

Press release 16th March, 2009

Orexo's Edluar (Sublinox) receives FDA approval for the treatment of insomnia

- *Meda expects to launch Edluar in the USA during 2nd half of 2009*
- *Orexo receives a milestone payment of USD 5 million from Meda*
- *Orexo's second major product approval in 12 months*

Orexo (NASDAQ-OMX:ORX) today announces that the US Food and Drug Administration (FDA) has approved Edluar (formerly Sublinox) 5 mg and 10 mg sublingual tablets for the short-term treatment of insomnia characterized by difficulties with sleep initiation. Orexo's partner Meda (NASDAQ-OMX: MEDA A) acquired the exclusive worldwide commercialization license for Edluar last year and they expect to launch the product in the US market during the 2nd half of 2009. Orexo will receive royalties on Meda's sales of Edluar.

This approval triggers a milestone payment to Orexo from Meda. The amount of the milestone is USD 5 million and is based upon the product labelling.

Commenting on the news Torbjörn Bjerke, CEO of Orexo, said *"I am delighted that the FDA has approved Edluar for the treatment of short-term insomnia. This is a great achievement by Orexo. Edluar provides a convenient sublingual administration and we believe that this offers insomnia sufferers an effective alternative. This is the second product approved in a major market within 12 months and is an excellent achievement. The milestone payment and the anticipated product launch during 2nd half of 2009 will continue Orexo's progress towards profitability."*

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Notes to Editors

About Edluar

Edluar (formerly known as Sublinox) is a fast-acting, sublingual formulation of the well-known substance zolpidem and has been approved for the temporary treatment of insomnia. It is based on Orexo's sublingual technology, involving a tablet placed under the tongue for fast and effective absorption of the active substance across the oral mucosa.

About Insomnia

Insomnia is the disturbance of a normal sleep pattern, characterized by the inability to fall asleep, or to stay asleep long enough to get a proper night's sleep. It is thought to affect 1 in 4 adults at some point during their lives. According to the U.S. Department of Health and Human Services, approximately 64 million Americans suffer from insomnia on a regular basis each year. Insomnia occurs 1.4 times more commonly in women than in men.

Insomnia can last for days, months or years and can be split into three categories:

- Transient insomnia, which lasts for 2-3 days
- Short-term insomnia, which lasts for more than a few days, but less than three weeks
- Chronic insomnia, which can be defined as insomnia most nights for three weeks or longer

About Orexo

Orexo is a pharmaceutical company focused on developing drugs for the treatment of pain and inflammation. The company has three products on the market as well as a competitive product portfolio in late stages of development. Sales and product development are mainly carried out through worldwide partnership agreements with larger pharmaceutical companies. Orexo has 128 employees, and has its head office located in Uppsala, Sweden.

Note:

This is information that Orexo AB (publ) is required to disclose pursuant to the Swedish Securities Markets Act. The information was provided for public release on March 16, 2009 at 08:30 CET.