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Veloxis Receives Envarsus XR® Package Insert Label Enhancements Based on Study of African-American Transplant Recipients

Veloxis Pharmaceuticals A/S (OMX: VELO) today announced that once-daily Envarsus XR® (tacrolimus extended-release tablets), indicated for the prophylaxis of organ rejection in kidney transplant patients converted from tacrolimus immediate-release formulations, in combination with other immunosuppressants, received FDA approval for label enhancements. These enhancements are related to the pharmacokinetics (PK) and pharmacogenomics (PG) studied in the ASERTAA trial, one of the largest trials of tacrolimus PK in African-American kidney transplant patients ever conducted.

African-American kidney transplant patients historically experience poorer outcomes as compared to other ethnic groups and this has been associated in part due to their expression of the CYP3A5*1 genotype, which codes for a cytochrome p450 enzyme that metabolizes tacrolimus, and shown to be present in approximately 80% of African-Americans. Patients expressing this genotype metabolize tacrolimus much more rapidly and as a result typically require higher tacrolimus doses. This may hinder efforts to obtain a therapeutic level potentially increasing the risk of organ rejection.

As previously reported, 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.

Based upon these findings, the FDA-approved label now contains ethnicity-specific dosing and unique genotyping guidance to Envarsus XR as shown below:

- The PK of Envarsus XR® converted from tacrolimus immediate-release to Envarsus XR® indicated that an 80% dose conversion factor is appropriate for African-American patients;

- Regardless of genotype status, the PK data collected for Envarsus XR® demonstrated similar exposure, lower Cmax, prolonged Tmax, and increased bioavailability when compared to tacrolimus immediate-release.

The importance of these label enhancements is that the dosing recommendations and expected PK profile even for these difficult populations remain the same as with other populations.

"The most notable difference was among CYP3A5*1-expressing African American patients where tacrolimus trough levels were achieved at the cost of 30% higher peak levels with immediate-release tacrolimus than with Envarsus XR, potentially magnifying the risk for known toxicities," said Jennifer Trofe-Clark, Pharm D, Clinical Transplant Pharmacist and Adjunct Associate Professor of Medicine at University of Pennsylvania. "As we enter an era of personalized and precision medicine, the results from this ethnicity-specific study represent the first opportunity in many years to advance and optimize immunosuppression management in African-American recipients," said Roy D. Bloom, M.D., Professor of Medicine, University of Pennsylvania and Medical Director of the Penn Kidney Pancreas Transplant Program.

"We are very excited about the label enhancements and our ability to further support the unique differences of Envarsus XR and generalize our data to an exclusively African-American kidney transplant population typically underrepresented in clinical trials." said Craig Collard, chief executive officer of Veloxis.

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 offices in New Jersey and North Carolina, 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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