April 3, 2017

Versartis Reports New Data on Long-Acting Somavaratan in Growth Hormone Deficiency at ENDO 2017

- Baseline characteristics of Phase 3 VELOCITY trial population balanced between study arms and comparable to Phase 2
- Further results from the VITAL trial in adult GHD
- Similar somavaratan PK/PD data in U.S. and Japanese children support using the same dose in the ongoing global and Japan Phase 3 trials
- Conference call and webcast scheduled for 4:30 pm ET today featuring Versartis management and pediatric endocrinologist Bradley Miller, M.D., Ph.D.

MENLO PARK, Calif., April 3, 2017 /PRNewswire/ -- Versartis, Inc. (NASDAQ:VSAR), an endocrine-focused biopharmaceutical company that is developing somavaratan, a novel, long-acting form of recombinant human growth hormone (rhGH) for growth hormone deficiency (GHD), announced that new data on somavaratan in pediatric and adult GHD were presented during the Endocrine Society's 99th Annual Meeting & Expo (ENDO 2017), being held April 1-4, 2017 in Orlando, Florida. Somavaratan was featured in four posters and an oral session over the weekend and three-year safety and efficacy results from the ongoing VISTA pediatric long-term safety study are scheduled to be presented during an oral session today from 11:15-12:45 ET. The presentations will be made available at http://www.versartis.com/pipeline/publications/.

"As an investigator in the North American and European VELOCITY study, I was pleased to see that the stratification procedures that were applied to the trial have created consistency across the Phase 2 and Phase 3 patient populations, as well as balance between the two Phase 3 study arms," said Philippe Backeljauw, M.D., Professor of Clinical Pediatrics, University of Cincinnati College of Medicine, Cincinnati Children's Hospital Medical Center. "These factors are important for the interpretation of the trial results, and the baseline characteristics in both studies reflect the type of GHD patient we treat in the United States. This provides essential context for endocrinologists reviewing the somavaratan Phase 3 data, which are anticipated this fall."

"Unlike children, adults with GHD are more sensitive to therapy with GH, so identifying an appropriate dosing strategy for a new, long-acting form of GH is important for physicians who are going to treat these patients, either in the Phase 3 setting or in everyday clinical practice," said Kevin C. J. Yuen, M.D., F.R.C.P., F.A.C.E., Medical Director, Swedish Pituitary Center at the Swedish Neuroscience Institute in Seattle. "In the Phase 2 VITAL trial, somavaratan was found to induce a robust IGF-I response in adults with GHD and these findings have helped identify a twice-monthly dosing schedule and starting doses for titration that can be applied in the adult Phase 3 trial expected to start later this year."

Pediatric GHD

POSTER PRESENTATION (31202): *Achievement of a Suitable Basis of Comparison in Phase 2 and Phase 3 Pediatric Somavaratan Clinical Trials (VERTICAL, VISTA, and VELOCITY Studies) and for the Comparison of Somavaratan to Daily Recombinant Human Growth Hormone (rhGH)*

Michael Stalvey, M.D., Assistant Professor and Physician, Fellowship Program Director, The University of Alabama at Birmingham, and colleagues compared the baseline characteristics of the 136 GHD children (104 randomized to twice-monthly somavaratan, 32 to daily rhGH) enrolled in the Phase 3 VELOCITY trial with those of the 64 GHD children who enrolled in the previously completed Phase 2a VERTICAL trial. The use of consistent inclusion/exclusion criteria in both trials and a stratification procedure to balance arms in the Phase 3 non-inferiority trial by region, expected median age, and expected median baseline IGF-I SDS has yielded similar treatment populations. No clinically meaningful differences exist between the somavaratan and daily rhGH arms of the Phase 3 VELOCITY trial or between the Phase 2 VERTICAL and Phase 3 VELOCITY trials. Thus, a valid basis of comparison between treatment populations has been achieved.

POSTER PRESENTATION (29268): *IGF Family Biomarkers in the Diagnosis of Pediatric Growth Hormone Deficiency (PGHD) in Somavaratan Clinical Trials*

George Bright, M.D., Global Pediatric Development Advisor for Versartis, and colleagues described an analysis of paired pretreatment IGF-I samples taken at screening and baseline from 196 subjects in the Phase 2a and Phase 3 trials of

somavaratan in pediatric GHD to help determine within subject variability of IGF biomarkers in the study populations. Within-subject variability of IGF-I shows concordance of paired pretreatment IGF-I in the majority of pre-pubertal PGHD patients. However, concordance is adversely affected by selection of lower IGF-I SDS cutoff values, and differences in paired IGF-I samples tend to increase at lower IGF-I concentrations and at older ages. The treatment outcome predictive value of pretreatment IGF-I samples and within-subject variability is under study.

LATE-BREAKING POSTER PRESENTATION (33003): *Pharmacokinetic and Pharmacodynamic (PK/PD) Analysis of Somavaratan (VRS-317), a Long-Acting Recombinant Human Growth Hormone (rhGH), in Japanese and US Children with Growth Hormone Deficiency (GHD)*

Tomonobu Hasegawa, M.D., Professor of Pediatrics, Division of Endocrinology & Metabolism, Department of Pediatrics, Keio University School of Medicine, and colleagues described a comparison of the pharmacokinetic and pharmacodynamic (PK/PD) properties between pediatric subjects in the Phase 2 U.S. and Japanese studies of somavaratan. Given the effect of body weight on somavaratan PK parameters in both studies, the data continue to support weight-based dosing. After adjusting for differences in body weight, differences in exposure between Japanese and US populations did not merit changes in dosing principles. PD responses to somavaratan, including IGF-I SDS and IGFBP3, were comparable between the two study populations. The results of this analysis support the utilization of the same 3.5 mg/kg twice-monthly US Phase 3 dose in the ongoing Japanese Phase 3 trial.

Adult GHD

ORAL PRESENTATION (31263): *Somavaratan, a Long-Acting Recombinant Human Growth Hormone (rhGH), for the Treatment of Adults with Growth Hormone Deficiency (AGHD): Results of VITAL, an Open-Label, Dose-Finding, International, Phase 2 Study (NCT02526420)*

Dr. Yuen and colleagues summarized the results from VITAL, an open-label, international, multicenter, Phase 2 study evaluating safety, starting dose, and dose titration for monthly somavaratan administration in adults with GHD. Subjects were stratified into 3 cohorts (≥ 35 years of age, < 35 years of age, or female subjects on oral estrogen) with different starting doses based on expected requirements for rhGH. Somavaratan was well tolerated and induced a robust IGF-I response, with sustained effect for approximately 2 weeks. Following the last study dose, IGF-I SDS returned to pre-dose values by day 22. The study yielded information required to optimize somavaratan treatment in adults with GHD, including the starting dose, dosing frequency and titration plan. Lower starting doses of somavaratan administered twice monthly are now being investigated in the adult extension study and will be used in the Phase 3 trial expected to start later this year.

POSTER PRESENTATION (31432): *Correlation Between Baseline IGF-I, Dose, and Response to Once-Monthly Somavaratan, a Long-Acting Recombinant Human Growth Hormone (rhGH), in the Open-Label, Dose-Finding, International, Phase 2 VITAL Study in Adults with Growth Hormone Deficiency (AGHD) (NCT02526420)*

Martin Bidlingmaier, M.D., Head Endocrine Laboratory, Medizinische Klinik und Polklinik IV, Ludwig-Maximilians University, München, and colleagues described an analysis of data from the Phase 2 dose-finding VITAL study in AGHD to evaluate the relationships between baseline (BL) IGF-I levels and somavaratan dose and IGF-I response, and between BL IGF-I and years since diagnosis of AGHD. Among adults with GHD, a clear distinction of IGF-I response to somavaratan and dose requirement based on BL IGF-I level was noted.

Conference Call/Webcast

The Versartis management team will host an ENDO review conference call and webcast today, April 3, 2017, at 4:30 pm ET, featuring Bradley S. Miller, M.D., Ph.D., Associate Professor in the Department of Pediatric Endocrinology at the University of Minnesota Masonic Children's Hospital. Dr. Miller is scheduled to present three-year data on somavaratan in pediatric GHD today at ENDO. The dial-in numbers are 877-407-0789 for domestic callers and 201-689-8562 for international callers. A live webcast of the conference call including a slide presentation will be available online from the investor relations page of the Company's corporate website at www.versartis.com.

After the live webcast, the call will remain available on the Versartis website, www.versartis.com, for 90 days. In addition, a telephonic replay of the call will be available until April 17, 2017. The replay dial-in numbers are 844-512-2921 for domestic callers and 412-317-6671 for international callers. Please use the replay conference ID number 13658330.

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 hydrophilic amino acids based on a proprietary XTEN® technology[1]. 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 September 2017, and the J14VR5 Phase 2/3 trial in Japan. Safety and efficacy data from 36 months of dosing in the Phase 2 trial and VISTA long-term safety study are scheduled to be presented during the Endocrine Society 2017 annual meeting. 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 by the end 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, 2016, which is 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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