



Press release

Orexo announces the approval of Abstral® in Japan

Uppsala, Sweden – September 20, 2013 – Orexo AB today announced the approval of Abstral® (fentanyl) sublingual tablets in Japan, where the product has been registered and will be sold by Kyowa Hakko Kirin Co., Ltd. Based on the agreement, the approval will trigger a milestone payment to Orexo.

Kyowa Hakko Kirin and its subsidiaries have the rights for Abstral in all markets except the US, where the rights are held by Galena Biopharma, Inc. In Japan, Abstral will be distributed jointly by Kyowa Hakko Kirin and Hisamitsu Pharmaceutical Co., Inc. The two companies are well established in the field of treatment of cancer pain. Kyowa Hakko Kirin and Hisamitsu Pharmaceutical are jointly selling Fentos® Tape (fentanyl citrate transdermal absorption product) since June 2010.

“With this approval, Abstral has now successfully been developed in the three major pharmaceutical markets in the world. The approval in Japan demonstrates again the capability of our organization as well as the value recognized by the regulatory authorities from new and advanced pharmaceutical sublingual formulations that improve treatment of patients. The approval in Japan is an exciting opportunity for Abstral and for Orexo and we are convinced that Kyowa Hakko Kirin is well positioned to successfully launch Abstral in Japan.” said Nikolaj Sørensen, President and CEO of Orexo.

Abstral is the leading rapid acting fentanyl product in Europe, where it achieved full year sales of EUR 41 million (US\$54 million) in 2012. In the first half of 2013, sales exceeded EUR 24 million (US\$32 million) corresponding to 27% growth period for period.

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About Abstral®

Abstral is a rapidly-disintegrating, sublingual (under the tongue) formulation of fentanyl, a well-established opioid used for the management of episodes of breakthrough pain experienced by cancer patients who are already receiving opioid analgesics for chronic pain. Abstral is approved in the US, EU and Canadian markets.

About Orexo AB

Orexo is an emerging 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® (buprenorphine and naloxone), for maintenance treatment of opioid dependence, in the United States. Zubsolv 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 and OTC market in the US (ORXOY). The largest shareholders are Novo A/S and HealthCap.

For information about Orexo AB, please visit www.orexo.com.

About Kyowa Hakko Kirin

Kyowa Hakko Kirin is a leading biopharmaceutical company in Japan focusing on its core business area of oncology, nephrology and immunology/allergy. Kyowa Hakko Kirin leverages antibody-related leading-edge technologies to discover and develop innovative new drugs aiming to become a global specialty pharmaceutical company which contributes to the health and well-being of people around the world.

For more information, visit www.kyowa-kirin.com.

Orexo is required under the Financial Instruments Trading Act to make the information in this press release public. The information was submitted for publication at 09:15 am CET on September 20, 2013.