Company Announcement no. 1/2015

To: NASDAQ OMX Copenhagen A/S Hørsholm, Denmark, 13 January 2015

Veloxis Confirms Receipt of U.S. Food and Drug Administration Decision

Veloxis Pharmaceuticals A/S (OMX: VELO) (Veloxis) today confirmed that it has received notice from the U.S. Food and Drug Administration (FDA) stating that FDA continues to take the position that the exclusivity for Astagraf XL should require delay in the formal approval of Envarsus® XR. FDA has stated that it would be prepared to approve Envarsus XR for use only in patients converted from an immediate release formulation of tacrolimus to Envarsus XR, subject to Veloxis not seeking approval for de novo use of Envarsus until on or after July 19, 2016. Veloxis continues to disagree with FDA's unprecedented position on this matter, and looks forward to presenting the merits of its case in support of final approval of Envarsus XR.

Envarsus XR is a once-daily extended-release tablet indicated for prophylaxis of organ rejection in kidney transplant patients. Although Envarsus XR has been found to be safe and effective, the FDA determined that the period of statutory exclusivity granted to another extended-release tacrolimus product, Astagraf XL, blocks Envarsus XR from being sold in the United States until that exclusivity period expires (July 2016) as previously announced by the Company on October 31, 2014.

On December 16, 2014, Veloxis filed a legal action against FDA, seeking an order requiring the FDA to grant immediate final approval to Envarsus XR. The parties are scheduled to appear in U.S. District Court for the District of Columbia for a status conference on January 14, 2015. There can be no assurance that Veloxis will be successful in its action against the FDA.

For more information, please contact:

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About Envarsus®

Tacrolimus is a leading immunosuppression drug used for the prevention of transplant allograft rejection after organ transplantation. Envarsus® (tacrolimus prolonged-release tablets) has received marketing authorization in the EU for prophylaxis of organ rejection in kidney and liver transplant recipients. In the US, Envarsus®, known as Envarsus® XR (tacrolimus extended-release tablets), has received Tentative Approval as a once-daily tablet version of tacrolimus for prophylaxis of organ rejection in kidney transplant patients in combination with other immunosuppressants. Envarsus® XR has received orphan drug designation in the U.S. Veloxis plans to commercialize Envarsus® XR in the US through its own sales force and in the EU through its partnership with Chiesi Farmaceutici SpA.

About Veloxis Pharmaceuticals

Based in Hørsholm, Denmark, with an office in New Jersey, Veloxis Pharmaceuticals A/S, or Veloxis, is a specialty pharmaceutical company. Veloxis' unique, patented delivery technology, MeltDose®, is designed to enhance the absorption and bioavailability of select orally administered drugs. Veloxis is listed on the NASDAQ OMX Copenhagen under the trading symbol OMX: VELO.

For further information, please visit www.veloxis.com.