

Company Announcement no. 1/2014

To: NASDAQ OMX Copenhagen A/S Hørsholm, Denmark, 8 January 2014

## Veloxis Pharmaceuticals Receives Notice of Allowance from U.S. Patent Office for Diurnal-Independent Administration of Envarsus®

Veloxis Pharmaceuticals A/S (OMX: VELO), today announced that United States Patent and Trademark Office (USPTO) has issued a Notice of Allowance for U.S. Application Serial Number 13/167,420, a patent which covers the diurnal-independent administration of Envarsus®.

The subject patent covers a method of administering Envarsus®, Veloxis' once-daily formulation of tacrolimus employing the company's proprietary MeltDose® technology, once-daily in the evening (as opposed to morning dosing) to a kidney transplant patient. A Notice of Allowance is issued following USPTO's determination that a patent can be granted from an application. Traditional, orally administered tacrolimus products are generally better absorbed in the morning and less well absorbed in the evening. Envarsus has shown comparable absorption, both morning and evening.

"The patent allowance highlights the potential dosing flexibility of our once-daily formulation of tacrolimus compared to other available formulations of tacrolimus," said William Polvino, M.D., president and chief executive officer of Veloxis. "In addition, the issuing of the diurnal patent for Envarsus® will further strengthen Veloxis' intellectual property portfolio for Envarsus®."

## For more information, please contact:

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## About Envarsus<sup>®</sup> (formerly LCP-Tacro™) and tacrolimus

Tacrolimus is a leading immunosuppression drug used for the prevention of transplant allograft rejection after organ transplantation. Envarsus® 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 Envarsus® 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.