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To: NASDAQ OMX Copenhagen A/S Hørsholm, Denmark, 21 September 2015

**Veloxis Announces Publication of Phase III-b STRATO Study of Envarsus® XR Demonstrating Reduction in Hand Tremors Compared to Twice-Daily Tacrolimus in Kidney Transplant Patients**

- *Study published in* Clinical Transplantation -

Veloxis Pharmaceuticals A/S (OMX: VELO) is announcing the publication of the Phase IIIb **S**witching S**T**udy of Kidney T**R**ansplant P**A**tients to LCP-**T**acr**O** (STRATO) in the journal *Clinical Transplantation*. The STRATO study was an open-label, multicenter study demonstrating that kidney transplant patients treated with once-daily Envarsus® XR (formerly known as LCP-Tacro) experienced a reduction in hand tremors following conversion from twice-daily tacrolimus, while maintaining comparable tacrolimus exposure. The results of this study have been presented previously at the 13th American Transplant Congress.

"Kidney transplant patients typically face many immunosuppressant medication side effects that diminish their quality of life," said Anthony Langone, M.D., associate professor and medical director of the Medical Specialties Clinic at Vanderbilt University. "The data from STRATO indicate that Envarsus XR, the Meltdose formulation of tacrolimus, may meaningfully reduce tremors without compromising drug efficacy. This should provide an additional option to potentially improve the quality of life for transplant patients."

Tremor is a common side effect of tacrolimus correlated with peak-dose drug concentration and is associated with a decrease in the quality of life (QOL). Envarsus® XR is a once-daily dose formulation of tacrolimus demonstrating flatter pharmacokinetics and greater bioavailability compared to twice-daily tacrolimus or Prograf®.

The STRATO study was a 2-sequence, open-label, prospective Phase IIIb, multi-center, clinical study. Kidney transplant patients who were stable on twice-daily tacrolimus and complained of hand tremor were switched to once-daily Envarsus® XR. Tremor was evaluated by independent, blinded neurologists applying the validated Fahn-Tolosa-Marin (FTM) tremor rating scale. In addition, tremor severity was also evaluated by an objective instrument (Tremorometer™), a quality of life questionnaire (QUEST) and a patient assessment of benefit (the Patient Global Impression of Change). Switch from twice-daily tacrolimus to Envarsus® XR resulted in improvement in FTM total score, tremor amplitude as measured by Tremorometer and quality of life [p-values < 0.05]. Both the patient- and physician-reported global assessments demonstrated significant overall improvement following the switch to Envarsus® XR ($p<0.0001$).

"The STRATO study demonstrated early evidence of the potential for reduction in tremors in transplant patients and helps to highlight the potential benefits of our novel drug delivery system and differentiates the profile of Envarsus XR compared to immediate release tacrolimus products," said William Polvino, M.D., president and chief executive officer of Veloxis. "As we prepare to launch Envarsus® XR in the U.S. in late 2015, we look forward to being able to offer a new therapeutic alternative for transplant physicians and recipients."

The article can be found at:
http://onlinelibrary.wiley.com/doi/10.1111/ctr.12581/abstract;jsessionid=439A07000AEE4CB6D3383EB341F627B9.f02t01

Veloxis Pharmaceuticals A/S
Agern Alle 24
Bygning 4, 2. sal
DK-2970 Hørsholm
CVR no. 26 52 77 67

**Envarsus® XR (tacrolimus extended-release tablets) – Important Safety Information**

**BOXED WARNING: MALIGNANCIES AND SERIOUS INFECTIONS**

**Increased risk for developing serious infections and malignancies with ENVARSUS XR or other immunosuppressants that may lead to hospitalization or deathINDICATIONS AND USAGE**

ENVARSUS XR is indicated for the prophylaxis of organ rejection in kidney transplant patients converted from tacrolimus immediate-release formulations, in combination with other immunosuppressants.

Limitation of Use: ENVARSUS XR extended-release tablets are not interchangeable or substitutable with other tacrolimus extended-release or immediate release products

**CONTRAINDICATIONS**

ENVARSUS XR is contraindicated in patients with known hypersensitivity to tacrolimus.

**WARNINGS AND PRECAUTIONS**

Immunosuppressants, including ENVARSUS XR, increase the risk of developing lymphomas and other malignancies, particularly of the skin.

Post-transplant lymphoproliferative disorder (PTLD), associated with Epstein-Barr Virus (EBV), has been reported in immunosuppressed organ transplant patients.

Immunosuppressants, including ENVARSUS XR, increase the risk of developing bacterial, viral, fungal, and protozoal infections, including opportunistic infections. These infections may lead to serious, including fatal, outcomes.

ENVARSUS XR is not interchangeable or substitutable with tacrolimus immediate-release products or other tacrolimus extended-release products.

Avoid the use of live attenuated vaccines during treatment with ENVARSUS XR. Inactivated vaccines noted to be safe for administration after transplantation may not be sufficiently immunogenic during treatment with ENVARSUS XR.

Cases of pure red cell aplasia (PRCA) have been reported in patients treated with tacrolimus.

**ADVERSE REACTIONS**

Most common adverse reactions (incidence ≥10%) reported with ENVARUS XR are: diarrhea and blood creatinine increased.

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**For full Prescribing Information, see the US Package Insert and Medication Guide at**
www.envarsusxr.com

**For more information, please contact:**
Veloxis Pharmaceuticals A/S
John Weinberg, M.D.
EVP & Chief Commercial Officer
Phone: +1 732 321 3208
Email: jdw@veloxis.com

**About Envarsus®**
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 U.S., Envarsus®, known as Envarsus® XR (tacrolimus extended-release tablets), is approved for the prophylaxis of organ rejection in kidney transplant patients converted from tacrolimus immediate-release formulations. Envarsus® XR has received orphan drug designation in the U.S. Veloxis plans to commercialize Envarsus® XR in the U.S. 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. Veloxis' unique, patented delivery technology, MeltDose®, is designed to enhance the absorption and bioavailability of select orally administered drugs. Veloxis is listed on the NASDAQ OMX Copenhagen under the trading symbol OMX: VELO.

For further information, please visit www.veloxis.com.