FDA Accepts Veloxis's Supplemental New Drug Application for the De Novo Indication for ENVARSUS XR®

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FDA Accepts Veloxis's Supplemental New Drug Application for the *De Novo* Indication for ENVARSUS XR®

Veloxis Pharmaceuticals A/S announced today that the U.S. Food & Drug Administration (FDA) has accepted for standard review the Company's supplemental New Drug Application (sNDA) which seeks a new indication for ENVARSUS XR (tacrolimus extended-release tablets) for the prophylaxis of organ rejection in kidney transplant patients in combination with other immunosuppressants. This indication is commonly referred to as the *de novo* indication. As previously announced, the sNDA was submitted to the FDA on March 7, 2018. FDA has set a target review date under the Prescription Drug User Fee Act (PDUFA) of January 7, 2019.

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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 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

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 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.

Attachment

- 2018.04.19 - Company Release 11 - U.S. FDA Accepts Veloxis sNDA for the De Novo Indication for ENVARSUS XR