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Veloxis Announces the Publication of ASERTAA (A Study of Extended Release Tacrolimus in African-Americans), a Phase IIIb study of ENVARSUS XR®

Veloxis Pharmaceuticals A/S is pleased to announce the publication of Results of ASERTAA, a Randomized Prospective Crossover Pharmacogenetic Study of Immediate-Release Versus Extended-Release Tacrolimus in African American Kidney Transplant Recipients in the March 2018 issue of the *American Journal of Kidney Diseases*.

As previously reported, ASERTAA, a Phase IIIb study of ENVARSUS XR® (tacrolimus extended-release tablets) was designed to compare the pharmacokinetics (PK) of ENVARSUS XR, a once-daily tacrolimus tablet, to generic twice daily tacrolimus immediate-release capsules in stable African-American renal transplant patients. The ASERTAA trial demonstrated that patients on Envarsus achieved therapeutic drug levels with a 30% lower peak concentration and 20% lower average dose compared to tacrolimus immediate-release regardless of genotype status. Importantly, patients expressing the CYP3A5*1 genotype on tacrolimus immediate-release reached a peak concentration as high as 26 ng/mL. In June 2016, Veloxis announced that the FDA had approved label enhancements containing ethnicity-specific dosing and unique genotyping guidance for Envarsus XR based on the results of the ASERTAA study.

Veloxis Pharmaceuticals Inc. Chief Scientific Officer Ulf Meier-Kriesche, M.D. said, "This is one of the largest pharmacogenetic studies of its kind, and the data suggest that African-American patients treated with ENVARSUS XR are able to reliably achieve adequate exposure to Tacrolimus without potentially toxic peak levels. For carriers of the *CYP3A5*1* gene, achieving adequate immunosuppression with IR-Tac came at the cost of a 30% higher peak concentration. Patients on ENVARSUS XR did not experience the higher peaks, and the pharmacokinetic profile was consistent regardless of genotype. The study reinforces our belief that ENVARSUS XR is an effective therapy to optimize immunosuppression management in African-American transplant patients."

To read the results of the ASERTAA Study, please follow this link:
http://go.envarsusxr.com/ASERTAA_AJKD

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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.

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.