Sunesis Partners With Clinigen Group to Initiate a Compassionate Use Program for Patients With Relapsed or Refractory Acute Myeloid Leukemia

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SOUTH SAN FRANCISCO, Calif., Dec. 3, 2015 (GLOBE NEWSWIRE) -- Sunesis Pharmaceuticals, Inc. (NASDAQ:SNSS) today announced that it has initiated a Compassionate Use Program for vosaroxin. The Compassionate Use Program will be made available to eligible patients in the U.S. and selected European countries diagnosed with relapsed or refractory acute myeloid leukemia (AML) and will be managed by Clinigen Group plc's (AIM:CLIN) Idis Managed Access (MA) division.

Vosaroxin is an investigational treatment and is currently not approved for use by any regulatory agency. Compassionate use programs are put in place to provide access to medicines for patients who have serious, or immediately life-threatening illnesses, and for whom no alternative treatment options are available. Access is provided in response to an unsolicited request from a physician for his/her patient with an unmet medical need.

Clinigen Group

"Sunesis is committed to providing patients and healthcare providers around the globe with more options for treating relapsed and refractory AML, a disease for which the standard of care has changed little in the last four decades," said Par S Hyare, VP Global Oncology Operations, Sunesis. "We are pleased to be working with Idis MA, a recognized leader in providing ethical access to medicines that address unmet needs and will be working towards gaining approval for vosaroxin in the U.S. and Europe for the treatment of relapsed and refractory AML."

Simon Estcourt, Managing Director of Idis Managed Access, Clinigen Group said: "AML is the most common acute leukemia affecting adults, with a very low survival rate, so there is a real need for new treatment options in these patients. By using our global logistical and regulatory expertise we will work with Sunesis and the AML community to provide ethical access to vosaroxin to help eligible patients who have no alternative treatment options."

For more information about Idis' services and its Managed Access Programs, healthcare professionals may contact Idis via telephone on +44 (0)1932 824 135, fax on +44 (0)1932 824 335. To contact Idis by e-mail, U.S. physicians only use vosaroxinUS@idispharma.com. Physicians from all other countries please use global@idispharma.com.

About vosaroxin

Vosaroxin is an anti-cancer quinolone derivative (AQD), a class of compounds that has not been used previously for the treatment of cancer. Preclinical data demonstrate that 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 AML in combination with cytarabine. Vosaroxin is an investigational drug that has not been approved for use in any jurisdiction.

About Sunesis Pharmaceuticals

Sunesis is a biopharmaceutical company focused on the development and commercialization of new oncology therapeutics for the potential 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.

About Clinigen Group

Clinigen Group is a global pharmaceutical and services company with a unique business model dedicated to delivering the right drug to the right patient at the right time. The Group consists of four synergistic businesses that provide medicines to patients with unmet medical need; through Clinigen CTS we manage the supply of commercial medicines for clinical trials, through Idis Managed Access we run early access programs for our own and other companies' portfolios, our Idis Global Access team works directly with healthcare providers to enable ethical compliant access to unlicensed medicines, and through Clinigen SP, we market our own portfolio of niche commercial products.

We are global leaders in ethically sourcing and supplying unlicensed medicines to hospital pharmacists and physicians for patients with a high unmet need. Our Managed Access business provides early access to unlicensed investigational medicines on behalf of pharmaceutical companies.

For more information, please visit www.clinigengroup.com.

This press release contains forward-looking statements, including statements related to Sunesis' estimated timelines for regulatory interactions and regulatory progress, including the anticipated submission of the MAA for vosaroxin with the EMA and plans to gain marketing approval of vosaroxin in the U.S., Sunesis' overall strategy, the design, conduct and results of clinical trials, including the expected progress in its kinase inhibitor pipeline, estimated new cases of AML, its prevalence across major global markets, prognosis for patients with AML, the need for and the role of vosaroxin as a potential new treatment option, and Sunesis' clinical development of vosaroxin, including the analysis of the results from the VALOR clinical trial. Words such as "anticipates," "estimates," "expect," "intends," "plan," "potential," "will" 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 may not be able to submit timely the MAA to the EMA, the risk that Sunesis' clinical studies for vosaroxin may not lead to regulatory approval in the U.S. or Europe, that Sunesis' development activities for vosaroxin could be otherwise halted or significantly delayed for various reasons, the risk that Sunesis' clinical studies for vosaroxin or other product candidates 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, risks related to the conduct of Sunesis' clinical trials, risks related to Sunesis' need for substantial additional funding to complete the development and commercialization of vosaroxin, and 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. These and other risk factors are discussed under "Risk Factors" and elsewhere in Sunesis' Quarterly Report on Form 10-Q for the quarter ended September 30, 2015. 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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