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Veloxis Pharmaceuticals' Once-Daily LCP-Tacro™ Meets Non-Inferiority Endpoint When Compared to Twice-Daily Tacrolimus Tablets in Stable Kidney Transplant Patients

Phase 3 Efficacy Results to be Presented at 15th Congress of the European Society for Organ Transplantation (ESOT)

HØRSHOLM, DENMARK, September 6, 2011 – Veloxis Pharmaceuticals A/S (OMX: VELO), formerly LifeCycle Pharma A/S, today announced that efficacy results from its Phase 3 study in stable kidney transplant patients suggests that its once-daily LCP-Tacro™ is non-inferior in efficacy compared to twice-daily standard tacrolimus tablets (Prograf®). Data will be presented in a rapid oral and poster presentation at 4:08 p.m. BST, Tuesday, September 6, at the 15th Congress of the European Society for Organ Transplantation (ESOT) in Glasgow, United Kingdom.

"Coupled with previously reported pharmacokinetic parameters, efficacy results from this Phase 3 trial suggest that LCP-Tacro may provide an alternative to twice-daily tacrolimus," said Prof Lionel Rostaing M.D., Ph.D., head of the Organ Transplant Unit at Toulouse University Hospital, France. "Further testing will focus on the frequency of dose adjustments, the incidence of adverse events, and potential patient compliance benefits."

The Phase 3 trial was an open-label, multicenter, prospective, randomized study enrolling 324 kidney transplant recipients 3-60 months post-transplant taking oral Prograf®. Patients were randomized to receive LCP-Tacro once-daily or to maintain their Prograf® regimen for 12 months. The primary efficacy endpoint was a composite of death, graft failure, biopsy-proven acute rejection (BPAR) via a local pathology reading or loss to follow-up within 12 months of randomization. Initial LCP-Tacro dose was 30% lower (15% for African Americans) than the pre-conversion Prograf® total daily dose. Trough levels of 4-15 ng/mL were targeted for both drugs.

The primary composite treatment failure endpoint was met by 4 patients (4.2 percent) in each group, p>0.999. As measured by the central blinded pathologist, the rates of BPAR were 0.6% for LCP-Tacro and 3.1% for Prograf® (p=0.214). LCP-Tacro patients, on average, required a daily dose that was 20% lower than patients receiving Prograf®, reflecting the improved absorption provided by Veloxis' proprietary MeltDose® formulation.

"The positive data from this trial suggest that LCP-Tacro may provide efficacy matching twice-daily tacrolimus but at a lower dose and using a once-daily dosing regimen," said William Polvino, M.D., chief executive officer of Veloxis. "Our second Phase 3 trial in *de novo* kidney transplant patients is ongoing and we expect to report results from that trial by the first quarter of 2013."

For more information, please contact:

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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.