

**Final STRATO Clinical Study Data Demonstrates Potential for LCP-Tacro™ to Improve Tacrolimus-Induced Tremors**

*Data from the STRATO Study Presented at the 13<sup>th</sup> American Transplant Congress*

Veloxis Pharmaceuticals A/S (OMX: VELO) today announced that data from the STRATO study demonstrates the potential for LCP-Tacro™ to improve tacrolimus-induced tremors in stable kidney transplant patients. The study, Switching Study of Kidney Transplant Patients with Tremor to LCP-Tacro™ (STRATO) clinical trial, was presented at the 13<sup>th</sup> American Transplant Congress, Abstract #B1022, on Sunday, May 19, 2013 in Seattle.

“Kidney transplant patients experience multiple side effects from the medicines they are required to take to prevent rejection of their kidneys. An example of this are hand tremors, that are both common and often affect the patient's quality of life,” said Anthony Langone, M.D., Associate Professor at Vanderbilt University and Medical Director of Renal Transplantation, Nashville Veteran Affairs Hospital. “Newer medications that can minimize side effects without compromising therapeutic activity would be of benefit to transplant patients.”

In this open-label trial, 44 kidney transplant patients who were stable on twice-daily tacrolimus and had a complaint of hand tremor were switched to once-daily LCP-Tacro™. Tremor was evaluated by independent neurologists using a validated rating scale (the FTM scale) and by an objective measurement of tremor frequency and amplitude by Tremorometer™. In addition, the patients and the clinicians separately assessed global sense of improvement following the switch to LCP-Tacro™.

Summary of Results: FTM tremor scale

		<b>Percent improvement following switch to LCP-Tacro</b>
<b>Total score</b>		-15% (p<0.05)
<b>Components of scale</b>		
	<b>Tremor severity rating</b>	-5% (p=NS)
	<b>Motor task performance testing</b>	-9% (p<0.05)
	<b>Functional impact assessment</b>	-35% (p<0.05)

Both the patient- and physician-reported global assessments demonstrated significant overall improvements following the switch to LCP-Tacro™ (p<0.001). Most patients in the study are continuing on a long-term extension phase of the study, receiving LCP-Tacro™.

“This study showed clinically meaningful improvement for renal transplant patients experiencing tremors,” said John C. Morgan, M.D., Ph.D., Associate Professor in the Movement Disorders Program, Department of Neurology at Medical College of Georgia. “Tacrolimus-induced tremor clearly impacts quality of life and this study demonstrated that when patients were switched to LCP-Tacro™ they experienced significant improvement in their ability to perform everyday tasks and improvement in their quality of life.”



**Two other Veloxis-sponsored abstracts will be presented at the conference.**

Abstract #B1036 , Sunday, May 19, 2013

A Phase 3, Double-Blind, Multi-Center, Non-Inferiority, Randomized Study to Examine the Efficacy and Safety of LCP-Tacro™ Tablets, Once Daily, Compared to Prograf® Capsules, twice Daily, in Combination with Mycophenolate Mofetil in *De Novo* Adult Kidney Transplantation: Baseline Characteristics  
Rostaing, L., Budde, K. and Bunnapradist, S.

*This presentation described the baseline characteristics of patients enrolled and randomized into the 3002 study in de novo kidney transplant patients.*

Abstract #B1034, Sunday, May 19, 2013

Improved Bioavailability of MELTDOSE Once-Daily Formulation of Tacrolimus (LCP-Tacro™) with Controlled Agglomeration Allows for Consistent Absorption Over 24 Hrs: A Scintigraphic and Pharmacokinetic Evaluation

Nigro, V., Glicklich, A., Weinberg, J.

*This Phase 1 study demonstrated that Veloxis' MeltDose formulation technology modifies the absorption characteristics consistent with once-daily pharmacokinetic profile and enhanced bioavailability.*

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**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 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).