Company Announcement no. 15/2014

To: NASDAQ OMX Copenhagen A/S Hørsholm, Denmark, 23 June 2014

Veloxis Announces Positive Two-Year Results from Pivotal Phase 3 Study of Envarsus® XR (tacrolimus extended-release tablets) in *de novo* Kidney Transplant Patients

Veloxis Pharmaceuticals A/S (OMX: VELO) today announced that two-year results of the pivotal Phase 3 clinical trial, Study 3002, of Envarsus® XR (tacrolimus extended-release tablets) in de novo kidney transplant patients continued to demonstrate non-inferiority compared to tacrolimus capsules (Prograf®; Astellas Pharma). Data will be presented in a late-breaker session at the World Transplant Congress (WTC) in San Francisco, entitled "Two-Year Results of Envarsus (Once-daily MeltDose Tacrolimus Tablets) vs Prograf (Twice-daily Tacrolimus Capsules): A Phase 3, Double-Blind, Double-Dummy, Multi-Center, Prospective, Randomized Study" at 6:30 p.m. PDT on July 27th.

Key points:

- Study 3002 was a randomized, double-blind and double-dummy Phase 3 study evaluating once-daily Envarsus XR compared to twice-daily Prograf in 543 *de novo* kidney transplant patients; the primary endpoint was non-inferiority of a composite endpoint of treatment failure that was evaluated after 12 and 24 months of treatment.
- The primary safety and efficacy time point was at the end of Year 1; these results were previously reported by Veloxis on June 27, 2013. The 3002 study was conducted under a Special Protocol Agreement with the FDA.
- Similar to one-year results, Envarsus XR demonstrated non-inferiority to Prograf on the primary endpoint at the two year time point:

Patients with Event	Envarus XR (N=268)	Prograf (N=275)	Difference (95% CI)
Treatment Failure Within 24 Months	62(23.1%)	75 (27.3%)	-4.14% (-11.38%, 3.17%)
All-Cause Mortality	11 (4.1%)	13 (4.7%)	
Graft Failure	11 (4.1%)	15 (5.5%)	
Biopsy Proven Acute Rejection	46 (17.2%)	50 (18.2%)	
Lost to Follow-up	4 (1.5%)	8 (2.9%)	

- Similar incidence of adverse events and predefined potentially clinically significant laboratory parameters were reported for Envarsus XR and Prograf after two years of treatment and the renal function was similar between the two treatment groups.
- The study results demonstrated that during long-term outpatient therapy from Month 12 onwards, Envarsus XR patients continued to require a daily dose that was approximately 20 to 25 percent lower than patients receiving Prograf, reflecting the improved bioavailability provided by Veloxis' proprietary MeltDose® formulation.
- Envarsus XR, is an investigational new drug under FDA review for the prevention of organ rejection in adult kidney transplant patients. The FDA Prescription Drug User Fee Act (PDUFA) action date is October 31, 2014

Quotes:

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, U.S.A. said, "Envarsus XR holds promise for kidney transplant patients and their physicians for a tacrolimus product with the convenience of once-daily dosing. These data provide comfort that the strong efficacy and safety results seen at one year continue out through two years following transplant."

William Polvino, chief executive officer of Veloxis said, "We are very pleased that the promising data and patient outcomes observed at the one year time point for Envarsus XR continue through the second full year post renal transplantation. We look forward to the completing the regulatory reviews for Envarsus XR in both Europe and the U.S. this year and in being able to bring this important once-daily therapeutic option to transplant patients."

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About Envarsus® XR and tacrolimus

Tacrolimus is a leading immunosuppression drug used for the prevention of transplant allograft rejection after organ transplantation. Envarsus XR (tacrolimus extended-release tablets), known as Envarsus in the EU, is an investigational new drug that is being developed as a once daily tablet version of tacrolimus for prophylaxis of organ transplant rejection. Envarsus XR has received orphan drug designation in the US. Upon approval, Veloxis plans to commercialize Envarsus XR in the US through its own sales force and in the EU through its partnership with Chiesi Farmaceutici SpA.

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® XR 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 Salix, Inc. Veloxis is listed on the NASDAQ OMX Copenhagen under the trading symbol OMX: VELO.

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