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# Versartis Presents Safety, Efficacy and IGF-I Data for Somavaratan in Pediatric Growth Hormone Deficiency at the 2016 Congress of the GRS & IGF Society

## Increasing somavaratan dose to the 3.5mg/kg twice-monthly now used in Phase 3 safely improved IGF-I SDS and height velocity from year 1 to year 2

MENLO PARK, Calif., Nov. 07, 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), presented safety, efficacy, and IGF-I data from somavaratan treatment in the combined Phase 2a and ongoing VISTA long-term safety study for pediatric GHD today during the 8th International Congress of the GRS & IGF Society. Will Charlton MD, MAS, FAAP, Senior Medical Director at Versartis, delivered an oral presentation and was the lead author on the featured poster, both of which will be made available on the Versartis website: http://ir.versartis.com/events.cfm.

"These results from patients in the somavaratan Phase 2a and long term VISTA study indicate that increasing the dose to 3.5mg/kg twice-monthly safely improved IGF-I SDS and height velocity and this dose now being evaluated in the Phase 3 VELOCITY trial," said Nancy M. Wright, MD, Assistant Clinical Professor at the Florida State University College of Medicine and Medical Director at Nancy Wright, MD, P.A. She is a co-author on the presentation and a somavaratan trial investigator. "Additionally, the safety profile following 2½ years of therapy is consistent with daily rhGH treatment. Somavaratan showed no novel safety signals. We look forward to the results of the ongoing Phase 3 trial in the third quarter of 2017."

**Oral Presentation**
The oral presentation entitled, "Results of Somavaratan (VRS-317) dose increase in the first two years of treatment in pre-pubertal children with growth hormone deficiency (GHD)", highlighted the changes in mean IGF-I SDS and height velocity (HV) between treatment duration at the lower initial doses totaling 5.0 mg/kg monthly and subsequently increased to a total of 7.0 mg/kg monthly in the Phase 2a and subsequent VISTA long-term safety study. Dosing frequency varied in Year 1; however, all 64 subjects initially received 5.0 mg/kg monthly in divided weekly, monthly or twice-monthly doses. Subjects initially in the weekly cohort increased to 7.0 mg/kg divided twice-monthly during the first treatment year, 5 subjects at month 6 and 15 subjects at month 9 and by Year 2, all had increased to the 3.5 mg/kg twice-monthly dose. Baseline mean IGF-I SDS for the total cohort was -1.7 (±0.78). The dose increase to 3.5 mg/kg twice-monthly resulted in increased mean IGF-I SDS peak from 0.09 (±1.35) during treatment duration at 5.0 mg/kg monthly to 0.60 (±1.42) at 7.0 mg/kg monthly — the upper end of the therapeutic range — and trough from -1.4 (±1.03) to -0.7 (±1.25). On the lower dose, transient IGF-I SDS excursions >2 were observed in 7 subjects, all in the monthly cohort. After the dose increase and move to twice-monthly dosing, IGF-I SDS excursions were observed in 9 subjects (range 2.01, 3.67). All peaks >2 SDS were transient and none were associated with AEs. Fewer subjects reported related AEs after the dose increase than before and no related SAEs were reported. The dose increase also maintained annualized HV into the second year of treatment at 5.0 mg/kg vs. 7.0 mg/kg total monthly dose (8.04±2.59 cm/yr vs. 7.96±2.32), and height SDS continued to improve (-2.3±0.63 vs. -1.7±0.76).

**Poster Session**
The poster entitled, "Safety Profile of Somavaratan (VRS-317), a Novel Long-Acting rhGH Fusion Protein, in Pre-Pubertal Children with Growth Hormone Deficiency (GHD)," reviewed safety data from 30 months of dosing in the Phase 1b/2a clinical trial and subsequent VISTA study. As reported previously, related adverse events (AEs) were all mild/moderate and transient. The most commonly reported AEs were injection site pain (31/64, 48%), injection site erythema (6/64, 9%), and headache (5/64, 8%). The frequency of related AEs declined substantially after the initial 6-month exposure period, and no related serious AEs were reported.

**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 safety and efficacy data from up to 30 months of dosing in the Phase 2 trial and VISTA long-term safety study were presented during the Endocrine Society and European Society of Paediatric Endocrinology 2016 annual meetings. In adult GHD, results have been reported from the Phase 2 VITAL trial in the U.S., Europe and Australia and a Phase 3 trial is expected to begin during the second half of 2017.

[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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