Company Announcement no. 12/2015

To: NASDAQ OMX Copenhagen A/S Hørsholm, Denmark, 4 May 2015

Envarsus® XR Demonstrates Improved Pharmacokinetic Profile in African-American Transplant Recipients

Data presented at the American Transplant Congress

Veloxis Pharmaceuticals A/S (OMX: VELO) today announced 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, demonstrated that a lower dose of once-daily Envarsus XR in African-American kidney transplant patients is sufficient to achieve therapeutic tacrolimus blood concentrations, compared to twice-daily immediate release tacrolimus. These data, which are from one of the largest trials of tacrolimus pharmacokinetics (PK) in African-American kidney transplant patients conducted to date, were presented at the American Transplant Congress (ATC) on May 3, 2015, in Philadelphia, in a presentation entitled "PK and Pharmacogenomics of Once-daily MeltDose® Tacrolimus (Envarsus® XR) vs. Twice-daily Tacrolimus: A Randomized Cross-over Study in Stable African-American Kidney Transplant Patients (ASERTAA)". There are several additional presentations on Envarsus XR at ATC, which are listed below.

African-Americans can be a challenging patient population for managing immune suppression, with historically poorer outcomes. Expression of the CYP3A5*1 genotype, which codes for a cytochrome p450 enzyme that metabolizes tacrolimus, was shown to be present in approximately 80% of African-Americans and that genotype commonly requires higher tacrolimus doses to obtain and maintain therapeutic levels of tacrolimus. Higher tacrolimus dosing has the potential to increase the risk of tacrolimus-associated adverse events. This study evaluated the PK profile of once-daily Envarsus® XR compared to twice-daily or immediate-release tacrolimus (IR-Tac) in this patient population.

- The overall PK differences (increased absorption [p<0.0001], lower peak blood concentrations [p<0.0001], less peak-to-trough fluctuation in blood levels [p<0.0001]) between Envarsus XR and IR-Tac capsules seen previously in studies of kidney transplant recipients were also confirmed in this exclusively African-American patient population.
- The optimal conversion ratio for once-daily extended release Envarsus XR was shown to be approximately 20% lower than the total IR-Tac.
- Peak tacrolimus concentration (Cmax) was reduced 30% for patients on Envarsus while intra-day fluctuation was reduced 50%.
- Envarsus XR's PK parameters were less impacted by CYP3A5 genotype. IR-Tac was more affected by the presence of the *1 allele, driven primarily by the need to increase dose to achieve therapeutic trough levels, which also resulted in an incremental increase in tacrolimus intra-day peak levels.
- Conversion of African-American patients from IR-Tac to Envarsus XR was demonstrated to be readily achieved with a reduction in dose of approximately 20% without concern for genotype status.

"The data seen in this study suggest that African-American patients treated with Envarsus are able to reliably achieve adequate blood levels at a lower dose than with traditional immediate-release tacrolimus and that they will not experience as high a peak blood level during the day," said Roy D. Bloom, M.D.,

Professor of Medicine, University of Pennsylvania and Medical Director of the Penn Kidney Pancreas Transplant Program. ”Envarsus may offer an important additional therapeutic option in our management of this traditionally hard-to-treat transplant population.”

”We developed Envarsus XR to be a formulation of tacrolimus that has an improved PK profile to both assist in the management of transplant patients and potentially impact their quality of life,” said William Polvino, M.D., president and chief executive officer of Veloxis. ”We are very excited with the results from this study that demonstrate that the pharmacokinetic performance differences of Envarsus XR previously seen have now been demonstrated in this focused study of African-American transplant patients.”

- Presentations on Envarsus XR accepted for presentation:
  - Abst.343, 5:30 PM, Sunday, May 3rd, 2015/Exhibit Hall E
    Comparison of Pharmacokinetics and Pharmacogenomics of Once-daily Extended-release MeltDose® Tacrolimus Tablets (Envarsus® XR) vs. Twice-daily
    Immediate-release Tacrolimus Capsules in Stable African American Kidney Transplant Patients: A Randomized Cross-over Study
    J. Trofe-Clark, PharmD; D. Brennan, MD; P. West-Thielke, Pharm; M. Milone, MD, PhD; M. Lim, MD; R. Bloom, MD

  - Abst.256, 5:30 PM, Sunday, May 3rd, 2015/Exhibit Hall E
    A Randomized Cross-over Phase IIIb Study of the Pharmacokinetics of Once-daily Extended-release MeltDose®
    Tacrolimus (Envarsus® XR) Versus Twice-daily Immediate-release Tacrolimus in African Americans (ASERTAA)
    J. Trofe-Clark, PharmD; D. Brennan, MD; P. West-Thielke, PharmD; M. Milone, MD, PhD; M. Lim, MD; R. Bloom, MD

  - Abst.405, 5:30 PM, Sunday, May 3rd, 2015/Exhibit Hall E .
    Improved Bioavailability and Reduced Dose Requirements of Novel, Once-daily, MeltDose® Tacrolimus Formulation Tablets (Envarsus® XR)
    Compared to Twice-daily Tacrolimus Capsules (Prograf®) in De Novo Kidney Transplantation: Results of a Phase 3, Double-Dummy, Randomized Trial
    J. Grinyó, MD; S. Bunnapradist, MD; S. Mulgaonkar, MD; S. Steinberg, MD

  - Abst.314, 5:30:, Sunday, May 3rd, 2015/Exhibit Hall E .
    Lipid Profiles over 2 Years Follow-up in De Novo Kidney Transplant Recipients Randomized to Once-daily MeltDose® Tacrolimus (Envarsus® XR) Vs.
    Twice-daily Tacrolimus (Prograf®): Results from a Phase 3, Double-blind, Double-dummy, Multicenter Trial
    S. Mulgaonkar, MD; O. Pankewycz, MD; S. Steinberg, MD FACP FASN

  - Abst.332, 5:30 PM, Sunday, May 3rd, 2015/Exhibit Hall E .
    Efficacy, Safety and Pharmacokinetics of Once-daily, MeltDose® Tacrolimus (Envarsus® XR) Versus Twice-daily Tacrolimus (Prograf®) in De Novo Kidney
    Transplant Recipient Sub-groups: A 2 Year Phase 3 Randomized, Double-blind, Double-dummy, Trial
    S. Bunnapradist, MD; J. Denny, MD; M. Waybill, MD; P. West-Thielke, Pharm; S. Steinberg, MD, FACP, FASN

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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.