

## Sunesis Pharmaceuticals Announces Presentation of Results From Phase 3 VALOR Trial at ASH Annual Meeting

December 7, 2014 12:30 PM ET

### Sunesis to Host Conference Call and Webcast Tuesday, December 9 at 10:30 AM Pacific Time

SOUTH SAN FRANCISCO, Calif., Dec. 7, 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 on Tuesday, December 9, at 8:45 AM Pacific Time in the "Late Breaking Abstracts" session of the 56<sup>th</sup> American Society of Hematology Annual Meeting in San Francisco, California. The presentation (abstract LBA-6, North Building, Hall D), titled "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)," will be available on the Sunesis website at [www.sunesis.com](http://www.sunesis.com) following the ASH presentation.

"Despite 40 years of intense clinical research, there remain no new approved treatments or standard of care for patients with relapsed or refractory AML," said Farhad Ravandi, M.D., Professor of Medicine, Department of Leukemia, University of Texas MD Anderson Cancer Center, and a principal investigator of the VALOR study. "Vosaroxin and cytarabine demonstrated increased overall survival and higher complete response rates in this setting without increased early mortality, a result particularly pronounced in the poorest prognosis treatment settings, including patients over 60 years old. These data support the use of this combination as a new treatment option for patients with relapsed or refractory AML."

"When we compare AML to other blood cancers, the complete absence of new therapies introduced in the last two decades, particularly in the United States, speaks to a massive void for so many patients," said Patricia J. Goldsmith, CEO of CancerCare®. "These patients should not wait any longer for a breakthrough; they deserve new treatment options today."

The randomized, double-blind, placebo-controlled Phase 3 VALOR trial enrolled 711 adult patients with first relapsed or refractory AML at 124 leading sites in 15 countries. Patients were stratified for age, geographic region and disease status and randomized one to one to receive either vosaroxin and cytarabine or placebo and cytarabine. Patients treated with vosaroxin achieved increased overall survival compared to those treated with placebo (7.5 months vs 6.1 months, HR=0.865), the primary endpoint, but this difference did not achieve statistical significance (p=0.06). The complete remission (CR) rate, the sole secondary efficacy endpoint in the trial, did demonstrate a significant difference for the vosaroxin combination arm (30.1% vs 16.3%, p < 0.0001).

In a pre-planned analysis accounting for the stratification factors at randomization, a significant improvement in overall survival was demonstrated (HR=0.830, p=0.02). The pre-planned analysis of all treatment strata included the following poor-prognosis patient categories: over 60 years old (7.1 months vs 5.0 months, HR=0.75, p=0.006, n=451), refractory disease (6.7 months vs 5.0 months, HR=0.87, p=0.26, n=301), and early relapsed disease (6.7 months vs 5.2 months, HR=0.77, p=0.05, n=256). Outcomes in patients under 60 years old or with late relapsed disease were comparable between treatment arms, with no improvement in overall survival. Across all strata, the CR and Composite CR (CR+CRp+Cri) rates were higher in the vosaroxin combination arm.

Given the complexity of interpreting the impact of transplantation therapy, a sensitivity analysis of overall survival censoring for hematopoietic stem cell transplantation was planned. In this analysis, patients receiving the vosaroxin combination had a median overall survival of 6.7 months versus 5.3 months for patients receiving placebo and cytarabine (HR=0.809, p=0.02).

Grade 3 or higher non-hematologic adverse events that were more common in the vosaroxin combination arm were

gastrointestinal and infection-related toxicities, consistent with those observed in previous company trials. The rate of serious adverse events was 55.5% in the vosaroxin combination arm compared to 35.7% in the placebo and cytarabine arm. All-cause mortality were comparable between the treatment arms (7.9% vs 6.6% for 30-day and 19.7% vs 19.4% for 60-day).

"As the largest randomized company-sponsored trial ever conducted in relapsed or refractory AML, VALOR provides a robust dataset that we are pleased to see presented at ASH's Late Breaking session," said Daniel Swisher, Chief Executive Officer of Sunesis. "We deeply appreciate the AML community's support of the VALOR study and look forward to soon sharing these data with regulators in both Europe and the U.S."

As previously announced, Sunesis has submitted a letter of intent describing the company's intention to file a Marketing Authorization Application (MAA) with the European Medicines Agency (EMA) seeking marketing authorization of vosaroxin plus cytarabine for the treatment of relapsed or refractory acute myeloid leukemia. Sunesis expects to file its MAA in the second half of 2015. Sunesis has requested a meeting with the U.S. Food and Drug Administration (FDA), which is anticipated to take place early in the first quarter of 2015.

### **Conference Call and Webcast Information**

Sunesis will host a conference call and slide webcast Tuesday, December 9, 2014, at 10:30 a.m. Pacific Time. The call can be accessed by dialing (866) 953-6858 (U.S. and Canada) or (617) 399-3482 (international), and entering passcode 63726372. To access the live audio, or the subsequent archived recording, visit the "Investors and Media - Calendar of Events" section of the Sunesis website at [www.sunesis.com](http://www.sunesis.com). The webcast will be recorded and available for replay on Sunesis' website for two weeks.

### **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 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>.

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*This press release contains forward-looking statements, including statements related to Sunesis' preliminary analysis, assessment and conclusions of the results of the VALOR trial, the efficacy and commercial potential of vosaroxin and Sunesis' regulatory strategy (including plans to commence a marketing authorization filing with the EMA). It is possible that such results or conclusions may change based on further analysis of the VALOR data. Words such as "believe," "expect," "explore," "look forward," "potential," "seek," "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' 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, the risk that Sunesis' plans to commence a marketing authorization filing with the EMA may change or such filing may be rejected by the EMA 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.*

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