Press release

Orexo successfully completes OX219 dose proportionality study ahead of schedule

Uppsala, Sweden – June 19th, 2012 - Orexo AB ("Orexo") today announced the successful completion of the dose proportionality study for OX219. OX219 is a sublingual formulation of buprenorphine and naloxone, which employs Orexo's proprietary technologies, and is intended for maintenance treatment of patients suffering from opioid-dependence.

OX219 dose proportionality study shows expected results ahead of schedule
The dose proportionality study was designed to document the bioavailability of buprenorphine and naloxone with increasing doses of OX219. The results of the study are in line with the projected dose proportionality and comparable to what has been observed in studies of other buprenorphine products.

OX219 project advances significantly with successful completion of dose proportionality study
Orexo is required to complete two pivotal pharmacokinetic trials on OX219– a dose-proportionality study and a comparative bioavailability trial versus Suboxone® to enable filing with the FDA. In addition to these, and before submitting an application for marketing authorization in the US, the necessary product stability data for the final tablet formulation must also be documented. Orexo has positive data three months stability data from OX219 tablets produced at Orexo's own manufacturing site in Uppsala. The OX219 programme now continues full speed with the imminent completion of the final pivotal, comparative bioavailability study, as well as generation of the necessary additional stability data for the product.

OX219 potentially the first new re-formulation product in a US$ 1.3 billion market
With completion of the OX219 dose proportionality study ahead of schedule, Orexo has taken a significant step towards being able to access the rapidly growing US$ 1.3 billion US market in treatments for opioid dependence. Opioid dependence is an expanding medical problem in the US with more than 2 million sufferers, making opioid dependency a more prevalent condition than, for example, type I diabetes. The societal burden associated with opioid dependence is correspondingly increasing and, in 2007, the cost of prescription opioid abuse, dependence and misuse in the US was estimated at US$ 55 billion[1].

Extensive market research evaluations performed by Orexo indicate that OX219 should be received as a welcome alternative to the currently established treatment options, given the product's high bio-availability, short disintegration time, small tablet size and not least it's well accepted taste profile. With these positive attributes, OX219 is anticipated to contribute to a high patient adherence to the treatment.

OX219 progress reinforces Orexo commercial strategy and value of Abstral deal
As announced on June 4th, Orexo is developing its plan for how best to establish a marketing presence in the US to support the commercialization of Abstral. With the progress of the OX219 clinical program ahead of schedule, and with the positive results reported today, it is anticipated that from early 2014 Orexo will be well positioned in the US market through full ownership of two commercial specialty pharmaceutical brands. Both of these products have been developed in-house using Orexo's proprietary sublingual (under the tongue) formulation technology.

Anders Lundström, Chief Executive, of Orexo said:
"I am very satisfied that Orexo has successfully passed this important milestone for OX219, and done so ahead of schedule. This strengthens my belief that OX219 has the potential to be the first new re-formulation product in a significant and growing US market where over two million patients qualify for treatment of opioid dependence. With a strong-cash position and full control of the US-rights to Abstral from January 1 – 2013, Orexo has established the basis for a successful US commercial presence with two brands from early 2014."

Peter Edman, Chief Scientific Officer, of Orexo said:
"I am very pleased that the dose-proportionality study has been completed in a timely fashion and, furthermore, that the results are in-line with FDA's expectation. This is a great achievement for Orexo's R&D and underscores our ability to drive focused clinical development activities with high-speed and excellent quality"

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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 is headquartered 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.

Through application of its proprietary technologies Orexo has, increased the bioavailability of the active ingredient, accelerated disintegration time, reduced tablet size and improved taste and "mouth feel". OX219 has the potential to be the 1st new entrant into a US$1.3bn market, with more than 2.3 million patients suffering from opioid dependence and where a majority of patients are not adequately treated today. OX219 is expected to be submitted to the FDA in Q1 2013.

About opioid addition in the US

1) Societal Costs of Prescription Opioid Abuse, Dependence, and Misuse in the United States. Birnbaum, H.G. (2011) *Pain Medicine* 12 (4) 657-667

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 19, 2012 at 08:30 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.