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## **Envarsus XR® to be Subject of Upcoming Presentations at 2019 American Transplant Congress**

Veloxis Pharmaceuticals (OMX: VELO) announced today that the Company's product, Envarsus XR (tacrolimus extended-release tablets), will be the subject of two oral and fifteen poster presentations at the American Transplant Congress June 1<sup>st</sup>-5<sup>th</sup>, 2019 in Boston, Massachusetts, USA. The presentations will highlight interesting data about Envarsus XR.

"We are encouraged by the tremendous amount of interest and commitment from the kidney transplant community in studying the potential benefits Envarsus XR and what this may offer our patients" said Ulf Meier-Kriesche, MD FAST, Chief Scientific Officer at Veloxis.

"Our momentum following the launch of the de novo indication earlier this year is strong going into the American Transplant Congress, and we are excited to spend the week with the transplant community focused on how we can continue to partner with them to improve the lives of kidney transplant patients" said Craig Collard, CEO of Veloxis.

### **Oral Presentations:**

West-Thielke P, Maldonado A, Patel SJ, Stevens DR, Meier-Kriesche U, Brennan D. What's in a High Dose? An Analysis of Tacrolimus Pharmacokinetic Parameters in Rapid Metabolizers [abstract]. *Am J Transplant.* 2019; 19 (suppl 3).

Cibrik D, West-Thielke P, Patel SJ, Stevens DR, Meier-Kriesche U. LCP-Tacrolimus (LCPT; Envarsus XR) Dosing Considerations in De Novo Kidney Transplant Recipients [abstract]. *Am J Transplant.* 2019; 19 (suppl 3).

### **Poster Presentations:**

West-Thielke P, Oberholzer J, Wang Y. Microfluidic Study Analyzing the Effect of Immediate-Release and Extended-Release Tacrolimus on Islet Function [abstract]. *Am J Transplant.* 2019; 19 (suppl 3).

Budde K, Bunnapradist S, Patel S, Stevens D, Meier-Kriesche U, Suwelack B. Dosing and Exposure over 2 Years with LCP-Tacrolimus (LCPT) vs. Immediate-Release Tacrolimus (IR-Tac) in De Novo Kidney Transplantation [abstract]. *Am J Transplant.* 2019; 19 (suppl 3).

Patel S, Khalil K, Lichvar A, Benedetti E, West-Thielke P. Time within Therapeutic Range: A Comparison of Three Tacrolimus Formulations within Ninety Days of Renal Transplant [abstract]. *Am J Transplant.* 2019; 19 (suppl 3).

Wolff R, Nasstrom A, Borscheid C, Martin C, Temelie A, Spong R, Keys D, Dunn TB. The Effect of a Novel Dosing Protocol for the De Novo Use of LCP Tacrolimus in Kidney Transplant Recipients Managed on a Steroid-Free Maintenance Immunosuppression Regimen [abstract]. *Am J Transplant.* 2019; 19 (suppl 3).



Belfield KD, Malhotra D, Waleed M, Cohen EA. Conversion from Tacrolimus Immediate Release to Tacrolimus Extended Release (Envarsus XR®): A Real World Cohort Highlighting Dosing Variability among Patients [abstract]. *Am J Transplant.* 2019; 19 (suppl 3).

Budde K, Bunnapradist S, Patel SJ, Stevens DR, Meier-Kriesche U, Suwelack B. Early Tacrolimus Trough Attainment in De Novo Kidney Transplant Recipients Treated with LCP-Tacrolimus (LCPT) vs. Immediate-Release Tacrolimus (IR-Tac) [abstract]. *Am J Transplant.* 2019; 19 (suppl 3).

Lineberger LR, Hollinger E, Kenyon N, Brokohf M, Alvey N. Evaluation of Envarsus XR in African American Kidney Transplant Recipients [abstract]. *Am J Transplant.* 2019; 19 (suppl 3).

Spagnoletti G, Salerno MP, Gennaro FDe, Romagnoli J, Citterio F. Combination of Extended-Release Tacrolimus Plus Everolimus Once Daily in De Novo Kidney Transplant Recipients: ER-Tac vs LCPT [abstract]. *Am J Transplant.* 2019; 19 (suppl 3).

Carthon CE, Hagopian JC, January SE, Gharabagi A, Santos RDelos, Horwedel TA. Delayed Achievement of Therapeutic Tacrolimus Levels with De Novo Extended-Release Tacrolimus Tablets and the Incidence of Rejection in Kidney Transplant Patients [abstract]. *Am J Transplant.* 2019; 19 (suppl 3).

Horwedel TA, Carthon CE, January SE, Gharabagi A, Santos RDelos, Hagopian JC. A Naturalistic Study of De Novo Extended-Release Tacrolimus Tablets vs. Tacrolimus Immediate-Release Capsules in Kidney Transplant Recipients [abstract]. *Am J Transplant.* 2019; 19 (suppl 3).

Hagopian J, Carthon C, January S, Gharabagi A, Santos RDelos, Horwedel T. Adverse Effect Differences between Tacrolimus-IR and LCP-Tacrolimus [abstract]. *Am J Transplant.* 2019; 19 (suppl 3).

January S, Horwedel T, Hagopian J, Carthon C, Gharabagi A, Santos RDelos. Impact of Tacrolimus Formulation on Tacrolimus Level Coefficient of Variations [abstract]. *Am J Transplant.* 2019; 19 (suppl 3).

Hagopian J, Carthon C, January S, Gharabagi A, Santos RDelos, Horwedel T. Difference in DSA Formation between Tacrolimus-XR and Tacrolimus-IR [abstract]. *Am J Transplant.* 2019; 19 (suppl 3).

Condon A, Mujtaba M, Patel SJ, Stevens DR, Meier-Kriesche U. In Depth Look at Acute Rejections in LCP-Tacrolimus (LCPT; Envarsus XR) and Immediate-Release Tacrolimus (IR-Tac)-Treated De Novo Kidney Transplant Recipients [abstract]. *Am J Transplant.* 2019; 19 (suppl 3).

Torabi J, Campbell A, Akalin E, Ajaimy M, Azzi Y, Pynadath C, Liriano-Ward L, Rocca JP, Graham JA. Utilization of LCP-Tacrolimus (ENVARUS XR) in Simultaneous Pancreas and Kidney (SPK) Transplant Recipients [abstract]. *Am J Transplant.* 2019; 19 (suppl 3).

The abstracts can be found at the 2019 American Transplant Congress website: <https://atcmeetingabstracts.com/>.



**For more information, please contact:**

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**About Veloxis Pharmaceuticals**

Veloxis Pharmaceuticals A/S is a commercial-stage specialty pharmaceutical company committed to improving the lives of transplant patients. A Danish company, Veloxis Pharmaceuticals A/S operates in the U.S. through Veloxis Pharmaceuticals Inc., a wholly-owned subsidiary headquartered in Cary, North Carolina, USA. Veloxis has successfully developed Envarsus XR (tacrolimus extended-release tablets) based upon the company's unique and patented delivery technology, MeltDose®, which is designed to enhance the absorption and bioavailability of select orally administered drugs. The company is focused on the direct commercialization of Envarsus XR in the U.S., expansion of partnerships for markets around the world, and acquisition of assets utilized in transplant patients and by adjacent medical specialties. Veloxis is listed on the NASDAQ OMX Copenhagen under the trading symbol OMX: VELO. For further information, please visit [www.veloxis.com](http://www.veloxis.com).

**About ENVARSUS XR® (tacrolimus extended-release tablets)**

**Indications and Usage**

ENVARSUS XR is indicated for the prophylaxis of organ rejection in de novo kidney transplant patients in combination with other immunosuppressants.

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

**Important Safety Information for ENVARSUS XR**

**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**

**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.



ENVARUSUS XR is not interchangeable or substitutable with tacrolimus extended-release capsules, tacrolimus immediate-release capsules or tacrolimus for oral suspension.

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

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

#### **Adverse Reactions**

De Novo kidney transplant patients: Most common adverse reactions (incidence  $\geq 15\%$ ) reported with ENVARUSUS XR are diarrhea, anemia, urinary tract infection, hypertension, tremor, constipation, diabetes mellitus, peripheral edema, hyperkalemia and headache.

Conversion of kidney transplant patients from immediate-release tacrolimus: Most common adverse reactions (incidence  $\geq 10\%$ ) reported with ENVARUSUS XR are diarrhea and blood creatinine increased.

**For full Prescribing Information, see the US Package Insert and Medication Guide at [www.envarsusxr.com](http://www.envarsusxr.com).**