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# Versartis Presents Data From Up to 30 Months of Somavaratan Treatment for Pediatric Growth Hormone Deficiency at the 2016 ESPE Annual Meeting

MENLO PARK, Calif., Sept. 12, 2016 (GLOBE NEWSWIRE) -- Versartis, Inc. (NASDAQ:VSAR), an endocrine-focused biopharmaceutical company that is developing somavaratan (VRS-317), a novel, long-acting form of recombinant human growth hormone (rhGH) for growth hormone deficiency (GHD), today announced that efficacy, safety, and adherence data from up to 30 months of somavaratan treatment in the Phase 2a trial and VISTA long-term safety study for pediatric GHD were presented during the 55th Annual Meeting of the European Society of Paediatric Endocrinology (ESPE). The meeting was held September 10-12, 2016, in Paris.

"We are pleased to see that the safety profile of somavaratan has been maintained with 30 months of treatment in the VISTA study, and that dosing compliance, which is critical for children to achieve their final target height, was still robust after 24 months of at-home administration," said Bradley S. Miller, M.D., Ph.D., Associate Professor in the Department of Pediatric Endocrinology at the University of Minnesota Masonic Children's Hospital and a study investigator. "Height velocity in Year 2 at the current Phase 3 dose was as good as or better than our available benchmarks, so we look forward to the outcome of the Phase 3 VELOCITY trial around this time next year."

In an oral presentation entitled, "Somavaratan (VRS-317) Treatment for Pediatric Growth Hormone Deficiency (GHD): Results at 2.5 Years," Dr. Miller reviewed efficacy and safety results from the Phase 2a clinical trial of somavaratan in treatment-naive, pre-pubertal GHD children (months 0-6 of treatment) and the subsequent VISTA study (**V**ersart**is** Long-Term Safety Study of Somavara**ta**n). The somavaratan dose increased during the VISTA study to 3.5 mg/kg of somavaratan twice-monthly (the dose currently being evaluated in Phase 3). Results suggest that somavaratan was safe and well tolerated through 30 months of drug exposure and at the Phase 3 dose, Year 2 Height Velocity (HV) was comparable to estimates from similar patients in the NCGS database of rhGH daily dosing in the US:

- Among the 57 patients evaluable for the Year 2 efficacy analysis, mean HV after the dose increase was comparable from Years 1 to 2 (8.1±2.2 vs. 7.8±2.3 cm/year), and mean height SDS continued to improve (-2.1±0.6 vs. -1.6±0.7).
- Catch up growth over the 2 year period was supported by mean bone age (BA) advancing by 2.4 years and mean height age by 2.7 years.
- The difference in mean years between chronological age and BA decreased over the course of the study: 1.5±0.8 at screening, 1.4±0.9 at Year 1, and 1.0±1.0 at Year 2.
- The frequency of Adverse Events (AEs) declined substantially after the initial 6 month exposure period, and the Phase 3 dose was safe and well tolerated in this study.

Additionally, Eric Humphriss, Vice President of Global Clinical Operations at Versartis, presented a poster entitled, "Adherence with Twice-Monthly, At-Home Dosing Schedule of Somavaratan (VRS-317) Long-Acting Growth Hormone Treatment in Children with Growth Hormone Deficiency (GHD)." An estimated 66%—77% of adults and children with GHD are noncompliant with daily rhGH injections, and this has been associated with reduced annual HV. Somavaratan was designed to reduce injection burden for patients and a twice-monthly dosing schedule is currently being evaluated in Phase 3. In this VISTA study analysis, somavaratan was administered at-home and treatment adherence was recorded by caregivers using an electronic patient-reported outcome diary (eDiary; Bracket, Inc.). Following 24 months of at-home dosing and over 2200 doses at the current Phase 3 dose, treatment adherence rate was 99.6%. These data suggest that a twice-monthly dosing regimen has the potential to improve treatment adherence and associated outcomes.

**About Somavaratan**
Somavaratan is Versartis' investigational, novel, long-acting form of recombinant human growth hormone (rhGH). This fusion protein consists of rhGH and specific sequences of naturally-occurring hydrophilic amino acids based on a proprietary XTEN®[1] technology. Somavaratan has been designed with the goal of improving therapeutic outcomes for children and adults with growth hormone deficiency (GHD), including enhanced adherence and convenience with a twice-monthly dosing schedule, fine gauge needle autoinjector device and room temperature storage.

Somavaratan is currently being evaluated for the treatment of pediatric GHD in the pivotal Phase 3 VELOCITY trial in the U.S., Canada and Europe, for which data are anticipated in Q3 2017, and the J14VR5 Phase 2/3 trial in Japan. Confirmatory two-year safety and efficacy data from Phase 2 trial patients in the VISTA long-term safety study were initially reported during the Endocrine Society Annual Meeting in April 2016. In adult GHD, top-line results from the Phase 2 VITAL trial in the U.S., Europe and Australia are expected during the second half of 2016.

[1]XTEN is a registered trademark of Amunix Operating Inc.

**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, 2015 and in our Quarterly Report on Form 10-Q for the three months ended June 30, 2016, 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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