Company Announcement no. 25/2013

To: NASDAQ OMX Copenhagen A/S Hørsholm, Denmark, 24 December 2013

**Veloxis Pharmaceuticals Envarsus® Granted Orphan Drug Status by U.S. Food and Drug Administration for Kidney Transplant Rejection Prophylaxis**

Veloxis Pharmaceuticals A/S (OMX: VELO), today announced that Envarsus® was granted Orphan Drug status by the U.S. Food and Drug Administration (FDA) for prophylaxis of organ rejection in patients receiving allogenic kidney transplants. The designation is to encourage the development of drugs that may provide significant benefit to patients suffering from rare diseases. Envarsus® is Veloxis' once-daily formulation of tacrolimus employing the company's proprietary MeltDose® technology.

"We have developed Envarsus® with the goal of improving the care and reducing the treatment burden of patients who have undergone a kidney transplant," said William Polvino, M.D., president and chief executive officer of Veloxis. "FDA recognition of the potential of Envarsus® as the only once-daily tacrolimus to be designated an Orphan Drug highlights these potential benefits. We continue to work on our New Drug Application (NDA), which we expect to submit by the end of 2013."

Orphan drug designation by the FDA is granted upon recognition that the prevalence of the U.S. target patient population is 200,000 patients or less. In the case of Envarsus®, the designation is based on a plausible hypothesis that Envarsus® may be clinically superior to currently marketed tacrolimus products in the U.S. Orphan drug designation entitles Veloxis to a waiver of the FDA prescription drug user fees for Envarsus® for the prevention of kidney transplant rejection. Additionally, U.S. data exclusivity protection may be extended for up to seven years if the FDA agrees that Envarsus has been shown to be clinically superior at the time of approval. Orphan designation does not mean the drug is safe and effective and legal to manufacture and market in the United States. The granting of an orphan designation request does not alter the standard regulatory requirements and process for obtaining marketing approval. Safety and effectiveness of a drug must be established through adequate and well-controlled studies.

**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.