Company Announcement no. 19/2013

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Phase III Clinical Study Data Demonstrating LCP-Tacro™'s Comparable Efficacy and Safety to Twice-Daily Tacrolimus Presented at the European Society for Organ Transplantation

Veloxis Introduces Envarsus® as Trade Name for LCP-Tacro™

Veloxis Pharmaceuticals A/S (OMX: VELO) today announced that data from the 3002, randomized, double-blind, double-dummy, Phase III study in 543 de novo kidney transplant patients will be presented at the European Society for Organ Transplantation as a late-breaker oral presentation at 8:30 a.m. CEST, Sept. 9, in Vienna. Veloxis' once-daily LCP-Tacro™, now with the trade name of Envarsus®, demonstrated comparable efficacy and safety compared to twice-daily tacrolimus (Prograf®).

"Tacrolimus is a cornerstone of management of kidney transplant patients; however, formulations of the drug that can simplify patient management and improve the treatment experience would be welcomed by the transplant community," said Prof Lionel Rostaing M.D., Ph.D., head of the Organ Transplant Unit at Toulouse University Hospital in France. "Envarsus® appears to be a promising candidate that could be of benefit for both physicians and their kidney transplant patients."

The primary endpoint of the study was a composite endpoint of treatment failure (biopsy-proven acute rejection or BPAR, graft failure, loss to follow up or death) that was evaluated after a 12-month treatment period to demonstrate the non-inferiority of Envarsus® compared to Prograf®. The treatment failure rate for Envarsus® was 18.3% compared to 19.6% for Prograf®, well within the 10% pre-specified non-inferiority margin.

"The 3002 study was our second successful Phase 3 clinical trial demonstrating Envarsus®' efficacy and safety in kidney transplant recipients," said William Polvino, M.D., president and chief executive officer of Veloxis. "We have already submitted and the EMA has accepted our MAA for European regulatory review and we are preparing our NDA for submission to the U.S. FDA by the end of 2013. We now look forward to interactions with regulatory authorities as we move closer to approval of Envarsus® in Europe and the U.S."

Three other Veloxis-sponsored abstracts will be presented at the conference.

Abstract #BO194; brief oral presentation, Monday, September 9, 2013, 5:05 p.m. CEST
Correlation Between Cmin and AUC for Novel Once-Daily Extended-Release Tacrolimus Tablets LCP-Tacro™
Osama Gaber, M.D., Rita R. Alloway, Kenneth Bodziak, M.D.
The correlation of AUC to Cmin with LCP-Tacro™ is strong, demonstrating that the current practice of therapeutic drug monitoring using Cmin as a measure of tacrolimus exposure can also be applied to LCP-Tacro™.

Abstract P508; Poster session, Sunday, September 8, 2013, 6:15 to 7:30 p.m. CEST
LCP-Tacro™-Associated Improvement in TAC-Induced Tremor is also Associated with Improvement in Quality of Life: Results of a Switching Study of Kidney Transplant Patients with Tremor (STRATO)
Roberto Gedaly, M.D., Steven M. Steinberg, M.D., FACP, Anthony Langone, M.D., John C. Morgan, M.D. Ph.D.,
The STRATO Study demonstrated that LCP-Tacro™ can reduce a troubling side effect of tacrolimus, tremor, and improve the quality of life of kidney transplant recipients.

Abstract P330; Poster session, Sunday, September 8, 2013, 6:15 to 7:30 p.m. CEST
Evaluation of Steady-State Pharmacokinetic Parameters of LCP-Tacro™ and Advagraf® in Healthy volunteers using a Systems Dynamic Model
Steven Gabardi, Pharm.D., FCCP, BCPS, Vincenza Nigro, Mary Johnson, Ph.D., Robert Nachtrieb Ph.D., John Weinberg, M.D.
Once-daily LCP-Tacro™'s MELTDOSE technology differs in tacrolimus PK characteristics compared to once-daily Advagraf. LCP-Tacro™ has shown increased bioavailability compared to Advagraf though more studies are warranted in kidney transplant patients to compare the two formulations.

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About Envarsus® (formerly LCP-Tacro™) and tacrolimus
Tacrolimus is a leading immunosuppression drug used for the prevention of transplant allograft rejection after organ transplantation. Envarsus® is an investigational drug that is being developed as a once daily tablet version of tacrolimus, with improved bioavailability, consistent pharmacokinetic performance and reduced peak to trough variability when compared to currently approved tacrolimus products. Transplant patients need to maintain a minimum blood level of tacrolimus for the prevention of transplant allograft rejection, but excessive levels may increase the risk of serious side effects such as nephrotoxicity, tremor, diabetes, high blood pressure, and opportunistic infections. Therefore, tacrolimus levels need to be managed carefully, and transplant patients are typically obliged to make frequent visits to the hospital for monitoring and dose adjustments after receiving a new organ.

About Veloxis Pharmaceuticals
Based in Hørsholm, Denmark, with an office in New Jersey, Veloxis Pharmaceuticals A/S, or Veloxis, is a specialty pharmaceutical company. The company's lead product candidate is Envarsus® for immunosuppression, specifically organ transplantation. Veloxis' unique, patented delivery technology, MeltDose®, can improve absorption and bioavailability at low scale up costs. Veloxis has a lipid lowering product, Fenoglide®, currently on the U.S. market that is commercialized through partner Santarus, Inc. Veloxis is listed on the NASDAQ OMX Copenhagen under the trading symbol OMX: VELO.
For further information, please visit www.veloxis.com.