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Veloxis Files with FDA for the De Novo Indication for ENVARSUS XR®

Veloxis Pharmaceuticals A/S announced today that it has submitted a supplemental New Drug Application (sNDA) to the U.S. Food & Drug Administration (FDA) seeking 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.

Craig Collard, CEO of Veloxis Pharmaceuticals A/S said "We are excited to re-file for the *de novo* indication for ENVARSUS XR and look forward to working with FDA as it reviews our filing."

The sNDA is based on data from multinational phase 3 study LCP-Tacro 3002, which evaluated the safety and efficacy of ENVARSUS XR compared to immediate-release tacrolimus capsules for the prevention of acute allograft rejection in over 500 *de novo* adult kidney transplant recipients. The primary endpoint was the incidence of treatment failures within 12 months. Treatment failure was a composite endpoint that included death, graft failure, biopsy-proven acute rejection or lost to follow-up. Results showed treatment failure rates of 18.3% for the ENVARSUS XR group and 19.6% for the immediate-release tacrolimus capsules treatment group, demonstrating ENVARSUS XR as non-inferior to immediate-release tacrolimus capsules.

ENVARSUS XR was approved by the FDA on 10 July 2015 for the prophylaxis of organ rejection in kidney transplant patients converted from tacrolimus immediate-release formulations in combination with other immunosupressants. Veloxis's original New Drug Application (NDA) for ENVARSUS XR sought approval for the *de novo* indication and was filed on 30 December 2013. FDA tentatively approved ENVARSUS XR for the *de novo* indication on 30 October 2014; however, final approval was blocked by the exclusivity of ASTAGRAF XL® which expired on 19 July 2016.

For more information, please contact:

Craig A. Collard
President & CEO
Phone: +1 919 591 3090
Email: cac@veloxis.com

About Veloxis Pharmaceuticals

Veloxis Pharmaceuticals A/S is a biopharmaceutical company focused on improving patient lives by identifying, developing, and commercializing meaningful products in transplantation and adjacent therapies. Utilizing our proprietary drug delivery technology, MELTDOSE®, Veloxis has developed and obtained FDA and EMA approval for our product, ENVARSUS XR® (tacrolimus extended-release tablets), to aid in the prophylaxis of organ rejection in transplant recipients. Our strategy is to continue to commercialize Envarsus XR in the U.S. with a direct salesforce and to license rights to Envarsus to proven commercial partners in other territories around the world. In addition to expanding use of Envarsus, Veloxis is actively seeking business development and licensing targets within the areas of transplantation and adjacent specialties, and therapeutics for rare or severe disease for which chronic therapy is initiated in the large hospital setting. Veloxis is listed on the NASDAQ OMX Copenhagen under the trading symbol OMX: VELO. For further information, please visit www.veloxis.com.