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Versartis Announces Completion of Enrollment in Phase 3 VELOCITY Trial of Somavaratan in Pediatric GHD

Total of 137 patients enrolled; top-line results expected in Q3 2017

MENLO PARK, Calif., Aug. 22, 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 the completion of enrollment in the Phase 3 VELOCITY trial of somavaratan in pediatric GHD. With 137 patients enrolled, the trial is powered at >90% to demonstrate non-inferiority of somavaratan compared to daily rhGH. Patients will be followed for the primary trial endpoint of height velocity at 12 months, as well as safety and pharmacodynamic secondary endpoints. Top-line results are anticipated in Q3 2017.

"For more than three decades, recombinant human growth hormone has been effective to treat children, adolescents and adults with growth hormone deficiency, but the daily injection schedule is inconvenient and can be painful or distressing for children and their caregivers. These issues may also lead to patient non-compliance and thus, reduced efficacy," said Alan D. Rogol, MD, PhD, an endocrinologist and Professor Emeritus at the University of Virginia School of Medicine. "Somavaratan may offer the least frequent dosing schedule with twice-monthly dosing, and with the Phase 3 VELOCITY trial now fully enrolled, it may be the first of the long-acting growth hormone preparations currently in development to become available for children with GHD."

"We are grateful to the patients and their families as well as the investigators who are taking part in VELOCITY. We look forward to completing this Phase 3 trial and reporting top-line results around this time next year," said Jay Shepard, Versartis' Chief Executive Officer. "In the meantime, the Versartis team is fully focused on advancing the somavaratan development program in North America, Europe and Japan and initiating our collaboration with Teijin, our Japanese partner for commercialization."

The **Ve**rsartis **Lo**ng-Acting Growth Hormone in **C**h**i**ldren compared **T**o Dail**y** rhGH (VELOCITY) Trial is a randomized, open-label, Phase 3 registration trial in the United States, Europe and Canada. This study enrolled naïve to treatment, pre-pubertal children with GHD who were randomized 3:1 to 3.5 mg/kg of somavaratan twice-monthly or daily rhGH at 34 µg/kg/day, the highest approved GHD dose on the labels of Genotropin® and Norditropin®.

As with patients who completed the prior Phase 2 trial of somavaratan in pediatric GHD, patients completing the Phase 3 VELOCITY trial will have the opportunity to transition to an ongoing, open-label, long-term safety study named VISTA (**V**ersart**is** Long-Term Safety Study of Somavara**ta**n). Versartis reported confirmatory two-year safety and efficacy data from Phase 2 extension study patients during the Endocrine Society Annual Meeting in Q2 2016.

Somavaratan's twice-monthly dosing schedule is the least frequent dosing interval in development for long-acting growth hormones. Somavaratan also has the potential to be the first long-acting growth hormone product to enter the market for pediatric GHD, with its clinical development program being the furthest advanced. In addition to the Phase 3 VELOCITY trial, the J14VR5 trial is underway in Japan in pediatric GHD and is expected to transition from Phase 2 to Phase 3 by the end of 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. Versartis retains global rights to somavaratan outside Japan, where it has a strategic alliance with Teijin Limited for commercialization and future development.

Analyst and Investor Symposium
Versartis will also host a breakfast symposium for institutional investors and equity research analysts on Thursday, September 15, 2016, from 8:00-10:30 am in New York City. The event will feature presentations from Dr. Alan Rogol and two additional leading experts in growth hormone deficiency as well as the Versartis management team. Details regarding the event webcast will be announced prior to the event. Analysts and investors may email IR@versartis.com for more information or to RSVP.

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 extension study patients 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 in Japan and other countries. 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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