Company Announcement no. 26/2015

To: NASDAQ OMX Copenhagen A/S Hørsholm, Denmark, 7 December, 2015

Veloxis Launches Envarsus® XR for Treatment of Kidney Transplant Patients in U.S.

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

Veloxis Pharmaceuticals A/S (OMX: VELO) today announced the U.S. launch of Envarsus® XR (tacrolimus extended-release tablets) for the prophylaxis of rejection in kidney transplant patients who require or desire conversion from immediate release tacrolimus products to once-daily Envarsus® XR.

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. Envarsus® XR has Orphan Drug status in the U.S. and has been issued a unique reimbursement J-code by the Centers for Medicare and Medicaid Services (CMS) for 2016 onwards. Veloxis will be marketing and selling Envarsus XR through its own dedicated specialty sales force in the U.S.

"This is an important milestone for our company and we are excited about providing an option to kidney transplant patients who are seeking a switch from their current immunosuppressant regimen," said Bill Polvino, president and chief executive officer of Veloxis. "Our sales force is now out in the field detailing transplant physicians about the potential benefits of Envarsus XR and our patient support services, for which we strive to be best-in-class, are now active. We expect prescription growth to be gradual and steady as existing transplant recipients are converted to Envarsus XR and we look forward to communicating the progress of our launch in the coming quarters."

For more information, please contact:
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About Envarsus® XR
Envarsus® (tacrolimus prolonged-release tablets) has received marketing authorization in the EU for prophylaxis of organ rejection in kidney and liver transplant recipients and in the U.S., branded as Envarsus® XR (tacrolimus extended-release tablets) for prophylaxis of organ rejection in kidney transplant patients converted from tacrolimus immediate release formulations in combination with other immunosuppressants. Envarsus® XR has received orphan drug designation in the U.S. 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. 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.

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.

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.

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

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