Sunesis Pharmaceuticals Focuses Resources on Development of Voreloxin (Formerly SNS-595)

June 3, 2008 1:49 PM ET

Development Leadership Team in Place to Advance Voreloxin to Late-Stage Trials
Strategic Realignment Includes Workforce Reduction to Streamline Operations

SOUTH SAN FRANCISCO, Calif., June 3, 2008 /PRNewswire-FirstCall via COMTEX News Network/ -- Sunesis Pharmaceuticals, Inc. (Nasdaq: SNSS) today announced a corporate realignment to focus on the development of the company's lead oncology product candidate, voreloxin (formerly SNS-595). In conjunction with this strategic restructuring, Sunesis expanded the company's late-stage development leadership team and announced a workforce reduction of approximately 60 percent, including the winding down of its research activities. These changes are intended to concentrate the company's financial and human resources on the strongest path to potential near-term value creation for the company's stockholders.

"Based on the promising clinical data achieved to date, we have made a strategic decision to focus the organization on generating critical clinical data by advancing our lead compound, voreloxin, into late-stage trials in the acute myeloid leukemia and ovarian cancer indications," said Daniel Swisher, Sunesis' Chief Executive Officer. "Late-stage development requires increased focus of our resources. We are also expanding and strengthening our development team with the additions of Drs. Steve Ketchum and Mary Bolton. Their extensive product development and regulatory expertise and track records of successful FDA submissions in a breadth of therapeutic areas will support our plan to advance voreloxin through late-stage trials."

Steven B. Ketchum, Ph.D., has been appointed as Senior Vice President, Research and Development and Mary G. Bolton, M.D., Ph.D., as Vice President, Clinical Development. In addition, Judith A. Fox, Ph.D., has been promoted to Vice President, Product and Preclinical Development and Glenn C. Michelson, M.D., has been promoted to Vice President, Clinical Strategy.

To date, voreloxin has demonstrated objective responses in both solid and hematologic tumors and has been consistently well tolerated in multiple clinical trials. Sunesis is currently conducting Phase 2 clinical trials of voreloxin as a single agent for the treatment of platinum-resistant ovarian cancer and previously untreated acute myeloid leukemia (AML), as well as a Phase 1b clinical trial of voreloxin in combination with cytarabine in relapsed/refractory AML. Data recently reported at the 44th ASCO Annual Meeting in the Phase 2 ovarian cancer trial demonstrated that 48 percent of platinum-resistant ovarian cancer patients treated at a dose of 48 mg/m2 once every 21 days achieved disease control, defined as stable disease for 90 days or more or a complete or partial response. Preliminary median progression- free survival in this group of patients was 13 weeks at this dose; twenty- three patients at this dose remained on study as of May 12, 2008. Later this month, at the European Hematology Association Congress, Sunesis will report updated data on voreloxin's activity alone, and interim data on voreloxin's activity in combination with cytarabine for the treatment of AML.

Sunesis continues ongoing trials in its earlier-stage clinical programs, including the Phase 1 dose-escalation study of its cyclin-dependent kinase inhibitor, SNS-032, and its pan-Aurora kinase inhibitor, SNS-314, and expects to report data from these clinical trials this year. The company plans to seek a development partner to support advanced clinical trials of SNS-314. Future development of SNS-032 will depend on achieving positive results from the ongoing trial.

With the closing of its internal discovery research activities, Sunesis will also explore opportunities to monetize the company's extensive fragment- based drug discovery capabilities, its preclinical programs and/or its intellectual property portfolio through a potential spin out or strategic alliance.

Sunesis will continue to benefit from any down-stream milestones or royalties based on future progress made in compounds emerging from its existing drug discovery collaborations with Biogen Idec Inc., Johnson & Johnson Pharmaceutical Research and Development LLC, Merck & Co., Inc. and SARcode Corporation. Sunesis anticipates that

one or more of these compounds may advance to clinical trials within the next twelve months.

With this restructuring, Sunesis is reducing its workforce by approximately 60 employees. In addition, executive team members Daniel C. Adelman, M.D., Senior Vice President, Development and Chief Medical Officer, William L. Schary, Ph.D., Vice President, Regulatory Affairs and Quality Assurance, Robert S. McDowell, Ph.D., Vice President, Research and Jennifer A. Troia, SPHR, Vice President, Human Resources and Corporate Operations, will be leaving the company. Employees affected by the restructuring will be eligible for a severance package that includes severance pay, continuation of benefits and professional outplacement services. A one-time charge of approximately $10.7 million is expected to be incurred in the second quarter of 2008. Approximately $8.0 million of this charge is related to the closing of the company's research facility. Approximately $2.5 million of the restructuring charge represents cash payments over the next twelve months for severance and other personnel related expenses.

"The decision to undertake this workforce reduction is a difficult one. I deeply appreciate all of the past contributions made on behalf of Sunesis by the talented and committed employees affected by this realignment. I am confident that the ongoing team will build upon their legacy as we aggressively advance voreloxin through late-stage clinical studies," said Mr. Swisher.

Actions taken today will allow the company to direct most of its resources into the late-stage development of voreloxin. Sunesis expects this realignment of personnel and programs to reduce annual operating expenses by more than $15 million, thus enabling increased investment into such development. Current burn rate guidance for the second half of 2008 is in the range of $12-15 million, including payment of severance and other restructuring charges.

About Voreloxin (formerly SNS-595)

Sunesis' lead compound, voreloxin (formerly 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. Voreloxin both intercalates DNA and inhibits topoisomerase II, resulting in replication- dependent, site-selective DNA damage, irreversible G2 arrest and rapid apoptosis. Voreloxin is currently being evaluated in a Phase 2 clinical trial (known as the REVEAL-1 trial) in previously untreated elderly AML patients, in a Phase 1b 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 Sunesis Pharmaceuticals

Sunesis is a clinical-stage biopharmaceutical company focused on the development 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.

Safe Harbor Statement

This press release contains forward-looking statements including without limitation statements related to the expected timing for completion of the restructuring plan; estimated restructuring charges to be incurred by Sunesis in the second quarter; anticipated benefits of the restructuring; potential safety and efficacy and commercial potential of voreloxin (formerly SNS-595); planned additional clinical testing and development efforts for the company's programs; the timing of enrollment in the ongoing Phase 2 clinical trial for voreloxin; the timing of announcements of clinical results for the company's programs; the company's plans to monetize the company's extensive fragment- based drug discovery capabilities and/or intellectual property portfolio; the advancement of compounds with the company's collaboration partners to clinical trials in 2008; the anticipated costs incurred by the company in connection with the restructuring; and

the company's anticipated burn rate for the second half of 2008. Words such as "promising," "supports," "optimistic," "look forward," "expects" 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 or those of its partners, including enrollment and reporting of results, could be halted significantly or delayed for various reasons; the risk that Sunesis' clinical trials for voreloxin or its other programs 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; the risk that Sunesis may not be able to monetize its fragment-based drug discovery capabilities and/or intellectual property portfolio; the risk that Sunesis' restructuring costs may be greater than anticipated; the risk that Sunesis' workforce reduction and any future workforce and expense reductions may have an adverse impact on Sunesis' internal programs, Sunesis' ability to hire and retain key personnel and may be distracting to management; 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, 2007, Sunesis' Quarterly Report on Form 10-Q for the quarter ended March 31, 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.

SOURCE Sunesis Pharmaceuticals, Inc.

http://www.sunesis.com