Company Announcement no. 28/2014

To: NASDAQ OMX Copenhagen A/S Hørsholm, Denmark, 16 December 2014

Veloxis announces that it has filed an action against the Food and Drug Administration, seeking an order requiring FDA to grant final approval to Envarsus® XR.

Veloxis Pharmaceuticals A/S (OMX: VELO) announced today that it has filed an action in federal district court for the District of Columbia against the Food and Drug Administration, seeking an order requiring FDA to grant final approval to 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, 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.

Veloxis believes that FDA's action is contrary to the requirements of the controlling statute, its regulations and longstanding agency precedent. Its lawsuit seeks a determination by the Court that Envarsus XR should be immediately approved for sale in the United States. There can be no assurance that Veloxis will be successful in its action against 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.