



Press release

Orexo commences patent infringement litigation against Actavis concerning Abstral® in the US

Uppsala, Sweden – February 05, 2015 – Orexo AB, today announced that it has filed a patent infringement action in United States District Court for the District of New Jersey, against Actavis Laboratories FL, Inc., Andrx Corporation, Actavis, Inc. and Actavis Pharma, 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 Abstral® (fentanyl) sublingual tablets in the U.S. prior to the expiration of Orexo’s U.S. patents listed in the FDA’s Orange Book for Abstral®. The listed patents are U.S. patents 6,759,059, 6,761,910 and 7,910,132 with expiration dates in September 2019. Galena Biopharma, Inc. (“Galena”) currently markets Abstral® and is the owner of the New Drug Application in the United States.

Orexo informed about Actavis’ filing of the ANDA in a press release on January 15, 2015.

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.

“Abstral has a significant market potential in the US, and the ANDA filing of generic versions could be expected. We have full confidence in our patents listed in FDA’s Orange Book today and intend to defend our rights vigorously together with our partner Galena.” said Nikolaj Sørensen, Orexo’s President and CEO.

For further information, please contact:

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About Abstral®

Abstral is the leading fast-acting fentanyl product in EU intended for treatment of breakthrough pain in cancer patients. Abstral employs Orexo’s proprietary sublingual delivery technology (under the tongue). After the product development Abstral was out-licensed to Kyowa Hakko Kirin Co., Ltd



and the European subsidiary ProStrakan Group plc, which still holds the rights in the EU and Japan, whereas Galena Biopharma Inc holds the rights for Abstral in the US.

For information about Abstral, please visit www.abstral.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 08:00 am CET on February 5, 2015.