Press release

Orexo takes large step forward on the road to improve treatment for people dependent on opioid pain killers

Uppsala, Sweden – July 2, 2012 - Orexo AB ("Orexo") has ahead of schedule completed a crucial comparative bioavailability study for its product OX219. The market in the US alone, for this type of treatment for people addicted to opioid pain killers, amounted to USD 1.3 bn in 2011. The study, which met the expectations of the key pharmacokinetic parameters, was completed on June 30 and is the final clinical study as discussed with the FDA, which means that all pivotal clinical data has now been generated. In the study, OX219 was tested against brand leader Suboxone®, where it demonstrated both comparative bioavailability for the two active ingredients, as well as positive results for product attributes which are important from the patient's perspective.

"The completion of this pivotal clinical program for OX219 ahead of schedule is a major accomplishment for Orexo," says Anders Lundström, CEO of Orexo. The study confirms the advantage of the proprietary technology fielded by Orexo, strengthening confidence that the Company will be able to bring OX219 to the market within 2013. With all pivotal clinical data in-house, meeting the expectations, we will now continue our work on how best to establish a commercial presence in the US. Opioid dependence is a major problem, afflicting two million Americans directly and costing the society billions of dollars," Lundström adds.

Like the brand leader, OX219 is a formulation of buprenorphine with naloxone added to prevent abuse. The study showed, besides comparative bioavailability, that in a direct comparison, test subjects preferred OX219 for three reasons: dissolve time and taste of the tablet and the overall mouth feel. These product attributes are particular important for therapies delivered for absorption across the mucosal lining of the mouth, and for people who have to take a daily treatment for an extended period of time.

During third quarter 2012 Orexo will meet with the FDA to discuss its planned submission of a US marketing authorization application. The program also awaits completion of product stability tests from the US manufacturing site.

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Details of the study
The study was successfully completed, showing comparable bioavailability of both buprenorphine and naloxone in OX219 to those of the existing marketed product; Suboxone. The data has met expectations and documents the required equivalence in the key critical pharmacokinetic parameters.

The study also provided further exciting insight into important product attributes of the OX219 formulation, which employs Orexo's sublingual technology. The median dissolve time of OX219 in the mouth was more than twice as fast than that of the marketed comparator tablet; the taste was rated better and the overall evaluation including mouth feel yielded a clear preference for OX219. When subjects were asked, taking all product attributes into consideration, as many as 77% (41 out of 53 subjects) preferred OX219. Orexo will continue to explore the importance of these features in future studies. From previous market research and experience, Orexo has learnt that taste, mouth feel and dissolve time are important attributes for sublingual delivery, which can be expected to influence patient compliance to treatment.

Managing fast growing opioid dependence

In the US, opioid dependence is a huge medical and socio-economic problem that can be linked to the number of prescriptions written for opioid-based pain killers intended for management of chronic pain, and which has grown very rapidly over the past decade. The 2010 National Survey on Drug Use and Health estimated that 1.9 million US citizens were addicted to opioid-based prescription pharmaceuticals.

Recently published data estimated the cost burden to American society associated with opioid abuse as very high and increasing. Based on 2007 figures, when the number of prescription drug abusers was 11% lower than the latest estimates from 2010, the authors estimated the cost at US$55 billion arising from increased healthcare expense, lost productivity and criminal justice costs.

Recent estimates suggests that 754,000 US citizens received treatment in the past year for opioid pain killer abuse, corresponding to 40% of patients with an addiction, but still leaving the majority of sufferers without any pharmacological intervention. Suboxone is currently the only available buprenorphine/naloxone combination product, and is the leading pharmacological therapy for opioid addiction in US, reporting sales of USD 1.3 billion in 2011.

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. The company 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 OX219

OX219 is a sublingual formulation of buprenorphine/naloxone using Orexo's extensive knowledge in sublingual formulations. OX219 is intended for maintenance treatment of people suffering from opioid dependence.

All pivotal clinical trial data for OX219 are now in-house and analysed. Transfer of the OX219 production process to Orexo's designated commercial scale manufacturing plant in the US is progressing well. The rate limiting step for completion of the regulatory submission is analysis and

reporting of product stability data from the US site following defined storage periods, which currently is projected for Q4-2012 and which will lead to a subsequent filing in the beginning of Q1-2013. During Q3-2012 Orexo will meet with FDA to discuss final content of its planned submission at a pre-NDA meeting.

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

Orexo is required under the Financial Instruments Trading Act to make the information in this press release public. The information was submitted for publication at 08:00 am CET on July 2, 2012.