemotherapy. Interim clinical data from this study continue to show that voreloxin can induce durable complete remissions.

- In Schedule A (72 mg/m<sup>2</sup> of voreloxin weekly for three weeks), 29 patients have been enrolled and treated.
  - 20 of 29 patients (69 percent) were 70 years of age or older.
  - The majority of patients had intermediate or unfavorable cytogenetics.
  - 12 patients achieved a complete remission (CR) or complete remission without full platelet recovery (CRp) for an overall remission rate of 41 percent.
  - Eight of 12 responders received one consolidation cycle of voreloxin and no responders received a second consolidation cycle.
  - Grade 3 or higher non-hematologic adverse events occurring in more than 10 percent of patients include mucosal inflammation, infections and fatigue.
  - The 30-day all-cause mortality rate was 17 percent, which compares favorably to standard induction chemotherapy. Infection was the most common cause of early mortality.
- In Schedule B (72 mg/m<sup>2</sup> of voreloxin dosed weekly for two weeks), 35 patients have been enrolled and treated.
  - 27 of 35 patients (77 percent) were 70 years of age or older.
  - The majority of patients had intermediate or unfavorable cytogenetics.
  - Data from these patients suggest that Schedule B is better tolerated. The incidence of Grade 3 or higher mucosal inflammation has been reduced by more than 50 percent relative to Schedule A. The 30-day all-cause mortality has also been reduced to 9 percent.
  - Anti-leukemic activity has been maintained. 10 patients achieved a CR or CRp for an overall remission rate of 29 percent.
  - The number of responders receiving either one or two consolidation cycles increased. All 10 responders received one consolidation cycle of voreloxin and seven of 10 responders received a second consolidation cycle. While still too early to calculate, this may contribute to an improved median duration of remission in Schedule B compared to Schedule A.
- In Schedule C (72 mg/m<sup>2</sup> of voreloxin dosed on days one and four), 28

patients have been enrolled and treated.

- It is still too early for a complete remission evaluation, but four CRs and two CRps of 19 evaluable patients have been achieved to date, while nine patients are too early to evaluate.
- As with Schedule B, early data from patients suggest that Schedule C is better tolerated than Schedule A and activity has also been maintained. The 30-day all-cause mortality is currently nine percent (two of 23).
- Based on the current safety profile of 72 mg/m<sup>2</sup> of voreloxin in Schedule C as well as the ongoing Phase 1b/2 experience of 90 mg/m<sup>2</sup> of voreloxin dosed on days one and four in combination with cytarabine, an additional cohort of approximately 20 patients will be enrolled at 90 mg/m<sup>2</sup> in Schedule C.
- The median duration of remission and the median overall survival have not yet been reached in any schedule.
- In Schedule A, five of 12 responders remain in remission for over seven months while four have relapsed and three have withdrawn from remission follow-up.
- In Schedule B, nine of 10 responders remain in remission to date.
- More than half of all patients in Schedules A and B have survived more than six months.

"Voreloxin's anti-leukemic activity in this previously untreated, older adult patient population with AML is promising," said Robert K. Stuart, M.D., Professor of Medicine, Division of Hematology/Oncology, Department of Medicine, Medical University of South Carolina, and an investigator in the study. "I am encouraged by the complete remissions observed thus far in patients who are unlikely to benefit from standard induction therapy. Additionally, the convenience of a ten minute injection is an added benefit for both staff and patients."

#### Phase 1b/2 Study of Voreloxin in Combination with Cytarabine in Relapsed/Refractory AML

Researchers also presented interim data from an ongoing Phase 1b/2 clinical trial testing voreloxin in combination with cytarabine. The Phase 1b/2 trial is designed to evaluate the safety, pharmacokinetics and anti-leukemic activity of escalating doses of voreloxin when administered on days one and four with cytarabine given either as a continuous infusion of 400 mg/m<sup>2</sup> daily for five days (CIV Schedule) or as a two hour IV bolus of 1 g/m<sup>2</sup> daily for five days (Bolus Schedule).

- The Phase 1 dose escalation in both the CIV and Bolus Schedules has been completed with a maximum tolerated dose/recommended Phase 2 dose of 80 mg/m<sup>2</sup> and 90 mg/m<sup>2</sup>, respectively.
- Between both schedules, 57 relapsed or refractory patients have been enrolled and treated in the dose escalation.
- In the Phase 1 portions of this study, infection related toxicities were the most common Grade 3 or higher adverse events. The overall incidence of Grade 3 or higher mucosal inflammation was 11 percent when patients from both the CIV and Bolus Schedules are combined.
- In the dose escalation, nine of 39 patients (23 percent) in the CIV Schedule and four of 18 patients (22 percent) in the Bolus Schedule achieved a CR or CRp. Responders included first relapse, second relapse, primary refractory and relapsed/refractory patients.
- In the CIV Schedule dose escalation, six of nine responders to date have had a remission of at least eight months and a third of responders went on to receive a bone marrow transplant.
- It is too early to evaluate remission duration in the Bolus Schedule dose escalation.
- Across both the CIV and Bolus Schedules, a total of 14 patients with primary refractory AML were enrolled and treated with a voreloxin dose of 80 mg/m<sup>2</sup> or higher. Five of 14 of these patients achieved a CR or CRp for an overall CR or CRp rate of 36 percent, which compares favorably relative to expected remission rates in this AML population of approximately 10 to 15 percent.
- In Phase 2, 16 AML patients in first relapse were enrolled in the CIV Schedule.
- Infection related toxicities were the most common Grade 3 or higher

- adverse events and no Grade 3 or higher mucosal inflammation was observed.
- Six CRs and one CRp were achieved for an overall CR or CRp rate of 44 percent, which compares favorably relative to the expected single agent cytarabine remission rate of approximately 20 percent. Five first relapse AML patients were enrolled in the dose escalation in the CIV Schedule at a dose of 80 mg/m<sup>2</sup> or higher, of whom none achieved a CR or CRp.
  - Three of seven responders had an initial remission, or CR1, of less than 12 months, and to date, five of seven responders remain in remission.
  - In the Bolus Schedule, both first relapse and primary refractory patients are currently being enrolled in Phase 2.

"Voreloxin has demonstrated anti-leukemic activity when administered in combination with both continuous infusion and bolus cytarabine," said Jeffrey Lancet, M.D, Assistant Professor and Section Chief of the Leukemia Program, Division of Hematologic Malignancies at the H. Lee Moffitt Cancer Center & Research Institute, and an investigator in this voreloxin/cytarabine combination study in AML. "Voreloxin has induced remissions in several difficult to treat AML patient populations, including relapsed, primary refractory and relapsed/refractory AML patients. I look forward to the final results of this study and the continued clinical investigation of voreloxin."

#### Phase 2 Study of Single Agent Voreloxin in Women with Platinum-Resistant Ovarian Cancer

Updated clinical data from the Phase 2 study of single agent voreloxin in women with platinum-resistant ovarian cancer were also presented at the ASCO 2009 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. Approximately a third of the study patients have also failed prior treatment with Doxil(R).

- Three dose cohorts of voreloxin have been studied, 48 mg/m<sup>2</sup> given every three weeks (N=65), 60 mg/m<sup>2</sup> given every four weeks (N=37) and 75 mg/m<sup>2</sup> given every four weeks (N=35). Enrollment completed in December of 2008. 16 patients in the 60 mg/m<sup>2</sup> and 75 mg/m<sup>2</sup> cohorts remain on study.
- Data from this trial show encouraging durable anti-tumor activity across all three dose cohorts. The overall response rate (ORR), as measured by GOG RECIST criteria, was eleven percent for each of the three dosing cohorts: two complete responses (CR) and five partial responses (PR) in cohort A (48 mg/m<sup>2</sup> q3 weeks), two CRs and two PRs in cohort B (60 mg/m<sup>2</sup> q4 weeks) and four PRs in cohort C (75 mg/m<sup>2</sup> q4 weeks).
- 74 patients (52 percent) experienced disease control, defined as an objective response or stable disease for 12 weeks or more.
- The median progression free survival (PFS) for cohort A was 82 days. The preliminary median PFS for cohorts B and C is 84 days and 109 days, respectively. There was a significant difference in PFS among the 3 dose cohorts (p = 0.019). PFS was significantly longer in the 60 and 75 mg/m<sup>2</sup> cohorts vs. 48 mg/m<sup>2</sup>, suggesting a benefit to higher voreloxin doses.
- Four PRs were achieved in the 44 women who were Doxil(R) failures for an ORR of nine percent and 28 (64 percent) achieved disease control.
- The preliminary median PFS in these Doxil(R) failure patients is 90 days. PFS was not statistically different from those who had not failed Doxil(R).
- Overall, the adverse event profile was similar across cohorts and voreloxin was generally well-tolerated. Grade 3 or higher adverse events occurring in more than 10 percent of patients include neutropenia, febrile neutropenia, and anemia.
- The incidence of febrile neutropenia was increased in cohort C (75 mg/m<sup>2</sup> q4 weeks), and was clinically manageable and within the range of other commonly used and approved agents in ovarian cancer.

"Voreloxin continues to demonstrate promising clinical activity in a vastly underserved patient population," said Robert P. Edwards, M.D., Professor of Obstetrics, Gynecology, and Reproductive Sciences and Vice Chair of the Division of Gynecologic Oncology at the University of Pittsburgh, and an investigator for the Phase 2 clinical trial. "I am encouraged by the preliminary data, including the activity in patients that are resistant or refractory to both platinum-based chemotherapy and Doxil(R)."

#### Conference Call Information

Sunesis management, joined by voreloxin clinical investigators, will host a conference call to discuss the voreloxin clinical data presented at the ASCO 2009 Annual Meeting today, Monday, June 1, 2009, at 1:00 p.m. ET / 10:00 a.m. PT. Individual and institutional investors can access the call via 1-877-856-1961 (U.S. and Canada) or +1-719-325-4787 (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](http://www.sunesis.com). The webcast will be recorded and available for replay on the company's website until June 15, 2009.

#### 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 over 13,000 new cases of AML were diagnosed and approximately 9,000 deaths from AML occurred in the U.S. during 2007. 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 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 2008 there were an estimated 21,650 new cases and more than 15,000 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, with five-year survival rates at less than 30 percent.

#### 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 the potential safety and efficacy and commercial potential of voreloxin, the efficacy and benefits of voreloxin as compared to currently available treatments, planned additional clinical testing and development efforts and the timing of interactions with regulatory authorities. Words such as "shows," "suggest," "will," "promising," "activity," "demonstrated," "encouraged," "preliminary," "continues" 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 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, including the pace of enrollment, 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/A for the year ended December 31, 2008, its quarterly report on Form 10-Q for the quarter ended March 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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