

Press release

New regulations will expand access to treatment of opioid dependence in the US

Uppsala, Sweden – September 18, 2015 – Orexo AB (publ) informs, that yesterday the United States Department of Health and Human Services (HHS) Secretary Sylvia M. Burwell announced important steps to increase access to the treatment of opioid dependence in the US.

According to HHS, overdoses from prescription opioid pain relievers claimed more than 16,200 lives in 2013. "The opioid epidemic knows no boundaries; it touches lives in cities, rural counties and suburban neighborhoods across the country," said Secretary Burwell. The resulting health, social, and economic consequences for communities across the country are enormous.

This announcement to increase access to Medication Assisted Treatment (MAT) builds on previous efforts by HHS and the US Congress to expand patient treatment options and develop an evidence-based initiative focused on three promising areas: informing opioid prescribing practices, increasing the use of naloxone, and increasing access to MAT.

A key action mentioned by HHS includes revising the regulations related to buprenorphine to safely and effectively increase patient access. "This cap on prescribing limits the ability of some physicians to prescribe to patients with opioid use disorder. The HHS revision to the regulation will be developed to provide a balance between expanding the supply of this important treatment, encouraging use of evidence-based MAT, and minimizing the risk of drug diversion." (HHS press release September 17, 2015, link www.hhs.gov/news/press/2015pres/09/20150917a.html.)

Orexo will continue monitoring the progress of these initiatives and identify areas where Orexo can provide support for improving patient access to treatment of opioid dependence in the US and across the world.

"Orexo is encouraged by the initiatives announced by HHS and their continued commitment to addressing the opioid epidemic. On a daily basis, through our interactions with physicians, we learn of their frustrations regarding the inability to treat more patients suffering from opioid dependence. We recognize this revision to the current regulations as another positive step forward that expands patient access to treatment and MAT," said Nikolaj Sørensen, CEO and President of Orexo AB.



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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. www.orexo.com

For information about ZUBSOLV and opioid dependence, please visit www.zubsolv.com and www.outthemonster.com.