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U.S. District Court Rules in Veloxis Litigation

U.S. District Court rules that Envarsus® XR is blocked in de novo setting
Veloxis submits labeling for use in conversion setting

Veloxis Pharmaceuticals A/S (OMX: VELO) today announced that the U.S. District Court for the District of Columbia ruled in favor of the U.S. Food and Drug Administration (FDA) in the lawsuit filed by Veloxis against FDA. The Court's ruling leaves intact FDA's October 30, 2014 tentative approval of Envarsus XR (tacrolimus extended-release tablets), which delays full approval for use in newly transplanted kidney transplant recipients ("de novo" patients). Veloxis has today submitted revised labeling to FDA with the goal of making Envarsus XR available as soon as possible for kidney transplant patients who wish to convert from twice-daily tacrolimus products to once-daily Envarsus XR. Veloxis expects its amendment to the labeling to be a Class 1 labelling change to the Envarsus XR NDA and subject to a 2-month PDUFA target timeline for FDA review. With an expected 2-month labeling review timeline, Veloxis plans to launch in the conversion segment in 4Q2015 following successful labeling review and approval by the FDA. PDUFA timelines are internal targets for the FDA and are not binding commitments. The actual review timeline may be shorter or longer than the target. Approval in the de novo setting will be delayed until expiration of the exclusivity period for Astellas' Astagraf XL® which will occur in July 2016, or Jan 2017 if pediatric exclusivity extension is awarded to Astellas.

"Today's court ruling has provided the needed clarity on the initial label indication for Envarsus XR in the U.S.," said William Polvino, M.D., president and chief executive officer of Veloxis. "With this uncertainty now removed, Veloxis looks forward to making Envarsus XR available in the appropriate patient segments in the U.S. as soon as possible. We believe that a more focused claim for treating conversion patients with Envarsus XR will be a path toward approval as soon as the fourth quarter of 2015. With launch, we will begin educating U.S. physicians on the benefits of Envarsus XR to manage their stable conversion patients."

Currently there are approximately 180,000 patients comprising the conversion population. There are approximately 17,000 new "de novo" patients transplanted each year.

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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 US, Envarsus®, known as Envarsus® XR (tacrolimus extended-release tablets), has received Tentative Approval as a once-daily tablet version of tacrolimus for prophylaxis of organ rejection in kidney transplant patients in combination with other immunosuppressants. Envarsus® XR has received orphan drug designation in the U.S. Veloxis plans to commercialize Envarsus® XR in the US through its own sales force and in the EU through its partnership with Chiesi Farmaceutici SpA.

About Veloxis Pharmaceuticals

Based in Hørsholm, Denmark, with an office in New Jersey, 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.

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