Company Announcement no. 13/2014

To: NASDAQ OMX Copenhagen A/S Hørsholm, Denmark, 22 May 2014

Veloxis Receives Positive Opinion from CHMP for Envarsus® for Treatment of Both Kidney and Liver Transplant Patients

Veloxis Pharmaceuticals A/S (OMX: VELO) today announced that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has adopted a positive opinion recommending the granting of a marketing authorization for Envarsus® for the prevention of organ rejection in adult transplant patients in the European Union (EU). The positive opinion is for both kidney and liver transplant recipients and includes both the de novo transplant and "switch" settings, as well as for treatment of rejection episodes resistant to treatment with other immunosuppressive products in adult patients. The CHMP's decision will be referred to the European Commission (EC) and if approved by the EC, Veloxis will receive marketing authorization for Envarsus® in all member states of the EU. The EC is expected to render a final decision for Envarsus® within three months of the opinion.

Key points:

- The positive opinion of the CHMP is based on review of the favorable results of the Envarsus® Phase III 3001 study in stable kidney transplant patients and 3002 study in de novo kidney transplant recipients as well as data from an extensive Phase I and II clinical program, which included both kidney and liver transplant patients.
- Studies 3001 and 3002 demonstrated that Envarsus® dosed once-daily was not inferior to the current leading transplant drug, Prograf® (tacrolimus), dosed twice-daily. The Phase I pharmacokinetic and Phase II efficacy data that was submitted in the MAA enabled extrapolation into the broader populations of both kidney and liver transplant recipients.
- The U.S. FDA has accepted for review Veloxis' New Drug Application (NDA) for Envarsus® for the prevention of organ rejection in kidney transplant patients and has set an action date of October 30, 2014 to respond to the submission. Veloxis does not expect to receive the additional liver indication in the U.S.
- Envarsus® received Orphan Drug Designation by the U.S. FDA for prophylaxis of organ rejection in patients receiving allogeneic kidney transplants.

This release does not have any material impact on the Company's previously stated financial projections for 2014.

Quotes:

William Polvino, chief executive officer of Veloxis said, "The positive CHMP opinion for both the kidney and liver transplant patient populations in the European Union reflects the potential promise of Envarsus for the two largest segments of solid organ transplant recipients. This is an important milestone for Veloxis as we move closer to bringing Envarsus® to market in the European Union. Veloxis, and our European marketing partner, Chiesi Farmaceutici, look forward to making this important therapeutic option available to transplant recipients."

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About Envarsus® 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 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 Salix, Inc.

Veloxis is listed on the NASDAQ OMX Copenhagen under the trading symbol OMX: VELO.