

Company Announcement no. 16/2014

To: NASDAQ OMX Copenhagen A/S

Hørsholm, Denmark, 30 June 2014

**Envarsus® XR Demonstrates Lower Treatment Failure Rate in African-Americans Compared to Twice-Daily Tacrolimus (Prograf®)**

- *Result seen across stable and de novo kidney transplant patients* -
- *Data to be presented at the World 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 a lower treatment failure rate in African-Americans compared with twice-daily tacrolimus (Prograf®). These study data will be presented at the World Transplant Congress (WTC), July 26 to 31, in San Francisco, in a presentation entitled "Lower Treatment Failures in Blacks and Older De Novo and Stable Kidney Transplant Recipients Treated with Envarsus XR Once-Daily MeltDose Tablets vs. Twice Daily Prograf Capsules". The presentation will occur at 6:30 pm – 8:00 PM, Sunday, July 27<sup>th</sup>, 2014. There are several additional presentations on Envarsus XR at WTC in addition to the subgroup analysis on African-American patients, which are summarized below.

Key points:

- Problem: Managing immunosuppression of African-American kidney transplant recipients can be challenging, as are clinical outcomes for this demographic group
- Envarsus XR is an extended release formulation of tacrolimus being designed for once-daily dosing, flatter pharmacokinetics and greater bioavailability compared to twice-daily Prograf (tacrolimus). Data from two Phase III trials were pooled (Envarsus XR n=428; Prograf n=433) and several pre-specified subgroup analyses were conducted
- African-American subgroup demonstrated significantly less efficacy failure in favor of Envarsus XR (-13.82%, CI=-27.22%, -0.31%)
- A second subgroup, older patients greater than 65 years of age demonstrated a similar significant result. Other pre-specified subgroups trended toward improved efficacy with Envarsus XR
- Other presentations on Envarsus XR accepted for presentation:
  - Abst.2160, 11:39 AM/ Wednesday, July 30<sup>th</sup>, 2014/Room 2005/2007.  
Once-daily Envarsus Demonstrates Comparable Efficacy and Safety to Twice-Daily Prograf: A Phase 3 Study for Prevention of Acute Allograft Rejection in De Novo Adult Kidney Transplant Recipients  
L. Rostaing, K. Ciechanowski, S. Bunnapradist, H.T. Silva, J.M. Grinyo, K. Budde
  - Abst. A208, 6:30 pm – 8:00 PM/Sunday, July 27<sup>th</sup>, 2014/Exhibit Hall.  
Once-Daily MeltDose Tacrolimus (Envarsus) Offers Dosing Flexibility and Maintains Therapeutic Activity When Make-Up Dose is Taken Outside of Schedule  
S. Gabardi, R. Nachtrieb, V. Nigro
  - Abst.A212, 6:30 pm – 8:00 PM/Sunday, July 27<sup>th</sup>, 2014/Exhibit Hall.  
Higher Initial Exposure of Envarsus Immediately Post Transplantation is Not Associated with Increased Risk of Delayed Graft Function in Kidney Transplant Patients Treated with Novel Once-daily MeltDose Tacrolimus (Envarsus) Vs. Twice-Daily Tacrolimus (Prograf): Results from A Phase 3, Double-Blind, Double- Dummy, Multi-Center, Randomized Trial

K. Budde, H.T. Silva, S.M. Steinberg, N. Kamar

- Abst.A210, 6:30 pm – 8:00 PM/Sunday, July 27<sup>th</sup>, 2014/Exhibit Hall.  
Rapid Attainment of Tacrolimus Trough Levels Early Post-Transplant Reduces Risk of Treatment Failure in De Novo Kidney Transplant Patients: A Covariate Analysis of a Phase 3 Double-Blind Study  
J.M. Grinyo, L. Rostaing, K. Budde, K. Ciechanowski, S. Bunnapradist, H.T. Silva
- Abst.A207, 6:30 pm – 8:00 PM/Sunday, July 27<sup>th</sup>, 2014/Exhibit Hall.  
Higher Starting Dose and Rapid Attainment of Tacrolimus Blood Levels with Envarsus Vs. Prograf is Not Associated with Increased Toxicity: Exploratory Analysis of A Phase 3, Double-Blind, Double-Dummy, Multi-Center, Randomized, Prospective Study of Envarsus (Once-daily MeltDose Tacrolimus Tablets) Vs. Prograf (Twice-daily Tacrolimus Capsules)  
H.T. Silva, S. Bunnapradist, S.M. Steinberg
- Abst. A2978, 6:30 pm – 8:00 PM/Sunday, July 27<sup>th</sup>, 2014/Exhibit Hall.  
Two-Year Results of Envarsus (Once-daily MeltDose Tacrolimus Tablets) vs Prograf (Twice-daily Tacrolimus Capsules): A Phase 3, Double-Blind, Double-Dummy, Multi-Center, Prospective, Randomized Study  
L. Rostaing, K. Ciechanowski, S. Bunnapradist, H.T. Silva, J.M. Grinyo, K. Budde,

Quotes:

**Suphamai Bunnapradist, M.D., professor of Medicine and Director of Kidney Transplant Research at the Ronald Reagan Medical Center and David Geffen School of Medicine at UCLA, California, USA.**, said, "The African-American kidney transplant population has been a particularly challenging one to manage and unfortunately we have not been able to bring clinical outcomes to the same level as other transplant patient groups. The results of this pooled analysis suggest that a once-daily formulation of tacrolimus with improved pharmacokinetics and better bioavailability may improve clinical outcomes in these patients. This would be the first important clinical advance for African-American transplant patients in many years. Additional studies with Envarsus XR are being conducted and planned in this population group and we look forward to gaining further understanding."

**William Polvino, M.D., president and chief executive officer of Veloxis** said, "We are developing Envarsus XR to improve the care and quality of life of organ transplant patients. Results to date have shown that Envarsus XR, based on our proprietary MeltDose formulation technology, improves the pharmacokinetic profile of tacrolimus enabling once-daily dosing and more stable and steady blood levels. The results presented at the World Transplant Congress suggest that this profile may translate into differential clinical results compared to other formulations of tacrolimus. Envarsus XR is now under regulatory review in the U.S. and we look forward to bringing this potentially important new medicine to patients."

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### **About Envarsus® XR and tacrolimus**

Tacrolimus is a leading immunosuppression drug used for the prevention of transplant allograft rejection after organ transplantation. Envarsus XR (tacrolimus extended-release tablets), known as Envarsus® in the EU, is an investigational new drug that is being developed as a once daily tablet version of tacrolimus for prophylaxis of organ transplant rejection.

### **About Veloxis Pharmaceuticals**

Based in Hørsholm, Denmark, with an office in New Jersey, Veloxis Pharmaceuticals A/S, or Veloxis, is a specialty pharmaceutical company. The company's lead product candidate is Envarsus® XR for immunosuppression, specifically organ transplantation. Veloxis' unique, patented delivery technology, MeltDose®, can improve absorption and bioavailability at low scale up costs. Veloxis has a lipid lowering product, Fenoglide®, currently on the U.S. market that is commercialized through partner Salix, Inc. Veloxis is listed on the NASDAQ OMX Copenhagen under the trading symbol OMX: VELO.

For further information, please visit [www.veloxis.com](http://www.veloxis.com).