Press release

Orexo reports regulatory approval of Edluar® in Europe

Uppsala, Sweden – June 18th, 2012 - Orexo AB ("Orexo") is pleased to report that Edluar® has received regulatory approval in Europe, according to information supplied by Meda AB ("Meda"), Orexo's global commercial partner for the product. Edluar®, a sublingual formulation of zolpidem, is indicated for treatment of insomnia characterized by difficulties with sleep initiation, and was developed by Orexo using the Company's proprietary sublingual formulation technologies

Two products based on Orexo sublingual know how now approved in EU and US
Edluar® is the second product developed by Orexo, which following Abstral®, has achieved the milestone of securing both EU and US regulatory approval. Edluar® has already been launched by Meda in the US and Canada, and will be launched in Europe during 2013, following completion of the national regulatory process in each country. Abstral, which is the leading new fast acting fentanyl product for treating episodes of break through pain in cancer patients has, since 2009, been launched successfully in many EU countries.

Edluar® and Abstral® with clear advantages from Orexo sublingual formulations
Edluar® and Abstral® are products which both utilise Orexo's proprietary sublingual formulation technologies. Since launch in Europe, Abstral® has recorded continuous strong growth in sales and increasing market share. This has been driven by patient and physician preference for Orexo's sublingual formulation which is able to provide rapid onset of effect, fast tablet disintegration, fast drug absorption and good local tolerability. Using Orexo's sublingual formulation technology Edluar®, like Abstral®, demonstrates these same product attributes.

Orexo will receive double digit royalty on Edluar® sales in Europe
Orexo received 20 MUSD upon signing of the agreement with Meda and 5 MUSD when Edluar® was approved by the FDA. The approval in Europe is not associated with any additional milestone payments, but Orexo is entitled to double digit royalties on European sales. Furthermore, Orexo will receive a similar royalty rate as Meda expands to new markets.

Anders Lundström, Chief Executive Officer, of Orexo said:
"The approval of Edluar® in Europe provides additional proof of our research and development capabilities at Orexo and underscores the strength of our proprietary sublingual technologies and know how. The approval of both Edluar® and Abstral® in the key markets of US, Canada and Europe further increases our confidence that we can repeat such success with our three proprietary projects (OX219, OX51 and OX27) which also are all based on Orexo's sublingual administration technology."

Nikolaj Sørensen, Chief Commercial Officer, of Orexo said:
"I am very pleased that our partner Meda has successfully obtained the European registration approval for Edluar®, and I am looking forward to the commercial launch in Europe 2013. I am confident the sublingual formulation is appreciated by the European patients and that there are attractive business opportunities for Edluar® in Europe."

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About Orexo
Orexo AB is an emerging specialty pharma company developing improved treatments using proprietary drug delivery technology. Orexo's expertise is within the area of reformulation technologies and especially sublingual formulations.
Orexo has a portfolio of revenue generating EU and US approved products currently marketed under licence and a pipeline of several reformulations of approved compounds for areas of unmet medical need. Orexo also has collaboration projects with several international pharma companies. Orexo AB with its headquarters in Sweden has 100 employees and is listed on NASDAQ-OMX. The largest shareholders are Danish Novo A/S and Swedish HealthCap.

About Edluar®
Edluar® is a fast-acting, sublingual formulation of the well-known substance zolpidem. Edluar® is based on Orexo's sublingual technologies, involving a tablet placed under the tongue for fast and effective absorption of the active ingredient across the oral mucosa. Edluar® is launched in the US and Canada, the global commercial rights are licensed to Meda AB.

About Abstral®
Abstral is the novel, rapidly-disintegrating, sublingual (under the tongue) formulation of fentanyl, a well-established opioid used for the management of episodes of breakthrough pain experienced by cancer patients who are already receiving opioid analgesics for chronic pain. Abstral® is launched in the EU, US and Canadian markets.

For information about Orexo please visit **www.orexo.com**

Note: This is information that Orexo AB (publ) discloses pursuant to the Financial Instruments Trading Act and/or Securities Market Act. The information was provided for public release on June 18, 2012 at 14:00 CET. This press release has been prepared in both Swedish and English. In the event of any discrepancy in the content of the two versions, the Swedish version shall take precedence.