Press release

Orexo provides update on simplified market situation for Zubsolv™ (OX219) in United States

Uppsala, Sweden – September 25, 2012 – The Swedish specialty pharmaceutical company Orexo AB today announce a major change in the competitive landscape for Zubsolv™, its treatment of opioid dependence, which has been submitted and currently is undergoing review at the FDA. Reckitt Benckiser Ltd announced this morning a voluntary discontinuation of the supply of Suboxone® tablets in United States, which currently account for approximately 35% of the US market.

The discontinued supply of the Suboxone® tablets will result in a simplified market situation, as the market will be fully converted to Suboxone® film prior to launch of Zubsolv, which is projected for Q3, 2013. According to the press release from Reckitt Benckiser Ltd, the decision was driven by data showing an increased unintentional pediatric exposure of the Suboxone® tablets, which are supplied in multi-dose bottles of 30 tablets, compared to the Suboxone® film that are individually wrapped in child resistant packages. The decision to discontinue the Suboxone tablet was taken by Reckitt Benckiser, and was not linked to any safety signal related to the two active ingredients in Suboxone® – ie buprenorphine and naloxone.

"Zubsolv™ from Orexo, will like the Suboxone® Film, be individually packaged in a child resistant blister. This technology, which Orexo has mastered for many years, is similar to how Abstral® is supplied to the US market. Neither the Suboxone® film nor Zubsolv™ will be susceptible to direct generic substitution, in the case a potential generic product is approved by the FDA and launched, since both products are protected by IP. Once withdrawal of the Suboxone® tablet has been completed, the market opportunity for generics basing their business model on substitution of AB-rated products, will be minimized", says Anders Lundström, CEO of Orexo.

"Orexo has been aware of this potential market development, and has in meetings with the FDA addressed this. The dossier which Orexo submitted to FDA on Zubsolv, earlier this month, is in concurrence with our understanding reached with the agency from the meetings in 2011 and July 2012. The news from Reckitt Benckiser is therefore not expected to have any implications on the Zubsolv™ application for a marketing authorization in US currently submitted", continues Anders Lundström, CEO of Orexo.

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About Orexo

Orexo AB is an emerging specialty pharmaceutical 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 with its headquarters in Sweden has 100 employees and is listed on NASDAQ-OMX. The largest shareholders are Novo A/S and HealthCap.

About Zubsolv™ (OX219)

Zubsolv™ is a novel sublingual formulation of buprenorphine /naloxone using Orexo's extensive knowledge in sublingual technologies. Zubsolv 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 dissolve time, reduced tablet size and improved taste resulting in a strong patient preference of Zubsolv in comparison with Suboxone® tablet. Zubsolv has the potential to be the first new entrant into a US$1.3bn market, with more than 2 million patients suffering from opioid dependence and where a majority of patients are not adequately treated today. Market potential for Zubsolv is at peak estimated at MUSD 500 in sales annually. Zubsolv application for approval was submitted to FDA in September 2012, commercial launch is expected Q3, 2013, subject to FDA approval of the application.

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 3:30pm CET on September 25, 2012.