Sunesis Pharmaceuticals Expands Hematology Franchise With Global Licenses to Two Kinase Inhibitor Programs

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BTK Inhibitor SNS-062 Licensed from Biogen Idec;
IND Anticipated in Approximately 12 Months

PDK1 Inhibitor Program Licensed from Millennium;
Development Candidate Selection to Take Place in 2014

Sunesis to Host Conference Call, Provide 2014 Outlook, Today at 11AM Eastern Time

SOUTH SAN FRANCISCO, Calif., Jan. 9, 2014 (GLOBE NEWSWIRE) -- Sunesis Pharmaceuticals, Inc. (Nasdaq:SNSS) today announced that it has expanded its hematology franchise through separate global licensing agreements for two preclinical kinase inhibitor programs. The company will host a conference call to discuss these agreements, as well as an outlook for 2014, today at 11:00 a.m. Eastern Time.

The first agreement, with Biogen Idec (Nasdaq:BIIB), is for global commercial rights to SNS-062, a potent and selective non-covalently binding oral inhibitor of BTK (Bruton's tyrosine kinase). BTK is a mediator of B-cell receptor signaling integral to the pathogenesis of B-cell malignancies. With characteristics and activity distinct from in-class compounds, SNS-062 may hold potential as a differentiated treatment for B-cell malignancies and other blood cancers. Sunesis anticipates filing an investigational new drug (IND) application for SNS-062 with the Food and Drug Administration in approximately one year to begin human clinical trials.

The second agreement, with Millennium: The Takeda Oncology Company, is for global commercial rights to several potential first-in class, pre-clinical inhibitors of the novel target PDK1 (phosphoinositide-dependent kinase-1). PDK1 is a key kinase and mediator of PI3K/AKT signaling, a pathway involved in cell growth, proliferation, differentiation, motility and survival. PDK1 inhibitors are expected to have unique effects on survival and invasion signaling and to be broadly active in both hematologic and solid tumor malignancies. Sunesis anticipates selecting a lead PDK1 development candidate this year to take into IND enabling studies.

Both BTK and PDK1 programs were originally developed under a research collaboration agreement between Biogen Idec and Sunesis. The PDK1 program was subsequently purchased by and exclusively licensed to Millennium in 2011 along with the more advanced program, MLN2480, a pan-RAF inhibitor currently in the maximum tolerated dose cohort expansion stage of a Millennium Phase 1, multicenter dose escalation study. SNS-062 and the PDK1 inhibitor will be developed exclusively by Sunesis. Sunesis anticipates only modest incremental expense associated with advancing both programs in 2014.

"These programs represent an exciting expansion of Sunesis' pipeline which, with vosaroxin, provide the opportunity to create a leading hematology franchise," said Daniel Swisher, Chief Executive Officer of Sunesis. "This pipeline is supplemented by other promising programs that continue their development through our collaborator-funded programs with Biogen Idec and Millennium. Taken together with vosaroxin, our wholly owned late-stage program, these efforts are expected to yield a number of important corporate milestones in the upcoming quarters, including a second quarter readout of the pivotal, Phase 3 VALOR trial of vosaroxin in first relapsed or refractory acute myeloid leukemia."

Mr. Swisher added: "We look forward to a transformative 2014, which will include data from investigator sponsored trials of vosaroxin that were initiated in 2013, and, with a positive outcome to VALOR, the transition from a development- to a commercial-stage company."

"As key mediators of signaling pathways known to drive a variety of hematologic and solid tumor malignancies, BTK and PDK1 are both compelling targets in the field of oncology," said Adam R. Craig, M.D., Ph.D., Executive Vice President, Development and Chief Medical Officer of Sunesis. "Both programs have unique and differentiating features: the PDK1 program may yield a first-in-class compound, while SNS-062, as a distinct, non-covalently binding molecule, may prove clinically effective in settings where other agents, such as in ibrutinib and/or idelalisib, have failed. We look forward to the opportunity to develop these compounds in a variety of oncology indications."

Conference Call Information

Sunesis will host an update conference call today, January 9 at 11:00 a.m. Eastern Time. The call can be accessed by dialing 877-546-5020 (U.S. and Canada) or 857-244-7552 (international), and entering passcode 47533862. 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 is being conducted at more than 100 leading sites in the U.S., Canada, Europe, Australia, New Zealand and South Korea. Patients 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 acute myeloid leukemia (AML). Additionally, vosaroxin has been granted fast track designation by the FDA for the potential treatment of relapsed or refractory AML in combination with cytarabine.

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.

This press release contains forward-looking statements, including statements related to the (i) efficacy, progress, timing, market potential and results of the two programs discussed in this release in-licensed from Biogen Idec and Millennium, and (ii) progress, timing and results of the VALOR trial and Sunesis' investigator sponsored trials. Words such as "anticipates," "may," "expected," "will," "promising," "look forward," "with a positive," "compelling," 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 Sunesis' clinical trials, 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 September 30, 2013 and Sunesis' 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 Sunesis' expectations with regard thereto or any change in events, conditions or circumstances on which any such statements are based.

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