



Press release

Orexo presents an update on the US opioid dependence market, and the commercial opportunities for Zubsolv™ (OX219)

Uppsala, Sweden – September 21, 2012 – The Swedish specialty pharmaceutical company Orexo presents today its view on the future market for treatment of opioid dependence in the US. Opioid dependence is a clinical condition, which increasingly is being recognized as having a major societal impact and financial cost. Recent estimates indicate that in the US the cost to society of opioid dependence reached USD 55.7 Bn.

Based on the continued growth in utilization of prescription based opioid products in US, and the associated growth in non-medical use of Rx-opioids, Orexo projects the US market for treatment of opioid dependence to continue growing and to reach USD 2 Bn in value by 2014. In addition to these main drivers, the recent years have yielded an increasing number of patients seeking treatment for their opioid dependence, and data suggest that patients also are likely to be treated over longer periods. Orexo will at the meeting also present the basis for the projected peak sales potential for Zubsolv previously stated to USD 500 mio.

Orexo today also presents its activities for how to differentiate Zubsolv™ from the single established competitor in the US market, Suboxone®, as well as the clinical programs the company has initiated to further strengthen the Zubsolv product platform over the coming years.

Based on the data achieved, Orexo plans to initiate a clinical program to document patient preference between Zubsolv and Suboxone® in patients who already are being treated with Suboxone. Additionally, Orexo is implementing a further clinical program, which is designed to document that opioid dependent patients can be treated with Zubsolv from the very first day the physician wishes to prescribe a buprenorphine based treatment. This is contrary to the current practice and labeled indication for Suboxone, in which patients have to be initiated on a different buprenorphine product prior to conversion to Suboxone.

Orexo is planning to launch Zubsolv during Q3 2013. During the first half of 2014 Orexo will be complementing the original two dose strengths with further pre-formulated dose options, thereby increasing the convenience for patients and physicians when using Zubsolv treatment. Orexo has also initiated development of a further complementary product formulation that provides a taste alternative to the current lemon/menthol flavor of Zubsolv. Based on the extensive development work completed for Zubsolv, Orexo projects that this product formulation will be ready for regulatory submission late 2013, and can be introduced into the US market during the second half of 2014.



At the meeting today, Orexo also describes the strategic commercialization options for Zubsolv and the projected sales force required to reach the high prescriber segment in the market. The value of a number of commercialization options are currently being analyzed including those of advancing into the US market in a risk-sharing partnership with a rented field force, a combination of a risk-sharing rented field force partnership with a co-promotion partner to increase the commercial foot-print, as well as the value of a strategic relationship with a large established commercial sales and marketing organization. As previously announced, Orexo plans to announce further information pertaining to its chosen commercialization strategy for Zubsolv, once this has been finalized.

The presented slides and a recording of the presentation can be found on Orexo website www.orexo.com.

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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.

For more 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 09:55 am CET on September 21, 2012.