Company Announcement no. 23/2013

To: NASDAQ OMX Copenhagen A/S Hørsholm, Denmark, 11 December 2013

Veloxis Pharmaceuticals Announces Initiation of ASERTAA Study of ENVARSUS® in African-American Kidney Transplant Recipients

Veloxis Pharmaceuticals A/S (OMX: VELO) today announced dosing of the first patient in ASERTAA (**A** **S**tudy of **E**xtended **R**elease **T**acrolimus in **A**frican-**A**mericans) Phase IIIb study of ENVARSUS® (formerly LCP Tacro™) in kidney transplant recipients. The ASERTAA study is designed to compare the pharmacokinetics (PK) of ENVARSUS®, a once-daily tacrolimus tablet, to generic twice daily tacrolimus capsules in stable African-American renal transplant patients.

African-American transplant recipients traditionally experience worse outcomes and require higher doses of immunosuppression. Approximately 50% of African-Americans express the CYP3A5*1 genotype resulting in the need to take high doses of tacrolimus to achieve adequate levels of immunosuppression. This could have implications for dosing with ENVARSUS®, which has shown that African-American transplant patients require a reduced dose while maintaining therapeutic levels. This study will measure the reduction in the dose required as well as conduct genotyping on the patients.

"African-American patients may require high doses of tacrolimus to achieve effective treatment," said Roy D. Bloom M.D., professor of Medicine, medical director, Penn Kidney Pancreas Transplant Program, University of Pennsylvania. "This study will determine if African-American renal transplant patients can benefit from the novel formulation technology of ENVARSUS® that may allow for the administration of lower doses to maintain adequate drug exposure, especially in transplant recipients who are expressors of the CYP3A5*1 genotype."

ASERTAA Study Design

In this cross-over design, the PK of ENVARSUS® in stable African-American renal transplant patients will be compared to the PK of generic twice-daily tacrolimus formulations. In addition, intra-patient variability, total daily dose reduction and analysis of the impact of polymorphic genotype expression will be evaluated. Health-related quality of life, medication adherence and side effect profiles via surveys of study participants will be collected and assessed.

For information about the study, please visit www.clinicaltrials.gov, clinical trials identifier NCT01962922

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.