Versartis Announces Data on Long-Acting Somavaratan for Growth Hormone Deficiency to be Featured in Late-Breaker Presentation at ENDO 2017

Similar PK/PD data between US and Japanese children treated with somavaratan support using the same dose in the ongoing US and Japan Phase 3 trials

MENLO PARK, Calif., March 02, 2017 (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), announced that a comparison of data from its U.S. and Japanese Phase 2 studies was accepted as a late-breaking poster presentation at the Endocrine Society’s 99th Annual Meeting & Expo (ENDO 2017), to be held April 1-4, in Orlando, Florida. The abstract has been published online and is available on the ENDO 2017 website. This is the sixth Versartis abstract that has been accepted for presentation at the conference, including five that were announced previously.

Comparison of the pharmacokinetic and pharmacodynamic (PK/PD) properties between U.S. and Japanese pediatric subjects showed similar responses achieved at the same range of somavaratan doses in both populations. In addition, variability between the two patient sets was minor, with no effect on treatment outcomes. These similarities support the utilization of the same 3.5 mg/kg twice-monthly US Phase 3 dose in the ongoing Japanese Phase 3 trial, which has been reviewed with Japan's Pharmaceuticals and Medical Devices Agency (PMDA). Below are details on each of the presentations.

Late-Breaker Pediatric GHD

LATE-BREAKING POSTER PRESENTATION (Poster Board: LB SAT 01)
Saturday, April 1, 2017 - 1:00 — 3:00 PM

Pediatric GHD

ORAL PRESENTATION (Oral Session: OR31-1)
Monday, April 3, 2017 - 11:15 AM - 12:45 PM
31135- Safety and Efficacy of Somavaratan (VRS-317), a Long-Acting Recombinant Human Growth Hormone (rhGH), in Children with Growth Hormone Deficiency (GHD): 3-Year Update of the VERTICAL & VISTA Trials (NCT01718041, NCT02068521)

POSTER PRESENTATION (Poster Board: SAT 016)
Saturday, April 1, 2017 - 1:00 — 3:00 PM
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)

POSTER PRESENTATION (Poster Board: SAT 015)
Saturday, April 1, 2017 - 1:00 — 3:00 PM
29268- IGF Family Biomarkers in the Diagnosis of Pediatric Growth Hormone Deficiency (PGHD) in Somavaratan Clinical Trials

Adult GHD

ORAL PRESENTATION (Oral Session: OR22-2)
Saturday, April 1, 2017 - 11:30 AM - 1:00 PM
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,
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. 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. Confirmatory 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.

1XTEN 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 September 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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