

Press release, December 14, 2010

Orexo reports phase I trial results for OX219, a novel sublingual tablet formulation for the treatment of opioid dependence

Uppsala, Sweden, December 14, 2010 - Orexo AB (STO: ORX) announces successful completion of the initial pharmacokinetic trial in the OX219 project. In the comparative bioavailability study, the OX219 buprenorphine/naloxone sublingual tablet formulation demonstrated favourable profiles compared to the comparator Suboxone®, which is the market leading product for treatment of opioid dependence. Global value of the opioid dependence market today is approximately US\$ 1.4 billion. Based on the positive results, Orexo will be meeting with the FDA during Q1-2011 to discuss the development program for OX219. Following the meeting with the FDA Orexo will make a final decision on the development of OX219.

"The successful outcome of this trial shows important progress for Orexo in building its proprietary pipeline and further confirms the quality of our drug reformulation capabilities. This is the first of many important steps towards our defined goal of becoming a leading specialty pharmaceutical company" says Dr Torbjörn Bjerke, President and Chief Executive Officer of Orexo."

OX219 is a novel sublingual tablet formulation of buprenorphine and naloxone for the treatment of opioid dependence within a framework of medical, social and psychological treatment. Buprenorphine is a long acting partial μ -opioid receptor agonist which relieves cravings for opioids of abuse. Naloxone is an opioid antagonist which is included to deter intravenous abuse. When taken sublingually as intended, naloxone is almost completely eliminated by first pass metabolism, but if injected it prevents getting a "high" and produces uncomfortable withdrawal symptoms in opioid dependent users.

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Notes to Editors

About Orexo

Orexo is a pharmaceutical company focusing on developing treatments for pain and inflammation. Orexo is developing proprietary products based on its proven reformulation technologies, targeted at the Specialty Pharmaceutical market. Orexo intends to commercialise some of these products itself in one or more major markets. Its development activity builds on Orexo's core competences in R&D, which have previously resulted in several successful products, currently out-licensed through worldwide partnership agreements to larger pharmaceutical companies.

Today, Orexo has four products on the market of which Abstral[™] is a leading product for the treatment of breakthrough pain in cancer patients in most of Europe.

Orexo also has three significant partnerships with major pharmaceutical companies for research and development programs: discovery stage collaborations with Ortho-McNeil Janssen and Janssen Pharmaceutica in respiratory inflammation and with Boehringer Ingelheim for pain, and a clinical stage development agreement with Novartis in gastrointestinal disorders.

Orexo's head office is located in Uppsala, Sweden.

More information can be found at www.orexo.com.

Note:

This is information that Orexo AB (publ.) is required to disclose pursuant to the Swedish Securities Markets Act. The information was provided for public release on December 14, 2010 at 09:00 a.m. CET.