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Versartis Announces Phase 3 VELOCITY Trial of Somavaratan in Pediatric Growth Hormone Deficiency Did Not Meet Primary Endpoint

MENLO PARK, Calif., Sept. 21, 2017 (GLOBE NEWSWIRE) -- Versartis, Inc. (NASDAQ:VSAR), an endocrine-focused biopharmaceutical company that is developing somavaratan, a novel, long-acting form of recombinant human growth hormone (rhGH) for growth hormone deficiency (GHD), today announced that the VELOCITY Phase 3 clinical trial of somavaratan in pediatric growth hormone deficiency (GHD) did not meet its primary endpoint of non-inferiority.

Non-inferiority versus daily growth hormone was not demonstrated in the intent to treat (ITT) population for the primary efficacy variable, height velocity (HV) at 12 months. The 12-month HV for ITT patients receiving somavaratan twice monthly was 9.44 cm, versus 10.70 cm for those receiving Genotropin[®]¹ daily. Non-inferiority was defined as the lower bound of the two-sided 95% confidence interval of the difference between somavaratan and Genotropin HV greater than or equal to -2.0 cm/year. In the ITT study population the lower bound of this confidence interval was -2.3 cm/year.

In the per protocol population (PP), non-inferiority was demonstrated. The 12-month HV for PP patients receiving somavaratan twice monthly was 9.71 cm, versus 10.63 cm for those receiving Genotropin daily.

Somavaratan was well tolerated with treatment discontinuation rate lower than for the Genotropin arm. No new emergent safety signals were observed.

"We are very surprised and disappointed to learn the outcome of the VELOCITY trial. Somavaratan showed height velocity in the range we had hoped, but it was not sufficient to demonstrate non-inferiority in this trial," stated Jay Shepard, President and CEO of Versartis, Inc. "We have done an initial analysis of the top-line data and are continuing to thoroughly review the results to gain greater insight into the trial outcome. We plan to provide a corporate update later this year. I would like to thank the investigators, pediatric GHD patients and families that participated in the VELOCITY trial."

About Versartis, Inc.

Versartis, Inc. is an endocrine-focused biopharmaceutical company initially developing somavaratan, a novel, long-acting form of recombinant human growth hormone in late-stage clinical trials for the treatment of GHD in children and adults. Somavaratan is intended to reduce the burden of daily injection therapy by requiring significantly fewer injections, potentially improving adherence and, therefore, treatment outcomes.

For more information on Versartis, visit www.versartis.com.

¹ Genotropin is a registered trademark of Pfizer Inc.

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