Press release

Favorable outcome from Zubsolv® patent infringement litigation against Actavis

Uppsala, Sweden, November 16, 2016 - Orexo AB (publ.) announces that the United States District Court for the District of Delaware ruled in Orexo's favor in one of the patent infringement litigations against Actavis Elizabeth LLC ("Actavis") regarding Zubsolv in the US. The other litigations regarding infringement by Actavis on Orexo's IP for Zubsolv continues.

Orexo commenced this patent infringement litigation in June 2014 in response to Actavis's Abbreviated New Drug Application ("ANDA") seeking approval to market and sell generic versions of Orexo's patented Zubsolv 1.4/0.36 mg and 5.7/1.4 mg buprenorphine/naloxone products. The Orexo patents in the litigation were US Patent No. 8,454,996 (expiring in September 2019) and US Patent No. 8,940,330 (expiring in September 2032).

The Court held that Orexo's '996 US patent is valid and infringed by Actavis's generic Zubsolv 1.4/0.36 mg and 5.7/1.4 mg buprenorphine/naloxone products. The Court also held that Orexo's '330 US patent is invalid. The decision prevents Actavis from commercializing their products in the US before September 24, 2019. However, and importantly, Actavis generic Zubsolv entry on the US market can be postponed until late 2032 if the decision regarding validity of the '330 patent is reversed on appeal, or if a favorable decision is reached in the separate litigation involving Orexo's US Patent No. 9,259,421. Also, another Zubsolv patent, US Patent No. 9,439,900, expiring in September 2032, was recently issued.

Orexo has throughout the patent litigation process maintained a strong confidence in the strength of our intellectual property. This first decision by the court enables Orexo to continue to execute on our strategy for Zubsolv, and making this product the preferred treatment for more patients. Orexo will continue to vigorously defend Zubsolv in the other on-going litigation processes against Actavis and will consider whether to appeal the portion of the decision relating to the validity of the '330 patent.

"With the validation and proven infringement of the '996 patent we will be able to continue our current strategy and leverage the opportunities arising from patients gaining expanded access to treatment in the US until at least late 2019. While I am disappointed with portions of the court's decision not to confirm the validity of the '330 patent, I maintain confidence in the strength of our new '421 and '900 patents and we are reviewing the possibilities to reverse the '330 decision through appeal with our lawyers. A positive outcome in the litigation of the new patents will sustain the exclusivity of Zubsolv until 2032." says Nikolaj Sørensen, CEO and President of Orexo AB.

Teleconference
CEO and President Nikolaj Sørensen and EVP and CFO Henrik Juuel will hold a teleconference today, November 16, 2016, at 3.30pm CET.
All questions related to the teleconference had to be sent in advance to **ir@orexo.com** at latest 2.30pm CET.
To attend to the conference please just dial:
(SE) +46 8 5059 63 06, (UK) +44 20 31 394 830 or (US) +1 866 928 7517.

For more information please contact:

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About Orexo
Orexo is a specialty pharmaceutical company commercializing its proprietary product Zubsolv® for treatment of opioid dependence in the US. Zubsolv is an advanced formulation of buprenorphine and naloxone using Orexo's unique knowledge and expertise in sublingual drug delivery. R&D is focusing on reformulation of known substances to new improved products that meet great unmet medical needs by using its patented proprietary technologies. Orexo's share is listed on Nasdaq Stockholm Exchange Mid Cap (STO:ORX) and is available as ADRs on OTCQX (ORXOY) in the US. Orexo's global headquarters and R&D are based in Uppsala, Sweden.

For more information about Orexo, please visit **www.orexo.com** or follow us on **Twitter** or **LinkedIn**. For further information about Zubsolv in the US, please visit **www.zubsolv.com**.