Sunesis Pharmaceuticals Announces Presentation of Updated Results from the VALOR Trial Examining Overall Survival in Patients Age 60 Years and Older with Relapsed/Refractory AML at the ASH Annual Meeting

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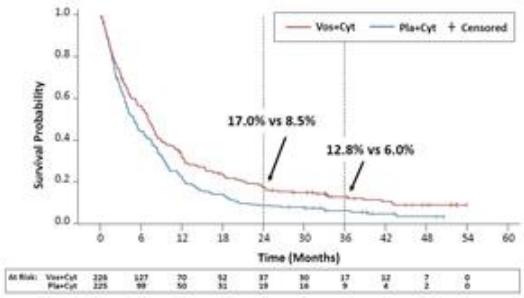
SOUTH SAN FRANCISCO, Calif., Dec. 05, 2016 (GLOBE NEWSWIRE) -- Sunesis Pharmaceuticals, Inc. (Nasdaq:SNSS) today announced the presentation of updated results from the VALOR trial examining overall survival in patients age 60 years and older with relapsed/refractory AML. The results are being presented today at 3:15 PM PT in an oral session titled “Acute Myeloid Leukemia: Novel Therapy, excluding Transplantation: Clinical trials of Novel Drugs and Combinations in AML” taking place from 2:45 PM – 5:45 PM PT at the 58th American Society of Hematology Annual Meeting in San Diego, California. The presentation (abstract 903, Marriott Marquis San Diego Marina, Ballroom AB), titled “Durable Overall Survival Benefit in Patients ≥ 60 Years with Relapsed or Refractory AML Treated with Vosaroxin/Cytarabine Vs Placebo/Cytarabine: Updated Results from the Valor Trial,” is available at www.sunesis.com.

"Clinical outcomes among patients with relapsed/refractory AML remain abysmal, particularly among older patients,” 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. "Results from the updated survival data from VALOR and the post-hoc analyses presented today, show compelling durable survival outcomes among older patients, and support the use of vosaroxin, in combination with cytarabine, as an important treatment option for this group of AML patients desperately in need of new therapies.”



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VALOR is a randomized, double-blind, placebo-controlled Phase 3 trial that enrolled 711 adult patients with first relapsed or refractory AML at 124 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. At the time of the primary analysis in October 2014, the overall survival (OS) was significantly improved with vosaroxin/cytarabine versus placebo/cytarabine in patients age 60 years and older (7.1 months vs 5.0 months, HR=0.75, p=0.0030), with a complete remission (CR) rate of (31.9% vs 13.8%, p < 0.0001).

The new data presented today from the VALOR trial include an updated survival analysis in the 451 patient subset age 60 and older, sensitivity analyses of OS in patients age 60 and older, and analyses examining the differences in treatment effect by age. The results demonstrate that, after a median of 39.9 months of follow-up, OS for patients age 60 years and older remains significantly improved for the vosaroxin/cytarabine arm compared to the placebo/cytarabine arm (figure 1), with survival curves remaining separated through 48 months.

Figure 1.

A graph accompanying this announcement is available at http://www.globenewswire.com/NewsRoom/AttachmentNg/7db20a54-6b19-4353-b1e0-65c36ec84063

Treatment Arm	Patients, n	Events, n (%)	Censored, n (%)	Median OS (95% CI)	P value (2-sided)
Pla+Cyt	225	212 (94.2%)	13 (5.8%)	5.0 (3.8-6.4)	0.0017
Vos+Cyt	226	199 (88.1%)	27 (11.9%)	7.1 (5.8-8.1)	

Of note, twice as many patients were alive on the vosaroxin-containing arm at both the 24 and 36 months’ time points highlighting the durability of benefit observed in this patient group.

An OS benefit with the addition of vosaroxin was observed consistently across smaller subgroups above 60 years (figure 2). Smaller age groups below 60 years did not demonstrate a similar OS benefit.

Figure 2.

	Median OS, months		
Patent Age	**Vosaroxin/Cytarabine**	**Placebo/Cytarabine**	**Hazard Ratio (95% CI)**
60-64 years (n = 124)	8.1	5.2	0.72 (0.49-1.06)
65-74 years (n = 293)	7.0	5.0	0.76 (0.60-0.97)
75-84 years (n = 34)	5.5	3.3	0.72 (0.36-1.45)

Sunesis also performed a multivariate survival analysis adjusting for baseline prognostic factors. In this analysis, the HR for OS in the ITT population was 0.80 (p=0.0114) and for patients age 60 and older the OS HR was 0.68 (p=0.0004).

“All of these data and analyses further underscore the consistency, durability and robustness of the survival benefit for patients age 60 years and older who received vosaroxin in the VALOR study,” said Daniel Swisher, President and Chief Executive Officer of Sunesis. “As we work toward a European regulatory decision for vosaroxin in this patient population, we remain committed to making vosaroxin available as a new treatment option for underserved patients with relapsed refractory AML. As our regulatory efforts progress, we also continue to advance active dialogues with potential pharma collaborators toward the goal of supporting a European market launch in 2017.”

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. 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 regulatory development and potential approval of vosaroxin by the EMA, potential collaborations and ability to commercialize vosaroxin in Europe. Words such as “expect,” “goal,” “may,” "potential" “advancing,” “anticipate,” “progress” 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, risks related to Sunesis' need for substantial additional funding to complete the development and commercialization of vosaroxin and other product candidates, the risk that Sunesis' clinical studies for SNS-062, 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, 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 September 30, 2016, 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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