

Investor service announcement no. 4/2014

To: NASDAQ OMX Copenhagen A/S

Hørsholm, Denmark, 3 June 2014

**Veloxis Announces Senior Level Appointments in Preparation for U.S. Commercialization of Envarsus® XR (tacrolimus extended-release tablets)**

Veloxis Pharmaceuticals A/S (OMX: VELO) today announced the hiring of senior level management in preparation for potential U.S. commercialization of Envarsus® XR (tacrolimus extended-release tablets) an investigational new drug under FDA review for the prevention of organ rejection in adult kidney transplant patients.

Key points:

- 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).
- Envarsus XR is under regulatory review at U.S. FDA with a PDUFA action date of Oct. 30, 2014.
- Veloxis is planning to market the product autonomously in the U.S. due to the relatively small sales force required to adequately service the organ transplant market.
- Bob Dufour has been appointed head of sales and marketing. Mr. Dufour has worked extensively in both sales and marketing roles at Abbott, Wyeth and Auxillium. Mr. Dufour has prior transplant commercial experience having managed the marketing activities for Wyeth's Rapamune transplant franchise.
- Steve Bourke has been appointed head of market access and reimbursement. Mr. Bourke has joined from Ipsen Pharmaceuticals where he was responsible for market access and patient services. Prior to that he worked for Celgene. Steve trained as a pharmacist and has worked as both a retail pharmacist and within a specialty pharmacy organization that provided patient access to specialized products.
- Michelle Mc Guinness has been appointed global head of regulatory affairs and quality assurance. Ms. Mc Guinness joins Veloxis with over 15 years of senior regulatory and quality affairs experience from Mylan, Octagon Research Solutions (now part of Accenture), Sanofi-Aventis, and Ranbaxy.
- Vincenza Nigro continues to lead the medical affairs activities for Veloxis. Ms. Nigro has extensive transplant experience from her prior work at Roche where she supported the mycophenolate franchise. In her role with Veloxis, Vincenza is responsible for publication strategy and for support of dissemination of scientific information to transplant physicians and surgeons and for the conduct of Phase IV clinical studies.

Quote:

**William Polvino, chief executive officer of Veloxis,** said, "The relatively small and concentrated organ transplant market in the U.S. enables Veloxis to retain all of the economics of Envarsus XR with a manageable sales and marketing investment. The expanded management team and newly organized management structure is part of that process as we prepare for the potential U.S. launch of Envarsus XR if approved by FDA later this year. We have assembled a strong senior team with considerable talent and depth of experience. We look forward to potential regulatory approvals for Envarsus XR in the U.S. and E.U. We believe that Envarsus XR represents an important potential therapeutic option to transplant



recipients and we have begun assembling the talent required to support the product, the physician community, and transplant patients.”

**For Investor and media contact:**

John Weinberg, M.D.

EVP & COO

Phone: +1 732 321 3208

Email: [jdw@veloxis.com](mailto:jdw@veloxis.com)

Johnny Stilou

EVP & CFO

Phone: + 45 21 227 227

Email: [jst@veloxis.com](mailto:jst@veloxis.com)

**About Envarsus® XR 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 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 Salix, Inc.

Veloxis is listed on the NASDAQ OMX Copenhagen under the trading symbol OMX: VELO.