Company Announcement no. 15/2013

To: NASDAQ OMX Copenhagen A/S Hørsholm, Denmark, 27 June 2013

Veloxis Announces Positive Results of 3002 Study: LCP-Tacro™ Meets Primary Efficacy and Safety Endpoints in *de Novo* Kidney Transplant Patients

- LCP-Tacro™, once-daily, demonstrated non-inferiority to Prograf®, twice-daily, based on the composite endpoint of treatment failure at one year (LCP-Tacro™ 18.3%, Prograf® 19.6%)
- Treatment failure rates through the first three months after transplant were 10.4% for LCP-Tacro™ and 14.2% for Prograf®
- Similar incidence of adverse events and impact on laboratory results reported for LCP-Tacro™ and Prograf®
- Regulatory submission to the FDA on track for second half of 2013
- Conference call to discuss the results will be held on 28 June at 8 a.m CEDT (2 a.m. EDT)

Veloxis Pharmaceuticals A/S (OMX: VELO) today announced LCP-Tacro™ successfully demonstrated non-inferiority compared to tacrolimus (Prograf®; Astellas Pharma) in its Phase III clinical trial, Study 3002. The Phase III randomized, double-blind and double-dummy study in 543 de novo kidney transplant recipients, with Prograf® as the comparator, met its primary efficacy and primary safety endpoints. The study was conducted under a Special Protocol Agreement with the FDA and the results are considered pivotal for the planned U.S. regulatory filing expected to occur in the second half of 2013.

"The results observed in this clinical trial suggest that new kidney transplant patients can begin with a regimen of once-daily LCP-Tacro™ rather than twice-daily as required with current tacrolimus products, without compromising efficacy and tolerability," said Dr. Suphamai Bunnapradist, M.D., Professor of Medicine and Director of Kidney Transplant Research at the Ronald Reagan Medical Center and David Geffen School of Medicine at UCLA, California, USA. "This is important because once-daily dosing should be beneficial for kidney transplant patients who are on life-long complex therapy."

LCP-Tacro™ demonstrated non-inferiority to Prograf® in preventing kidney transplant rejection, including in the early post-transplant period

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 LCP-Tacro™ compared to Prograf®. The treatment failure rate for LCP-Tacro™ was 18.3% compared to 19.6% for Prograf®, well within the 10% pre-specified non-inferiority margin.

Patients with Event	LCP-Tacro™ (N=268)	Prograf® (N=275)	Difference (95% CI)
Treatment Failure Within 12 Months	49 (18.3%)	54 (19.6%)	-1.35% (-7.94%, 5.27%)
All-Cause Mortality	8 (3.0%)	8 (2.9%)	
Graft Failure	9 (3.4%)	11 (4.0%)	
BPAR	35 (13.1%)	37 (13.5%)	
Lost to Follow-up	4 (1.5%)	5 (1.8%)	

Kaplan-Meier analyses showed comparable efficacy throughout the 12-month study period including the early post-operative days when patients are at greatest risk of organ rejection and graft failure. Within the first 3 months after transplant, when patients are at the greatest risk of rejection, the treatment failure rates for LCP-Tacro™ and Prograf® were 10.4% and 14.2%, respectively (p=0.124).

Comparable incidence of adverse events and lower dose required

The primary safety analyses were the differences between LCP-Tacro™ and Prograf® treatment groups at Month 12 (Day 360) with respect to the incidence of adverse events (AEs) and the incidence of predefined potentially clinically significant laboratory measures including: fasting plasma glucose; platelet count; white blood cell (WBC) count; aminotransaminases; total cholesterol; low density lipoprotein (LDL) cholesterol; triglycerides; and estimated glomerular filtration rate (eGFR). In all instances, there were no statistically significant differences between the two treatments. Specifically, renal function was similar between the two groups at 12 months, as was the incidence of malignancy, infections and new onset diabetes during this period.

The study results demonstrated that during long-term outpatient therapy from Month 3 onwards, LCP-Tacro™ patients required a daily dose that was approximately 15 percent lower than patients receiving Prograf®, reflecting the improved absorption provided by Veloxis' proprietary MeltDose® formulation.

"The 3002 study was a large blinded and randomized clinical trial and we are very pleased with the positive outcomes of this study," said William Polvino, M.D., chief executive officer of Veloxis. "The results were strong and compelling and we look forward to sharing the data with regulatory authorities in the U.S. and Europe as well as with the transplant community. We look forward to continuing to develop this new treatment option for transplant patients for whom there remain significant unmet medical needs."

These findings from the 3002 study add to the previously established clinical trial experience with LCP-Tacro™. These studies include the Phase III switch study announced in 2011, demonstrating non-inferiority to Prograf® in stable kidney transplant patients switched from Prograf® to LCP-Tacro™, together with the STRATO study announced earlier this year demonstrating the potential for LCP-Tacro™ to reduce tacrolimus-induced tremors. The regulatory submission of LCP-Tacro™, for the prophylaxis of kidney transplant rejection, to the U.S. Food and Drug Administration is planned for the second half of 2013.

These study results are not expected to have an impact on the 2013 financial outlook for Veloxis.

Conference call information

Veloxis will host a conference call at 8 a.m. CEDT (2 a.m. EDT) tomorrow, June 28, 2013, to comment on the results of this study.

To access the live conference call, please dial one of the following numbers:
+45 32 72 80 18 (Denmark)
+44 (0) 1452 555 131 (UK)
+1 866 682 8490 (USA)
Access code 99610146

Following the conference call, a recording will be available on the company's website www.veloxis.com.

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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 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 LCP-Tacro™ 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.