FDA Approves New Indication for ENVARSUS XR® (tacrolimus extended-release tablets)

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Veloxis Pharmaceuticals announced today that the U.S. Food & Drug Administration (FDA) approved a new indication for Envarsus XR (tacrolimus extended-release tablets) to prevent organ rejection in *de novo* kidney transplant patients in combination with other immunosuppressants. This indication is commonly referred to as the *de novo* indication.

Envarsus XR was approved for the prophylaxis of organ rejection in kidney transplant patients converted from tacrolimus immediate-release formulations in 2015 and has already been used in the conversion setting in more than 90% of the transplant centers in the U.S. The approval for *de novo* use provides an important new treatment option for kidney transplant patients and providers, where significant unmet need currently exists.

"Today marks the beginning of an exciting new chapter in immunosuppression. Kidney transplant patients will now be able to receive a refined and simplified gold standard treatment regimen from the beginning of the kidney transplant journey," said Ulf Meier-Kriesche, M.D. Chief Scientific Officer at Veloxis Pharmaceuticals, Inc.

The FDA's approval is based on the Phase 3 clinical development program which was a randomized, double-blind, double-dummy, Phase III study in 543 *de novo* kidney transplant patients that demonstrated comparable efficacy and safety compared to twice-daily tacrolimus (Prograf®).

The primary endpoint of the study was a composite endpoint of treatment failure (biopsy-proven acute rejection or BPAR, graft failure, loss to follow up or death) that was evaluated after a 12-month treatment period to demonstrate the non-inferiority of Envarsus® compared to Prograf®. The treatment failure rate for Envarsus® was 18.3% compared to 19.6% for Prograf®.

"There are approximately 200,000 patients living with a kidney transplant today and we have seen a significant number of them convert to Envarsus XR since our launch in December 2015. With the addition of the *de novo* indication, the roughly 16,000 adult patients who receive a kidney transplant each year will now have access to Envarsus XR following surgery. This approval is another example of Veloxis's commitment to transplant and the patients, donors and providers that make it all possible," said Craig A. Collard, Chief Executive Officer of Veloxis Pharmaceuticals A/S.

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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.

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.

ENVARSUS 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 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
De Novo kidney transplant patients: Most common adverse reactions (incidence ≥15%) reported with ENVARSUS 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 ≥10%) reported with ENVARSUS XR are diarrhea and blood creatinine increased.

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

Attachment

- 2018.12.19 Company Release 22 - FDA Approves New Indication for ENVARSUS XR® (tacrolimus extended-release tablets)