Sunesis Announces Publication in "Drugs" Detailing Molecular and Pharmacologic Properties of Vosaroxin

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SOUTH SAN FRANCISCO, Calif., Aug. 25, 2016 (GLOBE NEWSWIRE) -- Sunesis Pharmaceuticals, Inc. (Nasdaq:SNSS) today announced the publication of an article detailing the molecular and pharmacologic properties of vosaroxin as a new therapeutic for acute myeloid leukemia (AML) in the journal *Drugs*. The article, titled "Molecular and Pharmacologic Properties of the Anticancer Quinolone Derivative Vosaroxin: A New Therapeutic for Acute Myeloid Leukemia," is available online and will appear in the September 2016 print issue of *Drugs*.

The authors describe how the unique chemical and pharmacologic characteristics of vosaroxin, the first quinolone-based topoisomerase II inhibitor studied in clinical trials in cancer, may contribute to the efficacy and safety profile observed in Sunesis' Phase 3 VALOR trial, a randomized, double-blind, placebo-controlled trial of vosaroxin and cytarabine in patients with first relapsed or refractory AML. Vosaroxin is a DNA intercalating topoisomerase II inhibitor that causes the induction of apoptosis via double-strand DNA breaks, yet is chemically distinct from other topoisomerase inhibitors with its stable quinolone-based core. Due to the stability of this core, vosaroxin is not associated with significant formation of toxic metabolites, free radicals, or reactive oxygen species, which are associated with off-target organ damage and cardiotoxicity. Furthermore, vosaroxin evades two common mechanisms of drug resistance, as it is not a substrate for the P-glycoprotein efflux pump and its activity is maintained in cells with p53 deletion.

In the pivotal Phase 3 VALOR trial, a 2.1-month improvement in median OS among patients ≥ 60 years old was demonstrated, without an increase in early mortality, as compared to the control arm. Common side effects of vosaroxin included gastrointestinal effects, myelosuppression, and infection. Vosaroxin also demonstrates potent in vitro antitumor activity in various tumor types, including those resistant to other topoisomerase II inhibitors.

Vosaroxin is currently being tested in several investigator-sponsored studies, both as a single-agent and in combination with other therapies, for the treatment of AML and myelodysplastic syndromes. A Marketing Authorization Application for vosaroxin as a treatment for AML in Europe is currently under review by the European Medicines Agency.

"The chemical and pharmacologic characteristics of vosaroxin, including its chemically stable quinolone core, low off-target organ damage and ability to overcome common resistance factors, highlight its potential as a new and differentiated treatment option for certain cancers," stated Dr. Stephen A. Strickland, M.D., MSCI, Clinical Director of Acute Leukemia, Division of Hematology/Oncology at the Vanderbilt-Ingram Cancer Center, Assistant Professor of Medicine, Vanderbilt University Department of Medicine, and a lead author of the publication. "In particular, vosaroxin may be an effective therapeutic alternative for older AML patients, those with treatment-resistant disease, and those who have exceeded safe thresholds for anthracyclines or are at high risk for treatment-related cardiac damage. Overall, I believe vosaroxin represents a much needed treatment for patients with relapsed or refractory AML."

"Publication of this profile on vosaroxin in *Drugs* supports our goal of establishing vosaroxin as a meaningful advancement in the standard of care for patients with AML," said Daniel Swisher, Chief Executive Officer of Sunesis. "As we continue through the process for regulatory approval of vosaroxin in Europe, we also look forward to expanding the body of supportive data behind this therapeutic candidate as we advance several ongoing and planned investigator- or company-sponsored clinical studies."

About QINPREZO™ (vosaroxin)

QINPREZO™ (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.

Vosaroxin's Marketing Authorization Application for relapsed refractory AML is currently under review by the European Medicines Agency, and a regulatory decision regarding approval is expected in 2017.

The trademark name QINPREZO is conditionally accepted by the FDA and the EMA as the proprietary name for the vosaroxin drug product candidate.

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 improving the lives of people with cancer. Currently, the company is focused on pursuing regulatory approval in Europe for its lead product candidate, vosaroxin, for the treatment of relapsed or refractory acute myeloid leukemia in patients aged 60 and older, as well as advancing its novel kinase-inhibitor pipeline, which includes its proprietary non-covalent BTK-inhibitor, SNS-062.

For additional information on Sunesis, please visit http://www.sunesis.com.

This press release contains forward-looking statements, including statements related to Sunesis' corporate objectives, including the anticipated progress and potential approval of vosaroxin by the EMA, timing of potential market launch in Europe for vosaroxin, and further clinical development of vosaroxin and SNS-062. Words such as "believe," "goal," "look forward," "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 receive regulatory approval of vosaroxin 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, including its pipeline of kinase inhibitors, 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 other product candidates, 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 and other product candidates. 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, 2015, Sunesis' Quarterly Report on Form 10-Q for the quarter ended June 30, 2016, when available, 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.

Investor and Media Inquiries:
David Pitts
Argot Partners
212-600-1902

Eric Bjerkholt
Sunesis Pharmaceuticals Inc.
650-266-3717

Primary Logo

Sunesis Pharmaceuticals Inc