Investor service announcement no. 4/2015

To: NASDAQ OMX Copenhagen A/S Hørsholm, Denmark, 10 September 2015

**Envarsus® XR Data to be Presented at European Society of Transplantation**

*Full Data Set of ASTCOFF Study Presented Demonstrating Differentiated Pharmacokinetics Compared to Twice-Daily Prograf® and Once-Daily Astagraf®*

Veloxis Pharmaceuticals A/S (OMX: VELO) announced that the full data set of the ASTCOFF (**A ST**eady-state Pharmacokinetic **CO**mparison Of all **Tacrolimus F**ormulations) study, demonstrating the differentiated pharmacokinetic (PK) profile of Envarsus XR compared to Twice-Daily Prograf® and Once-Daily Astagraf® will be presented at the European Society of Transplantation Conference (ESOT) in Brussels. The presentation is entitled "A steady-state pharmacokinetic comparison of all FK-506 formulations (ASTCOFF study): an open label, prospective, randomized, two arm, three period crossover study", Abst. BO416, 8:00 AM, and will be presented Wednesday, September 16th, 2015/Studio 206. The presentation is available at http://www.veloxis.com/envarsus.cfm. There are several additional presentations on Envarsus® XR at ATC, which are listed below.

- ASTCOFF is the first PK study to compare all three branded tacrolimus formulations and highlights the PK differences in transplant recipients.
- Envarsus® XR PK parameters tended to differ significantly from Astagraf® and Prograf®, while Astagraf® and Prograf tended to be similar to each other.
- Envarsus® XR could be dosed at a level approximately 30 percent below either Prograf® or Astagraf® in this study while maintaining therapeutic blood levels with lower intra-day fluctuation and a prolonged time to peak. Conversely, once-daily Astagraf® did not show any statistically significant differences when compared to twice-daily Prograf in terms of Cmax, Tmax or intra-day fluctuation of blood levels.
- As such, Envarsus is NOT interchangeable or substitutable with other tacrolimus formulations. A lower dose of Envarsus is indicated compared with other products. The study provides additional guidance to optimize Envarsus conversion for clinicians managing tacrolimus therapy in patients. Primary results of this study were announced in June, 2015.

"The results from ASTCOFF provide additional evidence of the differentiated PK profile of Envarsus XR and will provide further guidance on how best patients can be switched to Envarsus," said William Polvino, M.D., chief executive officer of Veloxis. "We look forward to providing Envarsus XR as an option to kidney transplant patients in the United States before year-end".

Envarsus is currently approved for both kidney and liver transplant patients in the EU where the product is commercialized by partner Chiesi Farmaceutici SpA.

- Presentations on Envarsus XR accepted for presentation:

  - Abst. BO211, 5:00 PM, Monday, September 14th, 2015/Studio 202.
    "PK and Pharmacogenomics of Once-daily MeltDose® Tacrolimus (Envarsus® XR) vs. Twice-daily Tacrolimus: A Randomized Cross-over Study in Stable African American Kidney Transplant Patients (ASERTAA)"
    R. D. Bloom, M.D.; D. Brennan, M.D.; P. West-Thielke, PharmD; M. C. Milone, M.D., Ph.D.; J. Trofe-Clark, PharmD

The presentation is available at http://www.veloxis.com/envarsus.cfm

- Abst. BO212, 5:00PM, Monday, September 14th, 2015/Studio 202.
  "Pooled Analysis to Examine the PK and Safety of Once-daily Extended-Release MeltDose® Tacrolimus Tablets (Envarsus®) Vs. Twice–daily Tacrolimus (Prograf®) in *De Novo* Kidney and Liver Transplantation"
  S. P. Mulgaonkar, M.D.; D. DuBay, M.D.; S. Bunnapradist, M.D.

- Abst. O194, 8:00AM, Tuesday, September 15th, 2015/Silver Hall.
  "Drug Dose, Dose Adjustments, and Renal Function Among *De Novo* Liver Transplant Recipients Randomized To Envarsus® Tablets Once-daily vs. Prograf® Capsules Twice-daily: Results From A Phase 2 Study"
  D. DuBay, M.D.; W. C. Chapman, M.D., FACS; L. W. Teperman, M.D.

**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.

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

**For Investor and media 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 tracrolimus 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.