**Sunesis Pharmaceuticals Reports Second Quarter Financial Results and Recent Highlights**

July 29, 2013 4:01 PM ET

**VALOR Enrollment Exceeds 675 Patients**

**Cardiff University-Sponsored LI-1 Trial Monotherapy Treatment Arm Evaluated by DMEC**

**Investigator-Sponsored Phase I/II Trial Evaluating Vosaroxin in Combination with Decitabine in AML and MDS Initiated at MD Anderson Cancer Center**

***Sunesis to Host Conference Call Today at 5PM Eastern Time***

SOUTH SAN FRANCISCO, Calif., July 29, 2013 (GLOBE NEWSWIRE) -- Sunesis Pharmaceuticals, Inc. (Nasdaq:SNSS) today reported financial results for the quarter ended June 30, 2013. Loss from operations for the three and six months ended June 30, 2013 was $8.6 million and $16.4 million, respectively. As of June 30, 2013, cash, cash equivalents and marketable securities totaled $49.6 million.

"We continue to make substantial progress with the VALOR trial, a study with transformational potential in the treatment of AML," said Daniel Swisher, Chief Executive Officer of Sunesis. "With the goal of reaching a final sample size of at least 675 evaluable patients, the trial was designed to over enroll by 5% to 712 patients. As of today, enrollment has exceeded 675 patients, and we now expect to complete enrollment this quarter, with unblinding of the trial expected in the first half of 2014."

Mr. Swisher added: "As to the Cardiff University-sponsored LI-1 trial in front-line elderly AML, we have been informed that the DMEC will recommend that the monotherapy vosaroxin arm discontinue enrollment. We will be working closely with Cardiff University to better understand the outcomes in this study arm, and why they differed from our Phase 2 REVEAL-1 trial. We are confident in vosaroxin's broader potential, which we continue to explore through investigator-sponsored studies, such as the newly initiated MD Anderson Cancer Center trial in previously untreated AML and MDS."

Regarding the MD Anderson Cancer Center-sponsored, Phase I/II trial of vosaroxin and decitabine in AML and high-risk MDS, Adam R. Craig, M.D., Ph.D., Executive Vice President, Development and Chief Medical Officer of Sunesis, added: "This trial allows for the expanded development of vosaroxin in difficult-to-treat AML and MDS populations. Unique and non-overlapping anti-leukemic activities make vosaroxin and decitabine well suited for frontline combination therapy. We look forward to monitoring the progress of this study and to supporting MD Anderson and others in exploring the full potential of vosaroxin."

**Second Quarter 2013 and Recent Highlights**

- ***Continued strong execution of VALOR trial.*** In June, the independent Data and Safety Monitoring Board (DSMB) for the VALOR trial completed its fifth periodic safety review and recommended that the trial continue as planned without changes to study conduct. Per protocol, enrollment of the VALOR trial is continuing to 712 patients. As of July 29, 2013, over 675 patients have been enrolled, with full enrollment expected by the end of the third quarter of 2013. Unblinding is expected in the first half of 2014 after reaching 562 events and locking the final study database.

- ***Initiation of Investigator-Sponsored Phase I/II Trial Evaluating Vosaroxin in Combination with Decitabine in Acute Myeloid Leukemia and High-Risk Myelodysplastic Syndrome.*** Sunesis announced the initiation of a Phase I/II investigator-sponsored trial of vosaroxin in combination with decitabine in older patients with previously untreated acute myeloid leukemia (AML) and high-risk myelodysplastic syndrome (MDS). The trial is being conducted at the MD Anderson Cancer Center at the University of Texas under the direction of Naval Daver, M.D., Assistant Professor, Department of Leukemia and Farhad Ravandi, M.D., Professor of Medicine, Department of Leukemia and a principal investigator of VALOR. The open-label, single-arm trial is expected to enroll up to approximately 84 patients who will be treated with vosaroxin intravenously on days one and four in combination with decitabine for five consecutive days.

  The primary endpoints of the Phase I trial are to determine the safety, maximum tolerated dose, and dose limiting toxicity of vosaroxin in combination with decitabine in patients with high-risk MDS or AML who are unable or unwilling to receive standard cytarabine plus anthracycline based chemotherapy. The primary endpoint of the Phase II trial is to determine the

efficacy of the combination based on achievement of complete remission (CR) and CR with incomplete blood count recovery (CRi). Secondary endpoints include safety, CR duration, leukemia-free survival, and overall survival.

- ***LI-1 trial update***. Sunesis has been informed that the Cardiff University-sponsored LI-1 trial's Data Monitoring and Ethics Committee (DMEC) will be recommending to discontinue the monotherapy vosaroxin arm as it did not meet the pre-specified criteria for advancement. Enrollment of the first 50 patients in the combination arm of vosaroxin and LoDAC is now near completion and the first interim evaluation of that arm is expected to take place before year end. The LI-1 trial is being conducted under the direction of Professor Alan K. Burnett, Head of Haematology at Cardiff University.

- ***Announced peer reviewed publication featuring vosaroxin.*** In May, Sunesis announced the publication of a peer-reviewed paper in *Expert Opinion on Pharmacotherapy* entitled "Vosaroxin: a new valuable tool with the potential to replace anthracyclines in the treatment of AML?" In addition to an overview of the chemistry, pharmacokinetics and clinical development of vosaroxin, the paper explores the potential advantages of vosaroxin over anthracycline therapy, including overcoming resistance mechanisms, more site-selective DNA damage, and reduced formation of DNA adducts and reactive oxygen species, resulting in better tolerability.

- ***Strengthened Board of Directors.*** In June, Sunesis announced the appointment of Steve Carchedi to the Sunesis Board of Directors. Mr. Carchedi brings more than 30 years of commercial industry experience with GE Healthcare, Endo Pharmaceuticals, Enzon Pharmaceuticals, Johnson & Johnson and Bristol Myers Squibb, focused in Oncology, Neurology, Urology, Endocrinology and Cardiology.

**Financial Highlights**

- Cash and investments totaled $49.6 million as of June 30, 2013, as compared to $71.2 million as of December 31, 2012. The decrease of $21.6 million was primarily due to $19.0 million of cash used in operating activities and $2.8 million of principal payments against notes payable, which had an outstanding balance of $22.0 million as of June 30, 2013.

- Total revenue was $2.0 million and $4.0 million for the three and six months ended June 30, 2013, as compared to $1.5 million for each of the same periods in 2012. Revenue in the 2013 periods was due to deferred revenue recognized related to the royalty agreement with Royalty Pharma. Revenue in the 2012 periods was due to the receipt of a payment of $1.5 million from Biogen Idec in June 2012 for the advancement of pre-clinical work under the current agreement with Biogen Idec.

- Research and development expense totaled $7.7 million and $15.1 million for the three and six months ended June 30, 2013, as compared to $8.1 million and $14.7 million during the same periods in 2012. The decrease between the comparable three month periods was primarily due to a decrease of $0.9 million in drug manufacturing costs, partially offset by an increase in clinical trial expenses of $0.5 million. The increase between the comparable six month periods was primarily due to increased clinical trial expenses.

- General and administrative expenses for the three and six months ended June 30, 2013 were $2.9 million and $5.3 million, as compared to $2.2 million and $4.4 million for the same periods in 2012. The increases between the comparable periods were primarily due to higher personnel and professional service costs.

- Interest expense was $0.8 million and $1.6 million for the three and six months ended June 30, 2013, as compared to $0.3 million and $0.6 million for the same periods in 2012. The increase in 2013 was due to the draw-down of the second tranche of $15.0 million from the 2011 venture loan facility in September 2012.

- Net other income was $1.2 million for the three months ended June 30, 2013, as compared to $0.5 million for the same period in 2012. Net other expense was $1.8 million for the six months ended June 30, 2013, as compared to $4.3 million for the same period in 2012. The amounts for each period were primarily comprised of non-cash charges or credits for the revaluation of warrants issued in the underwritten offering completed in October 2010.

- Cash used in operations was $19.0 million for the six months ended June 30, 2013, as compared to $15.1 million for the same period in 2012. Net cash used in the 2013 period resulted primarily from the net loss of $19.8 million and changes in operating assets and liabilities of $3.2 million, partially offset by net adjustments for non-cash items of $3.9 million.

- Sunesis reported a loss from operations of $8.6 million and $16.4 million for the three and six months ended June 30, 2013, as compared to $8.8 million and $17.6 million for the same periods in 2012. Net loss was $8.2 million and $19.8 million for the three and six months ended June 30, 2013 as compared to $8.6 million and $22.5 million for the same periods in 2012.

**Conference Call Information**

Sunesis will host an update conference call today, July 29 at 5:00 p.m. Eastern Time. The call can be accessed by dialing (877) 703-6106 (U.S. and Canada) or (857) 244-7305 (international), and entering passcode 37128110. 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 the Sunesis website for two weeks.

**About VALOR**

VALOR is a Phase 3, randomized, double-blind, placebo-controlled, pivotal trial in patients with first relapsed or refractory AML. The trial's target enrollment is 712 patients at more than 100 leading sites in the U.S., Canada, Europe, South Korea, Australia and New Zealand. The VALOR trial is currently enrolling patients, who are randomized in a ratio of 1:1 to receive either vosaroxin on days one and four in combination with cytarabine daily for five days, or placebo in combination with cytarabine. The trial's primary endpoint is overall survival. For more information on the VALOR trial, please visit www.valortrial.com.

**About Vosaroxin**

Vosaroxin is a first-in-class anti-cancer quinolone derivative (AQD), a class of compounds that has not been used previously for the treatment of cancer. Vosaroxin both intercalates DNA and inhibits topoisomerase II, resulting in replication-dependent, site-selective DNA damage, G2 arrest and apoptosis. Both the U.S. Food and Drug Administration (FDA) and European Commission have granted orphan drug designation to vosaroxin for the treatment of AML. Additionally, vosaroxin has been granted fast track designation by the FDA for the potential treatment of relapsed or refractory acute myeloid leukemia in combination with cytarabine.

**About AML**

AML is a rapidly progressing cancer of the blood characterized by the uncontrolled proliferation of immature blast cells in the bone marrow. The American Cancer Society estimates there will be approximately 14,590 new cases of AML and approximately 10,370 deaths from AML in the U.S. in 2013. Additionally, it is estimated that the prevalence of AML across major global markets (U.S., France, Germany, Italy, Spain, United Kingdom and Japan) is over 50,000. 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 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, vosaroxin, in multiple indications to improve the lives of people with cancer. For additional information on Sunesis, please visit http://www.sunesis.com.

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This press release contains forward-looking statements, including statements related to the design, conduct, progress, timing and results of the VALOR trial, the LI-1 trial and Sunesis' other clinical programs discussed in this release. Words such as "progress," "expect," "to occur," "will," "complete," "continue," "look forward to," "towards," "target," remain," "potential," "strengthened," 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 substantial additional funding to complete the development and commercialization of vosaroxin, risks related to Sunesis' ability to raise the capital that it believes to be accessible and is required to fully finance the development and commercialization of vosaroxin, the risk that raising funds through lending arrangements may

restrict our operations or produce other adverse results, the risk that Sunesis' development activities for vosaroxin could be otherwise halted or significantly delayed for various reasons, the risk that Sunesis' clinical studies for vosaroxin may not demonstrate safety or efficacy or lead to regulatory approval, the risk that data to date 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, European Commission or other regulatory agencies, risks related to the conduct of Sunesis' clinical trials, risks related to the manufacturing of vosaroxin and supply of the active pharmaceutical ingredients required for the conduct of the VALOR trial, the risk of third party opposition to granted patents related to vosaroxin, and the risk that Sunesis' proprietary rights may not adequately protect vosaroxin. 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, 2012, Sunesis' Quarterly Report on Form 10-Q for the quarter ended March 31, 2013 and Sunesis' other filings with the Securities and Exchange Commission, including Sunesis' Quarterly Report on Form 10-Q for the quarter ended June 30, 2013, when available. 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 Sunesis' expectations with regard thereto or any change in events, conditions or circumstances on which any such statements are based.

**SUNESIS PHARMACEUTICALS, INC.**

**CONDENSED CONSOLIDATED BALANCE SHEETS**

**(In thousands)**

| | **June 30, 2013** | **December 31, 2012** |
|---|---|---|
| **ASSETS** | **(Unaudited)** | **(Note 1)** |
| Current assets: | | |
| Cash and cash equivalents | $ 6,605 | $ 14,940 |
| Marketable securities | 42,977 | 56,287 |
| Prepaids and other current assets | 998 | 1,705 |
| Total current assets | 50,580 | 72,932 |
| Property and equipment, net | 31 | 43 |
| Deposits and other assets | 23 | 42 |
| Total assets | $ 50,634 | $ 73,017 |
| | | |
| **LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)** | | |
| Current liabilities: | | |
| Accounts payable | $ 2,109 | $ 78 |
| Accrued clinical expense | 3,937 | 5,449 |
| Accrued compensation | 999 | 1,465 |
| Other accrued liabilities | 1,973 | 2,113 |
| Current portion of deferred revenue | 7,956 | 7,956 |
| Current portion of notes payable | 8,488 | 6,610 |
| Warrant liability | 9,776 | 8,070 |
| Total current liabilities | 35,238 | 31,741 |
| | | |
| Non-current portion of deferred revenue | 7,690 | 11,668 |
| Non-current portion of notes payable | 13,492 | 17,651 |
| | | |
| Commitments | | |

| | | |
|---|---|---|
| Stockholders' equity (deficit): | | |
| Common stock | 5 | 5 |
| Additional paid-in capital | 459,120 | 457,011 |
| Accumulated other comprehensive income | -- | 38 |
| Accumulated deficit | (464,911) | (445,097) |
| Total stockholders' equity (deficit) | (5,786) | 11,957 |
| Total liabilities and stockholders' equity (deficit) | $ 50,634 | $ 73,017 |

Note 1: The condensed consolidated balance sheet as of December 31, 2012 has been derived from the audited financial statements as of that date included in the Company's Annual Report on Form 10-K for the year ended December 31, 2012.

**SUNESIS PHARMACEUTICALS, INC.**

**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS**

**AND COMPREHENSIVE INCOME (LOSS)**

**(In thousands, except per share amounts)**

| | **Three months ended June 30,** | | **Six months ended June 30,** | |
|---|---|---|---|---|
| | **2013** | **2012** | **2013** | **2012** |
| | **(Unaudited)** | | **(Unaudited)** | |
| Revenue: | | | | |
| License and other revenue | $ 1,989 | $ 1,500 | $ 3,978 | $ 1,500 |
| Total revenues | 1,989 | 1,500 | 3,978 | 1,500 |
| | | | | |
| Operating expenses: | | | | |
| Research and development | 7,674 | 8,072 | 15,051 | 14,718 |
| General and administrative | 2,889 | 2,182 | 5,333 | 4,371 |
| Total operating expenses | 10,563 | 10,254 | 20,384 | 19,089 |
| | | | | |
| Loss from operations | (8,574) | (8,754) | (16,406) | (17,589) |
| | | | | |
| Interest expense | (768) | (316) | (1,599) | (631) |
| Other income (expense), net | 1,152 | 491 | (1,809) | (4,283) |
| Net loss | (8,190) | (8,579) | (19,814) | (22,503) |
| Unrealized loss on available-for-sale securities | (17) | (13) | (38) | (24) |
| Comprehensive loss | $ (8,207) | $ (8,592) | $ (19,852) | $ (22,527) |
| | | | | |
| Basic and diluted loss per common share: | | | | |
| | | | | |
| Net loss: | | | | |
| Basic | $ (8,190) | $ (8,579) | $ (19,814) | $ (22,503) |
| Diluted | (9,336) | (9,332) | (19,814) | (22,503) |

| | | | | |
|---|---|---|---|---|
| Shares used in computing net loss per common share: | | | | |
| Basic | 51,630 | 46,953 | 51,609 | 46,873 |
| Diluted | 53,268 | 47,286 | 51,609 | 46,873 |
| | | | | |
| Net loss per common share: | | | | |
| Basic | $ (0.16) | $ (0.18) | $ (0.38) | $ (0.48) |
| Diluted | $ (0.18) | $ (0.20) | $ (0.38) | $ (0.48) |

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