Press release 15 May 2008

Sublinox registration application submitted to the FDA

The registration application for Sublinox has been submitted to the US Food and Drug Administration (FDA). Sublinox (treatment of insomnia) contains zolpidem, a well-documented active substance, which is one of the world's most used substances for this disorder. Sublinox uses a unique, patented sublingual tablet formulation for fast, effective absorption. A recent phase III study confirmed that Sublinox gave faster onset of action than other zolpidem tablet formulations.

On 14 April, Meda acquired exclusive worldwide rights to Sublinox from Orexo, a Swedish pharma company. The greatest Sublinox sales potential is in the US, where Meda has its own marketing subsidiary, Meda Pharmaceuticals Inc. Market launch can be initiated after regulatory approval by the FDA. The submission to the FDA does not trigger a milestone payment to Orexo.

For more information contact:

Anders Larnholt, VP Investor Relations phone. +46 709 458 878, or +46 8 630 19 62

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Meda AB (publ), corporate ID: 556427-2812
Pipers väg 2A, Box 906, SE-170 09 Solna, Sweden
info@meda.se, www.meda.se, Tel: +46-8-630 19 00. Fax: +46-8-630 19 50