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Orexo reports positive feedback from pre-NDA meeting with FDA – clearing path for regulatory submission of OX219

A meeting with the US regulatory agency FDA held on July 17 has confirmed that the Swedish pharmaceutical company Orexo is on track with its preparation for a regulatory submission of a new drug approval (NDA) for its medicine for treatment of opioid dependency, OX219.

The meeting was a scheduled pre-NDA consultation and was undertaken to review critical regulatory issues, including adequacy of the clinical program and pre-clinical documentation, as well as the planned documentation on the product including the chemistry, manufacturing and control (CMC) plans, prior to submission of the actual documentation.

The feedback Orexo appreciated was an understanding that the two pivotal clinical studies for OX219 were adequate to support a regulatory submission and that no further clinical data were required pre-approval. The agency also concurred with pre-clinical documentation compiled by Orexo and did not request further data prior to submission of the NDA.

As previously communicated, Orexo is currently awaiting completion of certain technical stability data for OX219 during Q4-2012, related to transfer of the production process to the designated US manufacturing site. Based on the feedback received during the pre-NDA meeting, Orexo is confident that it can advance a part of this program, and now projects completion of the needed technical documentation during Q3-2012. Once these data have been achieved, an update of the projected submission date will be published.

"It is very good news for Orexo. Our meeting with FDA was constructive and we received a general confirmation of the approaches we have taken in developing OX219 for the US market," says Anders Lundström, CEO of Orexo. He adds:

"And it is also very good news for the two million people, who suffer from dependency of opioid pain killers in the US. Many are not treated today and I do think that we can offer a good alternative to the current treatment."

This supports the ambition of Orexo to be the first company to offer an alternative to the drug Suboxone ®, which reached sales of 1.3 billion USD in 2011 and has exhibited a steady growth of more than 15 per cent annually over the past years. Orexo estimates potential peak sales of 3-500 million USD annually of its new drug.

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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.
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 critical clinical trial data for OX219 are now in-house and are analysed. Transfer of the OX219 production process to Orexo's designated commercial scale manufacturing plant in the US is progressing well.

Through application of its proprietary technologies Orexo has increased the bioavailability of the active ingredient, accelerated disintegration time, reduced tablet size and improved taste resulting in a strong patient preference of OX219 in comparison with Suboxone tablet. OX219 has the potential to be the first 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. Market potential for OX219 is at peak estimated at year sales 300 – 500 MUSD.

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