Sunesis Pharmaceuticals Reports Positive Interim Data for SNS-595 Single-Agent Activity in Platinum-Resistant Ovarian Cancer

March 10, 2008 1:39 PM ET

SOUTH SAN FRANCISCO, Calif., March 10, 2008 /PRNewswire-FirstCall via COMTEX News Network/ -- Sunesis Pharmaceuticals, Inc. (Nasdaq: SNSS), a clinical-stage biopharmaceutical company focused on the discovery, development and commercialization of novel small-molecule therapeutics, today announced positive interim data from the company's ongoing Phase 2 clinical trial of its lead product candidate, SNS-595, in platinum-resistant ovarian cancer patients.

In this Phase 2 clinical trial, single agent SNS-595 has demonstrated disease control (defined as stable disease, partial response or complete response) in 31 of 35 patients evaluable for best response using GOG-RECIST criteria. Of these 31 patients, one patient had a complete response, four patients had partial responses (two unconfirmed) and 26 patients had a best response of stable disease. All patients enrolled in the trial have previously failed treatment with platinum-containing regimens, and fourteen of the 35 patients have also failed prior treatment with doxorubicin HCl liposome injection (Doxil(R)). Both platinum-resistant and Doxil-resistant patients in the Phase 2 clinical trial have responded to SNS-595 therapy.

"Recurrence rates among ovarian cancer patients remain high, and the majority of refractory patients are resistant to platinum-based therapies. Based on these interim data, SNS-595 appears to be a promising, active agent in a difficult-to-treat ovarian cancer patient population," said William P. McGuire, M.D., Medical Director of the Harry and Jeanette Weinberg Cancer Institute at Franklin Square, and a lead investigator for the Phase 2 trial.

Among forty-five patients with sufficient follow-up to yield safety data, SNS-595 was generally well tolerated at a dose level of 48mg/m2 administered once every three weeks. The most common adverse events reported thus far include nausea, fatigue, vomiting and alopecia. There was a low rate of febrile neutropenia or other Grade 3/4 adverse events, and manageable Grade 1/2 nausea or vomiting.

Based on the indications of clinical activity and the acceptable tolerability profile demonstrated to date among this patient population, the dose of SNS-595 in this trial has been increased to 60 mg/m2 over twenty-eight days. Patient accrual at this dose level is ongoing.

"We are pleased by the strong signal of activity emerging from our Phase 2 clinical trial of SNS-595 at the 48mg/m2 dose level. Based on the drug's observed safety profile and recommendations from advisors, we are exploring a higher dose of SNS-595 in this trial. Enrollment has begun at 60 mg/m2 and we expect to enroll approximately 30 patients at this dose by the third quarter of this year," said Daniel C. Adelman, M.D., Senior Vice President, Development and Chief Medical Officer of Sunesis. "Enthusiasm for SNS-595 among our clinical investigators is growing and enrollment in this trial has been accelerating. We expect to present further data from this Phase 2 clinical trial this year."

The interim clinical results are being presented in a poster, "A Phase 2 Trial of SNS-595 in Women with Platinum-Refractory Epithelial Ovarian Cancer" (Abstract # 290), at the 39th Annual Meeting on Women's Cancer hosted by the Society of Gynecologic Oncologists (SGO) in Tampa, Fla. through March 12, 2008.

About SNS-595

SNS-595 is a novel naphthyridine analog, structurally related to quinolones, a class of compounds which has not been used previously for the treatment of cancer. SNS-595 is a specific DNA intercalator and topoisomerase II poison, causing replication-dependent site-selective double strand DNA damage, irreversible G2 arrest and rapid apoptosis. In non-clinical evaluations, SNS-595 demonstrates broad and potent activity in xenograft, syngeneic and drug-resistant models. In addition to the Phase 2 clinical trial in ovarian cancer patients, SNS-595 is currently being evaluated in combination with cytarabine in a Phase 1b acute leukemia clinical trial. In clinical trials conducted to date, SNS-595 has been generally well tolerated and has shown objective responses in both solid and hematologic tumor types.

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 clinical-stage biopharmaceutical company focused on the discovery, development and commercialization of novel small molecule therapeutics for oncology and other serious diseases. Sunesis has built a broad product candidate portfolio through internal discovery and in-licensing of novel cancer therapeutics. Sunesis is advancing its product candidates through in-house research and development efforts and strategic collaborations with leading pharmaceutical and biopharmaceutical companies. For additional information on Sunesis Pharmaceuticals, please visit http://www.sunesis.com.

Safe Harbor Statement

This press release contains forward-looking statements including without limitation statements related to the potential safety and efficacy and commercial potential of SNS-595, planned additional clinical testing and development efforts, the timing of enrollment in the ongoing Phase 2 clinical trial and the announcement of clinical results. Words such as "look forward," "suggests," "may," "plans," "expects," "appears" 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, including enrollment and reporting of results, could be halted significantly or delayed for various reasons, the risk that Sunesis' clinical trials for SNS-595 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 and manufacturing of SNS-595 and risks related to Sunesis' need for additional funding. 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, 2006 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.

SOURCE Sunesis Pharmaceuticals, Inc.

http://www.sunesis.com