Press release – Uppsala, Sweden – November 28, 2012

New study by Orexo emphasizes importance of Zubsolv™ product characteristics in direct comparison to Suboxone® Film

Orexo AB (Orexo) today announced the successful completion of an acceptability study comparing Zubsolv (OX219) to Suboxone Film, which is the leading product for treatment of opioid dependence. The study shows that 9 out of 10 participants would choose Zubsolv over Suboxone Film for a daily treatment.

Zubsolv is a new sublingual tablet formulation of buprenorphine and naloxone for treatment of opioid dependence. The product is based on elements of Orexo's proprietary sublingual platform technology, which comprises enhanced trans-mucosal absorption of active pharmaceutical ingredients, mucosal micro-particle adhesion, as well as taste masking, formulated in a rapidly disintegrating sublingual tablet. These features are important attributes for pharmaceuticals administered sublingually. Improvement in taste and dissolve time has previously been associated with an enhanced treatment adherence in opioid dependent patients[1].

A previous preference study, which compared Zubsolv to the Suboxone Tablet, demonstrated that 8 out of 10 participants preferred Zubsolv. The current study was undertaken to assess the acceptability of Zubsolv in comparison to the Suboxone Film. The study was a cross-over trial in which 28 participants were given either Zubsolv or Suboxone Film in random order on separate study days. Key results indicate that Zubsolv was preferred by more than 8 out of 10 of the participants on all acceptance parameters tested, i.e. overall acceptability, taste masking, after taste experience, mouth-feel, and ease of administration. The study also confirmed a fast dissolve time for Zubsolv. When asked specifically about which product the participants would choose for a daily treatment, 9 out of 10 participants reported they would select Zubsolv.

Zubsolv has been submitted and has been accepted for review by the FDA, with approval projected for July 2013 and the US launch being planned for September 2013.

"The positive results in this study are very encouraging, and confirm that Zubsolv is well positioned to take a substantial share of the growing USD 1.5 billion market for treatment of opioid dependence. I am confident that the higher acceptability of Zubsolv will translate into an improved treatment adherence, and that it will aid in attracting a higher proportion of the five million patients currently suffering from opioid dependence into treatment." said Anders Lundström, President and CEO of Orexo.

On the basis of the results from this study, a comprehensive clinical program designed to fully explore and document the therapeutic potential of Zubsolv is being initiated. The first wave of studies will cover treatment initiation, treatment adherence and patient experiences during treatment of opioid dependent people with Zubsolv, and will help further differentiate Zubsolv from its competitors.

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[1] *Reckitt Benckiser Pharmaceuticals H1, 2012 presentation. July 2012*

About the study
The study was a cross-over trial performed in healthy adult subjects under Naltrexone block, in which 28 participants were given either Zubsolv or Suboxone Film in random order on separate days. The study compared a number of important product attributes including overall product acceptability, taste, aftertaste, mouth feel and ease of drug administration. Each product attribute was scored by all study participants using a visual analog scale (VAS).

About Zubsolv™
Zubsolv is a novel sublingual formulation of buprenorphine and 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 preference of Zubsolv in comparison with Suboxone tablet. Zubsolv has the potential to be the first new entrant into a growing USD 1.5 billion market, with more than five 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 above USD 500 million in sales annually.

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 US and EU approved products currently marketed under license 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, is listed on NASDAQ-OMX. The largest shareholders are Novo A/S and HealthCap.

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