Company Announcement no. 23/2014

To: NASDAQ OMX Copenhagen A/S Hørsholm, Denmark, 31 October 2014

**Veloxis announces tentative approval of Envarsus® XR**
**FDA states that approval will not be final until Astagraf XL® exclusivity expires; Veloxis is appealing this decision**

Veloxis Pharmaceuticals A/S (OMX: VELO) announced today that the U.S. Food and Drug Administration has informed Veloxis of the tentative approval of Envarsus® XR. FDA stated that the final approval of Envarsus XR will be delayed until expiration of the exclusivity period for Astellas' Astagraf XL®. Veloxis understands that this expiry is anticipated to occur July 19, 2016. FDA's approval notice stated that it is "subject to change on the basis of any new information that may come to FDA's attention."
Veloxis disagrees that exclusivity for Astagraf XL, which was not identified as a listed drug or relied upon to support approval of Envarsus XR, should require delay in the formal approval of Envarsus XR. Veloxis plans to immediately appeal this decision within FDA, and will pursue all options available to it.
The tentative approval notification received from FDA included agreement with manufacturing post-marketing commitments as previously proposed by Veloxis during NDA review as well as agreement on final labeling for the product. There were no other conditions attached to the NDA approval.

**For more information, please contact:**
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**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.