



Press release

Orexo broadens ZUBSOLV® product range and announces newly listed granted US patent.

Uppsala, Sweden – February 17, 2015 – Orexo AB (publ) announces today that it has initiated the launch of a new higher ZUBSOLV tablet strength (8.6 mg/2.1 mg buprenorphine/naloxone CIII sublingual tablets). Furthermore, a new patent covering ZUBSOLV was issued in the U.S. The patent is listed in the Orange Book by U.S. Food and Drug Administration and expires in 2032.

In December two new dosage strengths of ZUBSOLV were approved by the U.S. Food and Drug Administration (FDA). Orexo is now prepared to begin distribution and commence the launch of the 8.6 mg dosage, after having received final clearance of the REMS material. The updated REMS material is now published at www.BTODREMS.com. The new 8.6 mg dosage complements the existing dosage range of 5.7 mg/1.4 mg and 1.4 mg/0.36 mg tablets enabling more patients to receive their optimal dose in one tablet. The new ZUBSOLV dosage strength is based on the same advanced, proprietary sublingual tablet formulation used for the already launched ZUBSOLV tablets, providing higher bioavailability, fast dissolve time, small tablet size, and menthol flavor. The new dosage is expected to be available for patients in the first half of March.

In January the United States Patent and Trademark Office issued a new patent protecting ZUBSOLV, U.S. Patent No. 8,940,330. The patent is the fourth patent listed in the Orange Book by the FDA covering ZUBSOLV and expires on September 18, 2032.

“The continued development of the ZUBSOLV product range is a core element of Orexo’s strategy. We invest significant resources in developing the product through clinical research and pharmaceutical development to the benefit of patients suffering from opioid dependence. A solid patent protection platform is essential to enable these investments. With this latest patent, we gain additional confidence and commitment to our continued efforts to improve the treatment of opioid dependence.” said Nikolaj Sørensen, CEO and President of Orexo AB.

For further information, please contact:

Nikolaj Sørensen, President and CEO

Tel: +46 (0)703-50 78 88, E-mail: ir@orexo.com

About Orexo AB

Orexo is a specialty pharma company with commercial operations in the United States and R&D in Sweden developing improved treatments using proprietary drug delivery. The company is commercializing its proprietary product, ZUBSOLV® sublingual tablets, for maintenance treatment of opioid dependence, in the United States. The ZUBSOLV sublingual tablet is a novel formulation of buprenorphine and naloxone using



Orexo's extensive knowledge in sublingual technologies. Orexo has a portfolio of two approved and revenue generating products currently marketed under license in the US, EU and Japan. Orexo AB, with its headquarters in Sweden, is listed on Nasdaq Stockholm Exchange (STO: ORX) and its American Depositary Receipts (ADRs) trade on the OTCQX marketplace in the U.S. under the symbol, "ORXOY". The largest shareholders are Novo A/S and HealthCap.

For information about Orexo and ZUBSOLV, please visit www.orexo.com and www.zubsolv.com.

Orexo AB (publ) discloses the information provided herein pursuant to the Financial Instruments Trading Act and/or the Securities Markets Act. The information was submitted for publication at 8:30am CET on February 17, 2015.