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Versartis Presents 3-Year Somavaratan Safety and Efficacy Data and Pediatric Program Baseline Demographics at the 19th European Congress of Endocrinology

MENLO PARK, Calif., May 22, 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), announced that three-year safety and efficacy results for somavaratan and a comparison of baseline demographics within its Phase 2a and Phase 3 trials were presented during the 19th European Congress of Endocrinology (ECE), May 20 — 23, 2017 in Lisbon, Portugal.

"The three-year data from the VISTA study in children with GHD has shown safety and efficacy that is in line with contemporary registry data for daily rhGH," said Philippe F. Backeljauw, M.D., Professor of Clinical Pediatrics, University of Cincinnati College of Medicine, Cincinnati Children's Hospital Medical Center and a somavaratan trial investigator. "Our review of the baseline characteristics across the Phase 2 and Phase 3 pediatric studies showed similar treatment populations. Assuming the response profile is maintained in the Phase 3 VELOCITY study, there may be significant interest in somavaratan for the treatment of pediatric GHD, given the potential to decrease injection burden on patients and enhance adherence with therapy."

The poster entitled "3-Year Safety and Efficacy Update of the VERTICAL & VISTA Trials of Somavaratan (VRS-317), a Long-Acting rhGH, in Children with Growth Hormone Deficiency (GHD)," highlighted safety and efficacy data in 48 patients who completed three years of somavaratan treatment in the Phase 2a VERTICAL study and subsequent VISTA long-term safety study. Mean height velocity (HV) for years 1, 2, and 3, following a dose increase at the beginning of Year 2, was comparable to reported HV for daily rhGH therapy. Height SDS continued to improve over the course of treatment, IGF-I responses achieved the target therapeutic range, and change in bone age compared to chronologic age was consistent with observed changes in published literature for the ANSWER Registry for daily rhGH. Overall, the three-year results support the 3.5 mg/kg twice-monthly dose regimen being used in the ongoing Phase 3 VELOCITY trial.

The poster entitled "Achievement of a Suitable Basis of Comparison in Phase 2 and 3 Clinical Trials (VERTICAL/VISTA, and VELOCITY) Comparing Somavaratan vs Daily rhGH for Pediatric Growth Hormone Deficiency (PGHD)" compares the baseline characteristics of the patients in both arms of the Phase 3 VELOCITY trial and patients in the Phase 2a VERTICAL trial. Consistent inclusion/exclusion criteria were used in both trials and a stratification procedure balanced the arms in the Phase 3 non-inferiority trial. This approach yielded patient populations without clinically meaningful differences in baseline characteristics, either within the Phase 3 VELOCITY somavaratan and daily treatment arms or between the VERTICAL and VELOCITY trials. Thus, a valid basis of comparison between treatment populations was achieved.

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.

Cautionary Note on Forward-Looking Statements
This press release contains forward-looking statements for purposes of the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Forward-looking statements include statements regarding our intentions or current expectations concerning, among other things, plans and timing of our clinical trials and the potential for eventual regulatory approval of somavaratan. Forward-looking statements are not guarantees of future performance and are subject to risks and uncertainties that could cause actual results and events to differ materially from those anticipated, including, but not limited to, risks and uncertainties related to: our success being heavily dependent on somavaratan; somavaratan being a new molecular entity; the risk that somavaratan may not have favorable results in clinical trials or receive regulatory approval; potential delays in our clinical trials due to regulatory requirements or difficulty identifying qualified investigators or enrolling patients; the risk that somavaratan may cause serious side effects or have properties that delay or prevent regulatory approval or limit its commercial potential; the risk that we may encounter difficulties in manufacturing somavaratan; if somavaratan is approved, risks associated with its market acceptance, including pricing and reimbursement; potential difficulties enforcing our intellectual property rights; our reliance on our license of intellectual property from Amunix Operating, Inc. and our need for additional funds to support our operations. We discuss many of these risks in greater detail

under the heading "Risk Factors" contained in our Annual Report on Form 10-K for the year ended December 31, 2016 and in our Quarterly Report on Form 10-Q for the three months ended March 31, 2017, which are on file with the Securities and Exchange Commission (SEC). Forward-looking statements are not guarantees of future performance, and our actual results of operations, financial condition and liquidity, and the development of the industry in which we operate, may differ materially from the forward-looking statements contained in this press release. Any forward-looking statements that we make in this press release speak only as of the date of this press release. We assume no obligation to update our forward-looking statements whether as a result of new information, future events or otherwise, after the date of this press release.

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