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**Veloxis Pharmaceuticals to Present Data Differentiating LCP-Tacro™ from Available Tacrolimus Formulations at the Transformational Therapies and Diagnostics in Transplantation Conference**

Veloxis will give two upcoming data presentations that further define the profile of LCP-Tacro compared to other tacrolimus formulations. The first study demonstrates the potentially flexible dosing that may improve dosing convenience for transplant patients. A second study demonstrates the enhanced bioavailability of tacrolimus driven by LCP-Tacro's proprietary formulation, compared to another once-daily tacrolimus formulation, which could enable lower doses of tacrolimus to be used to prevent organ rejection. Both studies will be presented at the American Society of Transplantation (AST) and European Society for Organ Transplantation (ESOT) Joint Meeting on Transformational Therapies and Diagnostics in Transplantation, Oct. 12 to 14, in Nice, France.

"LCP-Tacro is a proprietary formulation of Tacrolimus using our MeltDose® technology that may have the potential to improve the tolerability and convenience of long-term organ rejection prevention pharmacotherapy in organ transplant patients," said William Polvino, M.D., president and chief executive officer of Veloxis Pharmaceuticals. "The data to be presented at this conference suggest that LCP-Tacro may improve patient convenience along with requiring a lower dose."

Twice-daily tacrolimus shows faster absorption, higher peak concentrations and a greater area under the curve (AUC) with the morning dose compared to the evening dose. Nigro et al., (Abst. # 17) investigated the pharmacokinetics (PK) of morning and evening dosing of once-daily LCP-Tacro. They found that the PK profile of LCP-Tacro of morning and evening doses were not significantly different suggesting that patients could administer the drug in the morning or evening without affecting its PK profile.

LCP-Tacro has been administered at a lower dose than twice-daily tacrolimus in clinical trials to obtain equivalent blood levels but it has not yet been compared to an once-daily tacrolimus formulation available in the EU and other non-US markets. Abstract # 18 compared the PK of LCP-Tacro to the PK of once-daily Advagraf® in healthy subjects. LCP-Tacro demonstrated significantly higher systemic exposure to tacrolimus than Advagraf, suggesting that LCP-Tacro can be administered at a lower dose than an alternative once-daily tacrolimus formulation to generate equivalent blood levels.

**About LCP-Tacro™ and tacrolimus**

Tacrolimus is a leading immunosuppression drug used for the prevention of transplant allograft rejection after organ transplantation. LCP-Tacro™ is an investigational drug that it is being developed as a once-daily tablet version of tacrolimus, with improved bioavailability, consistent



pharmacokinetic performance and reduced peak-to-trough variability when compared to currently approved tacrolimus products. Transplant patients need to maintain a minimum blood level of tacrolimus for the prevention of transplant allograft rejection, but excessive levels may increase the risk of serious side effects such as nephrotoxicity, tremor, diabetes, high blood pressure, and opportunistic infections. Therefore, tacrolimus levels need to be managed carefully, and transplant patients are typically obliged to make frequent visits to the hospital for monitoring and dose adjustments after receiving a new organ.

### **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 LCP-Tacro™ 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 Santarus, 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).

### **For U.S. investor and media contacts:**

John Weinberg, M.D., Chief Commercial Officer  
Veloxis Pharmaceuticals A/S  
(732) 321-3208  
[jdw@veloxis.com](mailto:jdw@veloxis.com)