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Versartis Initiates Phase 3 Trial of Somavaratan in Japan for Children with Growth Hormone Deficiency Following Completion of Phase 2

MENLO PARK, Calif., Sept. 26, 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 initiation of the Phase 3 portion of its J14VR5 trial in Japanese children with GHD following the completion of the Phase 2 portion of the trial. Versartis noted the following:

- Following a successful End-of-Phase 2 meeting with Japan's Pharmaceuticals and Medical Devices Agency (PMDA), Versartis has initiated the Phase 3 portion of the J14VR5 study
- Pharmacokinetic (PK), pharmacodynamic (PD) and safety data from the Phase 2 and Phase 2 extension portions of J14VR5 were reviewed as part of the End-of-Phase 2 consultation
- The Phase 3 portion of the trial is being conducted using the same 3.5 mg/kg twice-monthly dose as is being used in the Phase 3 VELOCITY trial
- The Phase 3 portion will enroll approximately 48 subjects; 23 subjects from the Phase 2 portion of the study have currently enrolled in the Phase 3 portion of the trial

Jay Shepard, Versartis' Chief Executive Officer, commented, "This represents another significant milestone for Versartis as we will now have Phase 3 pediatric trials underway for somavaratan in the major world markets for GHD. Japan is a very important potential market for us and our collaboration partner, Teijin, which already serves the endocrinology community there. We look forward to the potential to offer a less burdensome treatment option to GHD children and their families than the currently available daily treatments."

The J14VR5 trial consists of a Phase 2 single dose stage to determine safety, pharmacokinetics and pharmacodynamics and support dose selection in naïve-to-treatment Japanese GHD children, followed by the repeat dose Phase 3 stage to obtain 12-month safety and efficacy data. Patients who completed the first stage were permitted to enter a repeat dose extension study, at the 3.5 mg/kg twice-monthly dose, prior to initiation of the Phase 3 portion. All patients participating in Phase 3 will also be offered the opportunity to continue treatment in an open-label extension study.

Safety, PK and PD observed in Japanese GHD children dosed with somavaratan during the Phase 2 stage of the trial were comparable to those collected previously in U.S. children treated with somavaratan during the Versartis single dose Phase 1b study. Somavaratan was generally well-tolerated, and the safety profile of somavaratan was characterized by primarily mild to moderate and transient related adverse events (AEs) consistent with those typically reported and observed in children starting daily rhGH in Japan. In the ongoing Phase 2 extension study, one potentially related serious AE (seizure) was reported in a child with both a medical history and clinical findings consistent with a preexisting condition. Data from the Phase 2 stage will be submitted to a scientific conference during the first half of 2017.

"The study's Steering Committee, the study's Data Safety Monitoring Board, and the PMDA have reviewed the results of the Phase 2 and Phase 2 extension portions of J14VR5 and are in alignment with our plans to move forward with the Phase 3 program in Japan," said Dr. Colin Hislop, Versartis' Chief Medical Officer. "We are pleased that all three bodies support our plans to move forward with the Phase 3 program, underscoring that somavaratan was found to be safe and well-tolerated in Japanese subjects. Additionally, we were pleased to present updated data at the European Society for Paediatric Endocrinology (ESPE) Annual Meeting earlier this month, which showed that somavaratan's safety profile was maintained across 30 months of dosing, and we expect to have data out to a minimum of four years on some children at the time of potential marketing authorization applications for the United States, Europe and Japan."

The Phase 3 stage of the J14VR5 trial is a single-arm, multi-center trial evaluating the safety and efficacy of 3.5 mg/kg twice-monthly somavaratan (same dose and regimen as the VELOCITY Phase 3 trial). Estimated enrollment is approximately 48 subjects, and the PMDA has agreed that subjects from the Phase 2 part of the trial may continue into Phase 3.

Enrollment in the Phase 3 trial is expected to be completed in the third quarter of 2017, with topline data expected in 2018.

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 auto-injector 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 the third quarter of 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, the long-term safety study from the Phase 2 VITAL trial is underway 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, target enrollment 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). 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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