September 2, 2016

Versartis Presents Efficacy, Safety, Metabolic and Adherence Data for Somavaratan in Oral Session at the International Congress of Endocrinology

MENLO PARK, Calif., Sept. 02, 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 data on efficacy, safety (including metabolic parameters), and treatment adherence from up to 30 months of somavaratan treatment in the pediatric long-term safety study (now named VISTA), were presented during the 17th International Congress of Endocrinology, being held August 31 to September 4, 2016, in Beijing. Highlights from the three oral presentations include:

- Safety profile was maintained at 30 months of dosing
- HbA_{1c} levels were stable overall during the treatment period
- Bone age advanced in line with height velocity over two years of treatment
- Treatment adherence rate was 99.6% after 24 months of at-home dosing and over 2200 doses at the current Phase 3 dose

Presentation Summaries

Somavaratan (VRS-317) Treatment for Pediatric Growth Hormone Deficiency (GHD): Results at 2.5 Years:

Eric Humphriss, Vice President of Global Clinical Operations at Versartis, and Will Charlton MD, MAS, FAAP, Senior Medical Director at Versartis, detailed 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). As reported previously, 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) and 57 subjects were evaluable in the Year 2 analysis at this dose level. After dose increase, mean height velocity (HV) 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 in the 48 patients evaluable in months 24-30 no new types of AEs were reported. Results of this study through 30 months suggest that the Phase 3 dose regimen was safe and well tolerated and produced Year 2 HV comparable to NCGS database estimates of rhGH daily dosing in the US.

HbA_{1c} over Two Years of Treatment with Somavaratan (VRS-317) in Children with Growth Hormone Deficiency (GHD):

The effects of long-acting rhGH preparations on metabolic status have not been well-characterized, although the risk of development of diabetes mellitus (DM) in children treated with rhGH is considered minimal. Dr. Charlton described efforts to characterize whether treatment of GHD children with somavaratan may have effects on their glucose metabolism as measured by HbA_{1c}. HbA_{1c} was measured in the VISTA study at months 6, 18, and 30 of treatment exposure with somavaratan. Mean HbA_{1c} was 5.2±0.31% at 6 months (n=59), 5.3±0.33% at 18 months (n=56), and 5.3±0.29% at 30 months (n=45). A minority of individual subjects showed minor changes in HbA_{1c} over time. No changes in mean HbA_{1c} were observed with increased exposure to somavaratan, and no subjects developed DM. Overall, somavaratan did not elicit meaningful effects on insulin sensitivity as assessed by HbA_{1c} in pre-pubertal GHD children.

Treatment Adherence with Weekly, Twice-Monthly and Monthly Dosing of Somavaratan (VRS-317), a Long-Acting Growth Hormone Treatment for Children with Growth Hormone Deficiency (GHD), After 24 Months of At-Home Dosing:

Mr. Humphriss presented updated data on treatment adherence following 24 months of at-home dosing in the VISTA study of somavaratan. 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%-- identical to the result at 18 months. These

data suggest that a twice-monthly dosing regimen has the potential to improve treatment adherence and associated outcomes, as an estimated 66%—77% of adults and children with GHD are noncompliant with daily rhGH injections, and this has been associated with reduced annual height velocity.

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 compliance 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 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 compliance 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.

Contacts:

Corporate & Investors:
Joshua Brumm
Chief Financial Officer
(650) 963-8582
IR@versartis.com

Corporate Communications:
Christine Labaree
Evergreen Communications
(650) 600-1697
christine@evergreencomms.com

Investors:
Nick Laudico/David Burke
The Ruth Group
(646) 536-7030/7009
nlaudico@theruthgroup.com
dburke@theruthgroup.com