Sunesis Pharmaceuticals Announces Late-Breaking Presentation of Phase 3 VALOR Trial at ASH Annual Meeting

November 17, 2014 9:06 AM ET

SOUTH SAN FRANCISCO, Calif., Nov. 17, 2014 (GLOBE NEWSWIRE) -- Sunesis Pharmaceuticals, Inc. (Nasdaq:SNSS) today announced that results from the Company's Phase 3 VALOR trial of vosaroxin and cytarabine in patients with relapsed or refractory acute myeloid leukemia (AML) will be presented in a late-breaking oral presentation at the 56th American Society of Hematology Annual Meeting, taking place December 6-9 in San Francisco, California.

"We are very pleased that VALOR, the largest randomized company-sponsored trial ever conducted in relapsed or refractory AML, has been accepted as a late-breaking presentation at ASH," said Daniel Swisher, Chief Executive Officer of Sunesis. "Despite meaningful progress in other hematologic malignancies, relapsed refractory AML remains a disease where outcomes are unacceptably poor and drug therapy has changed little in the last forty years. We believe the results of VALOR demonstrate a clinically meaningful and important advancement in the treatment of this disease, and we appreciate the opportunity to share the full dataset with the medical community."

Details of the VALOR presentation and two related AML presentations at the ASH Annual Meeting are as follows:

VALOR Late-Breaking Oral Presentation (LBA-6)

Title:	Improved Survival in Patients with First Relapsed or Refractory Acute Myeloid Leukemia (AML) Treated with Vosaroxin Plus Cytarabine Versus Placebo Plus Cytarabine: Results of a Phase 3 Double-Blind Randomized Controlled Multinational Study (VALOR)
Presenter:	Farhad Ravandi, M.D., Professor of Medicine, Department of Leukemia, University of Texas MD Anderson Cancer Center
Session:	Late-Breaking Abstracts Session (7:30 AM - 9:00 AM)
Date:	Tuesday, December 9, 2014, 8:45 AM
Room:	Moscone Center, North Building, Hall D
Abstract Link:	https://ash.confex.com/ash/2014/webprogram/Paper77078.html

MD Anderson Cancer Center Phase I/II Study Oral Presentation (385)

Title:	Phase I/II Study of Vosaroxin and Decitabine in Newly Diagnosed Older Patients with Acute Myeloid Leukemia and High Risk Myelodysplastic Syndrome
Presenter:	Naval Daver, M.D., Assistant Professor, Department of Leukemia, University of Texas MD Anderson Cancer Center
Session:	Acute Myeloid Leukemia: Novel Therapy, excluding Transplantation: New Drugs II (10:30 AM - 12:00 PM)
Date:	Monday, December 8, 2014
Room:	Moscone Center, South Building, Gateway Ballroom 103
Abstract Link:	https://ash.confex.com/ash/2014/webprogram/Paper75224.html

Prevalence and Incidence of AML (958)

Title:	Prevalence and Incidence of Acute Myeloid Leukemia May be Higher than Currently Accepted Estimates Among the ≥65 Year-Old Population in the United States
Presenter:	Sean Turbeville, Ph.D., Sunesis
Session:	Acute Myeloid Leukemia: Clinical Studies: Poster I (5:30 PM - 7:30 PM)
Date:	Saturday, December 6, 2014
Room:	Moscone Center, North Building, Hall E
Abstract Link:	https://ash.confex.com/ash/2014/webprogram/Paper72296.html

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 QINPREZO 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 QINPREZO for the treatment of AML. Additionally, QINPREZO has been granted fast track designation by the FDA for the potential treatment of relapsed or refractory AML in combination with cytarabine. QINPREZO is an investigational drug that has not been approved for use in any jurisdiction.

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

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 18,860 new cases of AML and approximately 10,460 deaths from AML in the U.S. in 2014. 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.

This press release contains forward-looking statements, including statements related to Sunesis' preliminary analysis, assessment and conclusions of the results of the VALOR trial, and the efficacy and commercial potential of vosaroxin. It is possible that such results or conclusions may change based on further analysis of the VALOR data. Words such as "will," "believe," 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' preliminary analysis,

assessment and conclusions of the results of the VALOR trial set forth in this release may change based on further analysis of such data and the risk that Sunesis' clinical studies for vosaroxin may not lead to regulatory approval. 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, 2013, and Sunesis' other filings with the Securities and Exchange Commission, including Sunesis' Quarterly Report on Form 10-Q for the quarter ended September 30, 2014. 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.

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

Eric Bjerkholt
Sunesis Pharmaceuticals, Inc.
650-266-3717

 Sunesis

Sunesis Pharmaceuticals, Inc.