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Veloxis Announces U.S. FDA Approval of Envarsus® XR for Treatment of Kidney Transplant Patients

- *Envarsus® XR is Indicated for Patients Converted from Tacrolimus Immediate-release Formulations* **-**

- *Envarsus® XR is Expected to be Available for Patients and Physicians in 4Q2015*

Veloxis Pharmaceuticals A/S (OMX: VELO) today announced U.S. Food and Drug Administration (FDA) approval of Envarsus® XR (tacrolimus extended-release tablets) for the prophylaxis of rejection in kidney transplant patients who require or desire conversion from other twice-daily tacrolimus products to once-daily Envarsus® XR. Veloxis expects Envarsus® XR to be available to patients in the United States and their physicians in 4Q2015.

Envarsus® XR is an extended release formulation of tacrolimus designed for once-daily dosing, with flatter pharmacokinetics and greater bioavailability compared to twice-daily tacrolimus. The FDA marketing approval is based on the review of two Phase III trials and several Phase II trials in kidney transplant recipients. In all of the clinical trials, Envarsus® XR dosed once daily demonstrated significantly higher bioavailability and a flatter PK profile, compared to the current leading transplant drug, Prograf® (immediate release tacrolimus), dosed twice-daily.

"This is a proud moment for everyone at Veloxis and we appreciate the hard work by our study investigators and the participation of the patients in our studies", Bill Polvino, chief executive officer of Veloxis said. "We are now aggressively moving forward with completing the buildup of our commercial organization as planned, including the recruitment of our sales force who will promote Envarsus® XR to transplant physicians in the U.S. We look forward to making Envarsus XR available to patients later this year."

"We are very pleased to have a new treatment option available for kidney transplant recipients," said Anthony Langone, M.D., associate professor and medical director of the Medical Specialties Clinic at Vanderbilt University. "Patients must receive immunosuppression as lifelong therapy and Envarsus XR holds promise for kidney transplant patients and their physicians as a tacrolimus product with the convenience of once-daily dosing."

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 death

INDICATIONS 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.

Medication errors, including substitution and dispensing errors, between tacrolimus immediate-release products and tacrolimus extended-release products were reported outside the U.S. This led to serious adverse reactions, including graft rejection, or other adverse reactions due to under- or over-exposure to tacrolimus. ENVARSUS XR is not interchangeable or substitutable with tacrolimus immediate-release products or other tacrolimus extended-release products.

ENVARSUS XR caused new onset diabetes after transplant (NODAT) in kidney transplant patients, which may be reversible in some patients. African-American and Hispanic kidney transplant patients are at an increased risk.

ENVARSUS XR, like other calcineurin-inhibitors, can cause acute or chronic nephrotoxicity. Consider dosage reduction in patients with elevated serum creatinine and tacrolimus whole blood trough concentrations greater than the recommended range. The risk for nephrotoxicity may increase when ENVARSUS XR is concomitantly administered with CYP3A inhibitors (by increasing tacrolimus whole blood concentrations) or drugs associated with nephrotoxicity.

ENVARSUS XR may cause a spectrum of neurotoxicities. The most severe neurotoxicities include posterior reversible encephalopathy syndrome (PRES), delirium, seizure, and coma; others include tremors, paresthesias, headache, mental status changes, and changes in motor and sensory functions.

Mild to severe hyperkalemia, which may require treatment, has been reported with tacrolimus including ENVARSUS XR. Concomitant use of agents associated with hyperkalemia may increase the risk for hyperkalemia.

Hypertension is a common adverse reaction of ENVARSUS XR therapy and may require antihypertensive therapy.

The concomitant use of strong CYP3A inducers may increase the metabolism of tacrolimus, leading to lower whole blood trough concentrations and greater risk of rejection. In contrast, the concomitant use of strong CYP3A inhibitors may decrease the metabolism of tacrolimus, leading to higher whole blood trough concentrations and greater risk of serious adverse reactions. Therefore, adjust ENVARSUS XR dose and monitor tacrolimus whole blood trough concentrations when coadministering ENVARSUS XR with strong CYP3A inhibitors or strong CYP3A inducers.

ENVARSUS XR may prolong the QT/QTc interval and cause Torsade de Pointes. Avoid ENVARSUS XR in patients with congenital long QT syndrome. Consider obtaining electrocardiograms and monitoring electrolytes periodically during treatment in patients with congestive heart failure, bradyarrhythmias, those taking certain antiarrhythmic medications or other products that lead to QT prolongation, and those with electrolyte disturbances. When coadministering ENVARSUS XR with other substrates and/or inhibitors of CYP3A, a reduction in ENVARSUS XR dosage, monitoring of tacrolimus whole blood concentrations, and monitoring for QT prolongation is recommended.

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. If PRCA is diagnosed, consider discontinuation of ENVARSUS XR.

ADVERSE REACTIONS

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

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

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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® (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.

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