Company Announcement no. 17/2014

To: NASDAQ OMX Copenhagen A/S Hørsholm, Denmark, 28 July 2014

Envarsus® Receives European Marketing Authorization for Treatment of Both Kidney and Liver Transplant Patients

Veloxis Pharmaceuticals A/S (OMX: VELO) and Chiesi Farmaceutici S.p.A. today announced that the European Commission (EC) has granted marketing authorization for Envarsus® for the prevention of organ rejection in adult kidney and liver transplant patients in the European Union (EU).

Key points:

- The EMA marketing authorization 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 marketing authorization 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.
- There are approximately 20,000 kidney transplants performed each year in the EU and approximately 7,000 liver transplants.
- Chiesi Farmaceutici S.p.A., through an exclusive license and distribution agreement with Veloxis, will hold the Marketing Authorization and commercialize Envarsus® in the European Union.
- Veloxis' New Drug Application (NDA) for Envarsus® XR for the prevention of organ rejection in kidney transplant patients is under regulatory review by the U.S. FDA and has a PDUFA action date of October 30, 2014. Veloxis does not expect to receive the additional liver indication in the U.S.
- Envarsus® XR received Orphan Drug Designation by the U.S. FDA for prophylaxis of organ rejection in patients receiving allogeneic kidney transplants.

The content of this release will have no influence on Veloxis' financial guidance for 2014 which was provided on 5 March 2014.

Quotes:

Professor Lionel Rostaing, Toulouse University Hospital, France said, "We are very pleased to have a new treatment option available for our transplant patients. Patients must receive immunosuppression as lifelong therapy and Envarsus represents a new once-daily treatment option that may allow patients to more consistently maintain their prescribed treatment regimen."

William Polvino, chief executive officer of Veloxis said, "This approval enables our partner, Chiesi, to offer a novel alternative therapy to kidney and liver transplant patients in the European Union. It further validates our clinical development plan and our underlying MeltDose technology. We now look forward to the initial launch of Envarsus in EU markets starting late this year."

Paolo Chiesi, Corporate R&D Head and Vice President of Chiesi Farmaceutici said, "Chiesi is delighted to have been part of the team which achieved this successful product approval in Europe. As marketing authorization holder we are fully committed to execute both the commercialization and roll out of an important program of further clinical studies for this innovative product. We believe Envarsus will be a valuable therapeutic for a broad population of transplant recipients, and its inclusion in the Chiesi portfolio provides an excellent strategic fit for the business as we expand our activities in the area of specialty care."

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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 (tacrolimus prolonged release tablets) has received marketing authorization in the EU for prophylaxis of organ rejection in kidney and liver transplant recipients. In the US Envarsus, known as Envarsus XR (tacrolimus extended-release tablets), is an investigational new drug under FDA review that is being developed as a once daily tablet version of tacrolimus for prophylaxis of kidney 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.

About Chiesi Farmaceutici

Chiesi Farmaceutici is a research-focused international group, with more than 75 years of experience headquartered in Parma (Italy). Chiesi researches, develops and commercializes innovative pharmaceutical solutions in the respiratory therapeutics, specialist medicine and rare diseases areas.
In 2013, Chiesi achieved sales of over 1.2 billion Euros, constituting double digit growth over 2012. Its R&D centers in Parma (Italy), Paris (France), Rockville (USA), Chippenham (UK) and the R&D team of the newly-acquired Danish company Zymenex, integrate their efforts to advance Chiesi's pre-clinical, clinical and registration programs. The Chiesi Group employs approximately 3900 people, 480 of which are dedicated to R&D activities.

For more information, please visit www.chiesi.com