Company Announcement no. 18/2015

To: NASDAQ OMX Copenhagen A/S Hørsholm, Denmark, 14 August 2015

Veloxis Pharmaceuticals Envarsus® XR Granted Orphan Drug Status by U.S. Food and Drug Administration for Kidney Transplant Rejection Prophylaxis

Veloxis Pharmaceuticals A/S (OMX: VELO), today announced that Envarsus® XR was granted Orphan Drug status by the U.S. Food and Drug Administration (FDA) for prophylaxis of organ rejection in patients who convert from immediate-release tacrolimus. Envarsus® XR received marketing authorization from the FDA on July 10, 2015.

"We view Orphan Drug status as the FDA's recognition of the differentiated profile and the unique 'switch' indication of Envarsus® XR compared to other tacrolimus products," said William Polvino, M.D., president and chief executive officer of Veloxis. "We now look forward to making Envarsus® XR available to conversion patients by the end of 2015."

Orphan drug designation is designed is to encourage the development of drugs that may provide significant benefit to patients suffering from rare diseases. The designation is granted by the FDA upon recognition that the prevalence of the U.S. target patient population is 200,000 patients or less. Orphan drug designation entitles Veloxis to a waiver of the FDA prescription drug user fees for Envarsus® XR as well as for potential tax incentives. Additionally, U.S. data exclusivity protection may be extended for up to seven years.

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

For more information, please contact:

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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.