Company Announcement no. 16/2015

To: NASDAQ OMX Copenhagen A/S Hørsholm, Denmark, June 24, 2015

Envarsus® XR Demonstrates Differentiated Pharmacokinetic Profile Compared to Twice-Daily Prograf® or Once-Daily Astagraf XL® in Stable Kidney Transplant Patients

Veloxis Pharmaceuticals A/S (OMX: VELO) today announced top-line results of the ASTCOFF study, **A** **ST**eady-state Pharmacokinetic **CO**mparison Of all **F**K-506 **F**ormulations, demonstrating that once-daily Envarsus® XR (tacrolimus extended-release tablets), an investigational new drug under FDA review for the prevention of organ rejection in adult kidney transplant patients, achieved differentiated pharmacokinetics (PK) when compared to twice-daily tacrolimus (Prograf®) or a once-daily tacrolimus product (Astagraf XL®).

ASTCOFF is the first pharmacokinetic study to compare all three of these branded formulations of tacrolimus and is a two-sequence, three-period crossover study, designed to compare the steady-state PK profiles of Envarsus XR tablets (Veloxis Pharmaceuticals Inc., New Jersey, USA), Astagraf XL (Astellas Pharma US, Inc., Northbrook, IL) capsules administered once-daily and Prograf capsules (Astellas Pharma US, Inc., Northbrook, IL) administered twice-daily in stable renal transplant patients. Patients were dosed with each drug for seven days and blood samples were obtained over 24 hours to obtain pharmacokinetic data.

This study confirmed previously published data for Envarsus and showed greater bioavailability ($p<0.0001$) and a flatter PK profile characterized by lower peak-to-trough fluctuation ($p<0.001$) and delayed time to peak concentrations of 6 hrs ($p=<0.001$) compared to both Prograf and Astagraf. At equivalent exposure, Envarsus achieves at least a 30% dose reduction requirement and a substantively lower peak blood concentration ($p=<0.005$) compared to the two comparator products.

"This novel scientifically rigorous study design implemented by Dr. Simon Tremblay and our team demonstrates that there are potentially clinically meaningful differences between tacrolimus formulations and provides results to transplant clinicians that can be directly applied to patient management." said Rita Alloway, PharmD, Research Professor of Medicine, University of Cincinnati Medical Center.

"The results from ASTCOFF provide additional evidence of the differentiated PK profile of Envarsus XR and will provide further guidance on how best patients can be switched to Envarsus," said William Polvino, M.D., chief executive officer of Veloxis. "We look forward to providing Envarsus XR as an option to transplant patients in the near future."

For Investor and media contact:

John Weinberg, M.D.
EVP & COO
Phone: +1 732 321 3208
Email: jdw@veloxis.com

Johnny Stilou
EVP & CFO
Phone: + 45 30 53 33 64
Email: jst@veloxis.com

About Envarsus® XR
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.

Veloxis Pharmaceuticals A/S
Agern Allé 24
Bygning 4, 2. Sal
DK-2970 Hørsholm
CVR no. 26 52 77 67