Press release

Orexo commences patent infringement litigation against Actavis

Uppsala, Sweden – June 27, 2014 – Orexo AB today announced that it has filed a patent infringement action in United States District Court for the District of Delaware, against Actavis Elizabeth LLC and its parent company Actavis, Inc. (collectively "Actavis").

The lawsuit was filed in response to an Abbreviated New Drug Application ("ANDA") filed by Actavis. In its application, Actavis seeks to market and sell generic versions of Orexo's patented ZUBSOLV® (buprenorphine and naloxone) products in the U.S. prior to the expiration of Orexo's U.S. Patents listed in the FDA's Orange Book. The listed patents in the Orange Book are U.S. patents, 8,454,996 (expiration September 2019), 8,470,361 (expiration October 2029) and 8,658,198 (expiration December 2027).

Because Orexo AB timely initiated a lawsuit against Actavis, the FDA is statutorily precluded from approving Actavis´ ANDA for 30 months, or until a district court decision finding the patents invalid or not infringed, whichever occurs earlier. The 30 month stay period began as of the date Orexo AB received the Notice Letter from Actavis that notified Orexo of the ANDA filing.

"The ZUBSOLV® products have a significant market potential and the ANDA filing of generic versions could be expected. Orexo has since the development of the ZUBSOLV® products was initiated, worked with leading internal and external experts to ensure a solid patent portfolio to protect the products. We have full confidence in our patents listed in FDAs Orange Book today and intend to defend our rights vigorously." said Nikolaj Sørensen, Orexo's president and CEO.

For further information, please contact:
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About ZUBSOLV® Sublingual Tablets
ZUBSOLV® (buprenorphine and naloxone) sublingual tablets (CIII) are indicated for the maintenance treatment of opioid dependence and should be used as part of a comprehensive treatment plan, which includes counseling and psychosocial support. Treatment should be initiated under the direction of physicians who are certified under the Drug Addiction Treatment Act of 2000, and who have been assigned a unique identification number ("X" number).
ZUBSOLV® sublingual tablets can be abused in a manner similar to other opioids, legal or illicit. Clinical monitoring appropriate to the patient's level of stability is essential. Liver function tests

should be monitored before and during treatment. Children who take ZUBSOLV® sublingual tablets can have severe, possibly fatal, respiratory depression. Emergency medical care is critical. Keep ZUBSOLV® sublingual tablets out of the sight and reach of children.
Adverse events commonly observed with the sublingual administration of buprenorphine/naloxone sublingual tablets during clinical trials and post-marketing experience are headache, nausea, vomiting, hyperhidrosis, constipation, signs and symptoms of withdrawal, insomnia, pain and peripheral edema.

Further information on ZUBSOLV® sublingual tablets can be found at **www.zubsolv.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 technology and commercial operations in the United States. 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 EU and US. Orexo AB, with its headquarters in Sweden, is listed on NASDAQ OMX Stockholm Exchange 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, please visit **www.orexo.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 08:00am CET on June 27, 2014.