Company Announcement no. 4/2014

To: NASDAQ OMX Copenhagen A/S Hørsholm, Denmark, 13 March 2014

U.S. FDA Accepts Veloxis' New Drug Application for Envarsus® for the Prevention of Organ Rejection in Kidney Transplant Patients

Veloxis Pharmaceuticals A/S (OMX: VELO) today announced the U.S. FDA accepted for standard review the company's New Drug Application (NDA) for Envarsus® for the prevention of organ rejection in adult kidney transplant patients. Envarsus® is Veloxis' once-daily tacrolimus based on the company's proprietary MELTDOSE technology.

Key points:

- FDA has set a target review date under the Prescription Drug User Fee Act (PDUFA) of October 3, 2014
- The NDA was submitted to the FDA on 30 December, 2013
- The NDA is based on two Phase III studies, 3001 and 3002, in which Envarsus demonstrated non-inferiority compared to twice daily tacrolimus (Prograf®) based on a composite endpoint of treatment failure at one year
- The clinical program comprised 25 studies and enrolled over 1,000 patients
- Envarsus is a once-daily formulation of tacrolimus that demonstrates a smoother pharmacokinetic profile and enables lower dosing to maintain therapeutic blood levels compared to twice-daily tacrolimus
- Envarsus received Orphan Drug Designation by the U.S. FDA for prophylaxis of organ rejection in patients receiving allogeneic kidney transplants

For more information, please contact:

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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.