



Company Announcement no. 1/2012

To: NASDAQ OMX Copenhagen A/S

Hørsholm, Denmark, January 4, 2012

Veloxis Pharmaceuticals Announces Initiation of STRATO Study of LCP-Tacro™ in Kidney Transplant Recipients Experiencing Tremors

Veloxis Pharmaceuticals A/S (OMX: VELO) today announced dosing of the first patient in the STRATO (**Switching kidney TRAnsgraft patients with Tremor to LCP-tacro**) Phase IIIb study of LCP-Tacro™ in kidney transplant recipients experiencing drug-induced tremors. The STRATO study is designed to explore whether a conversion of patients who have symptomatic tremor from treatment with standard immediate release twice-daily tacrolimus capsules to extended release once-daily LCP-Tacro™ tablets leads to a measurable improvement in tremor.

Drug-induced tremor is a concerning side effect experienced by almost half of transplant patients taking twice-daily tacrolimus, the current standard of care therapy. Evidence suggests that tacrolimus-induced tremor is related to peak concentration levels that usually occur approximately two hours after dosing. LCP-Tacro™, currently in Phase III development for prophylaxis of rejection in kidney transplant recipients, utilizes Veloxis' proprietary extended release formulation based on the MeltDose® technology, which offers once-daily administration and a flatter pharmacokinetic profile. This characteristic is postulated to be potentially beneficial in mitigating peak-related neurotoxic effects of tacrolimus.

"We believe this is the first trial in kidney transplant recipients that will utilize a sophisticated and reproducible measurement of tremor," said Dr. Anthony J. Langone, M.D., Assistant Professor of Medicine at Vanderbilt University Medical Center. "This study will determine if renal transplant patients who currently experience tremors have a measurable reduction in symptoms after conversion to LCP-Tacro™, while maintaining comparable drug exposure. In addition to improving tremor symptoms and quality of life in patients with tremors, LCP-Tacro™ may obviate the need for dose-reductions and address compliance issues that may stem from experiencing neurotoxicity related to tacrolimus."

STRATO Study Design

Patients experiencing tacrolimus-related neurotoxicity, as demonstrated by moderate-to-severe tremors, on immediate release tacrolimus products, will be enrolled in this Phase IIIb study of kidney transplant recipients. Patients will be converted to once-daily LCP-Tacro™ and their neurotoxicity symptoms assessed using the Fahn-Tolosa-Marin tremor rating scale, as well as by tremorometer readings. Quality of life assessments will also be undertaken to determine the level of improvement during the study.

For information about the study, please visit www.clinicaltrials.gov, clinical trials identifier NCT01438710.



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About LCP-Tacro™ and tacrolimus

Tacrolimus is a leading immunosuppression drug used for the prevention of transplant allograft rejection after organ transplantation. LCP-Tacro™ 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 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. Clinical development is the core of Veloxis' efforts to develop a product portfolio which includes the Company's lead product candidate, LCP-Tacro™, for immunosuppression, specifically organ transplantation, and products to combat certain cardiovascular diseases. Veloxis adapts new technologies on a fast commercial timetable. Veloxis' unique, patented delivery technology, MeltDose®, can improve absorption and bioavailability - at low-scale up costs - not only for a broad spectrum of drugs already on the market but also for new chemical entities. Veloxis has a lipid lowering product, Fenoglide®, currently on the U.S. market and a diversified near and medium term pipeline with three clinical stage product candidates and a number of projects in preclinical development. Veloxis is listed on the NASDAQ OMX Copenhagen under the trading symbol OMX: VELO.

For further information, please visit www.veloxis.com.