Sunesis Announces Updated Clinical Data of Voreloxin in Platinum-Resistant Ovarian Cancer

October 27, 2008 1:53 PM ET

- Preliminary Data from SNS-314 Phase 1 Clinical Trial Also Presented at EORTC -

SOUTH SAN FRANCISCO, Calif., Oct 27, 2008 /PRNewswire-FirstCall via COMTEX News Network/ -- Sunesis Pharmaceuticals, Inc. (Nasdaq: SNSS) today announced a presentation of updated interim results from an ongoing Phase 2 clinical trial demonstrating that the Company's lead product candidate, voreloxin, shows promising efficacy and safety as a single agent in patients with platinum-resistant ovarian cancer. Ovarian cancer remains an unmet medical need with high recurrence rates, and the majority of patients ultimately become resistant to platinum-based therapies. These data show encouraging durable anti-tumor activity in the 48 mg/m2 cohort, as measured by partial and complete responses, and preliminary progression-free survival (PFS). Voreloxin has been generally well tolerated at dose levels of 48 mg/m2 and 60 mg/m2.

"Voreloxin continues to demonstrate promising clinical activity in a vastly underserved patient population," said William McGuire, M.D., Medical Director of the Harry and Jeanette Weinberg Cancer Institute at Franklin Square and principal investigator for the Phase 2 clinical trial. "I am encouraged by the preliminary data from the 48 mg/m2 cohort. When compared to other commercially available drugs that are used in the platinum-resistant setting, voreloxin has a similar response rate and a reasonable toxicity profile."

"The preliminary data from the 60 mg/m2 cohort suggests activity similar to that of the 48 mg/m2 cohort. This is expected since the weekly dose intensity is approximately the same. We are encouraged by the pace of enrollment in the 75 mg/m2 cohort and anticipate initial response and safety data from this cohort in the spring of next year," said Dr. Mary Bolton, Vice President, Clinical Development at Sunesis.

The ongoing Phase 2 trial is an open-label, multi-center study of voreloxin as a single agent in recurrent ovarian cancer patients who have platinum-resistant disease, defined as progression within six months of completing platinum-based chemotherapy or progression while on platinum-based therapy. To date, over 120 patients have enrolled in the trial, with enrollment completed in the 48 mg/m2 cohort dosed every three weeks and the 60 mg/m2 cohort dosed every four weeks. In the 48 mg/m2 cohort, of the 65 women evaluable for best response using GOG-RECIST criteria, two patients had a complete response, five patients had partial responses and 46 patients achieved stable disease. Thirty patients (46%) achieved disease control, defined as stable disease for 90 days or more or a complete or partial response. The preliminary median PFS was 82 days, or 11.7 weeks, at the 48 mg/m2 dose. Six patients remain on study in this dose cohort.

In the 60 mg/m2 cohort, the Company reported early efficacy data for 32 of the 35 patients treated at this dose who were evaluable for best response using GOG-RECIST criteria. Of these 32 patients, preliminary data show one patient had a complete response, two patients had partial responses and 20 patients achieved stable disease. The data at the 60 mg/m2 dose are not yet mature enough to calculate disease control or PFS. Thirteen patients remain on study in this dose cohort.

Voreloxin has been generally well tolerated in the platinum-resistant ovarian cancer population in both cohorts, with a total incidence of febrile neutropenia below 10%. This safety profile supported increasing the dose intensity by more than 25% to 75 mg/m2 dosed every four weeks. The Company has enrolled 22 of 30 patients in the 75 mg/m2 cohort and is on track to complete enrollment by the end of 2008. Additional clinical data from all three cohorts are expected in the first half of 2009.

All patients enrolled in the trial have previously failed treatment with platinum-containing regimens in less than 6 months, and approximately one-third of the patients across the dosing cohorts have also failed prior treatment with doxorubicin HCl liposome injection (Doxil(R)). Both platinum-resistant and Doxil-failure patients in this trial have responded to voreloxin therapy.

These data were discussed in a poster session on October 25, 2008, entitled "A Phase 2 Trial of Voreloxin (SNS-595) in Women with Platinum-Resistant Ovarian Cancer" Abstract 1607 at the 12th Biennial Meeting of the International Gynecologic Cancer Society (IGCS) in Bangkok, Thailand. A copy of the poster is available at http://www.sunesis.com.

Voreloxin Mechanism of Action and SNS-314 Interim Phase 1 Clinical Results Presented at EORTC-NCI-AACR Meeting

Researchers also presented results from nonclinical studies of voreloxin, a naphthyridine analog structurally related to the quinolones, which have not been previously used clinically for cancer treatment. Data from these studies showed that voreloxin appears to be a potent anti-cancer agent through the intercalation of DNA and inhibition of topoisomerase II, which leads to site-selective DNA damage in replicating cells, cell cycle arrest and cell death. Through its validated mechanism of action and distinct chemical structure, voreloxin selectively and potently pushes dividing cells into apoptosis, evades common drug resistance pathways and may have advantages over other topoisomerase inhibitors.

These results were discussed in a poster session on October 24, 2008, entitled "Voreloxin (formerly SNS-595) is a Potent DNA Intercalator and Topoisomerase II Poison that Induces Cell Cycle Dependent DNA Damage and Rapid Apoptosis in Cancer Cell Lines" Abstract 598 at the EORTC-NCI-AACR Symposium on Molecular Targets and Cancer Therapeutics, Geneva, Switzerland. A copy of the poster is available at http://www.sunesis.com.

In addition, researchers presented preliminary results from an ongoing Phase 1 clinical trial of SNS-314 in patients with advanced solid tumors. SNS-314 is a potent and selective pan-Aurora kinase inhibitor. Aurora kinases play a key role in orderly progression through mitosis and have been implicated in a wide range of human tumors, including melanoma, colon, breast, ovarian, gastric and pancreatic tumors. Sunesis reported on a total of 24 patients enrolled into seven cohorts with a dose range of 30 mg/m2 to 1440 mg/m2 given weekly for 3 weeks on a 28-day cycle. There was one dose limiting toxicity (DLT) of grade 3 neutropenia. No other DLTs or grade 3 or higher related adverse events have been observed. At the 240 mg/m2 dose level and above, inhibition of Histone-H3 phosphorylation, a biomarker of Aurora activity, is observed. Pharmacodynamic assessment of drug-mediated target modulation is ongoing. No objective responses have been observed to date. Dose escalation continues and cohort 8 at 1800 mg/m2 is currently enrolling patients. SNS-314 exposure levels at this dose may correspond to preclinical exposure levels where objective anti-tumor activity was observed in animal models.

These results were discussed in a poster session on October 23, 2008, entitled "Phase 1 Trial of SNS-314, a Novel Selective Inhibitor of Aurora Kinases A, B, and C, in Advanced Solid Tumor Patients" Abstract 283 at the EORTC-NCI-AACR Symposium on Molecular Targets and Cancer Therapeutics, Geneva, Switzerland. A copy of the poster is available at http://www.sunesis.com.

About Voreloxin

Voreloxin is a first-in-class naphthyridine analog, a chemical structure closely related to that of the quinolone antibacterial agents. Voreloxin exerts potent anti-cancer activity through a mechanism that involves intercalation into DNA and an inhibition of topoisomerase II activity that results in replication-dependent, site-selective double-strand breaks in DNA followed by G2 arrest and apoptosis. Voreloxin is currently being evaluated as a single agent in a Phase 2 clinical trial (known as the REVEAL-1 trial) in previously untreated elderly patients with acute myeloid leukemia (AML), in a Phase 1b/2 clinical trial combining voreloxin with cytarabine for the treatment of patients with relapsed/refractory AML, and as a single agent in a Phase 2 clinical trial in platinum-resistant ovarian cancer. In clinical trials conducted to date, voreloxin has been generally well tolerated and has shown objective responses in both solid and hematologic tumor types.

About SNS-314

SNS-314, a potent and selective pan-Aurora kinase inhibitor, is being studied in a Phase 1 dose-escalating clinical trial in patients with advanced solid tumors.

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 will be 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 (formerly SNS-595) and SNS-314, planned additional clinical testing and development efforts, the timing of clinical trial enrollment and the anticipated announcement of clinical results. Words such as "may," "will," "appears," "suggest," "expects," "preliminary," "interim," "promising," "encouraging" 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 discovery and development activities could be halted significantly or delayed for various reasons, the risk that Sunesis' clinical trials for voreloxin and SNS-314 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' preclinical 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 Sunesis' product candidates, risks related to Sunesis' need for additional funding and the risk that Sunesis' proprietary rights may not adequately protect the Company's product candidates. These and other risk factors are discussed under "Risk Factors" and elsewhere in Sunesis' annual report on Form 10-K for the year ended December 31, 2007, its quarterly report on Form 10-Q for the quarter ended June 30, 2008 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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