



Press release

## Orexo Receives Paragraph IV Notice Letter Concerning Abstral® in the US

**Uppsala, Sweden – January 15, 2015** – Orexo AB, today announced that it has, together with its partner Galena Biopharma, Inc. (“Galena”), received a “Paragraph IV” patent certification notice from Actavis Laboratories FL, Inc. (“Actavis”). The Notice Letter advice Orexo of Actavis’s filing of an Abbreviated New Drug Application (“ANDA”) with the U.S. Food and Drug Administration seeking approval of generic versions of Abstral® (fentanyl) sublingual tablets prior to the expiration of Orexo’s patents listed in the Orange Book. Galena currently markets Abstral® (fentanyl) sublingual tablets and is the owner of the New Drug Application in the United States.

“We are working closely with our partner Galena to review the details of this Notice Letter and will decide on our response within the statutory timeline of 45 days from receipt of the Notice. Together with our partner Galena we intend to vigorously enforce the intellectual property rights around Abstral,” said Nikolaj Sørensen, Orexo’s President and CEO.

### **For further information, please contact:**

Nikolaj Sørensen, President and CEO

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

Henrik Juuel, CFO and EVP

Tel: +46 (0)722-20 94 77, E-mail: [ir@orexo.com](mailto: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](http://www.orexo.com) and [www.zubsolv.com](http://www.zubsolv.com).

### **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](http://www.abstral.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 January 15, 2015.*