



Press release

Orexo signs license and supply agreement with Mundipharma for Zubsolv® in Australia and New Zealand

Uppsala, Sweden – July 10, 2019: Orexo AB (publ.), the fully integrated specialty pharmaceutical company addressing opioid addiction and pain, today announces the company has signed an agreement granting Mundipharma Pty Limited (Mundipharma Australia) the exclusive rights to commercialize Orexo's lead product, Zubsolv®, for the treatment of opioid dependence, in Australia and New Zealand.

As Mundipharma Australia has supported Orexo to obtain marketing authorization for Zubsolv in Australia it has been a natural step to continue the collaboration. Under the terms of the agreement, Orexo will be responsible for product supply and Mundipharma Australia will take responsibility for commercialization of Zubsolv in Australia and New Zealand. Orexo will receive royalties on future net sales and the launch is expected to take place in the first half of 2020.

In Australia, an estimated 735,000 people used opioids for non-medical purposes in 2016-2017,¹ and more than 50,000 people received pharmacotherapy treatment for opioid dependence in 2018.² There were about 17,000 hospitalizations with a diagnosis of opioid dependence in 2016-2017,³ and 1,045 opioid-induced deaths among Australians aged 15-64 years in 2016.⁴

Zubsolv is used for the treatment of opioid dependence as part of a comprehensive treatment plan including counselling and psychosocial support. It is commercialized by Orexo in the US, the largest market for buprenorphine/naloxone products. Zubsolv is also approved in Europe where partnering discussions are on-going.

“We have worked closely with Mundipharma in Australia for the last year to prepare for the launch of Zubsolv in Australia, and I am pleased we have reached an agreement to continue this partnership. In recent months, we have also been working intensively to establish a streamlined supply chain for Zubsolv outside the US to enable access to this new efficient treatment option. Mundipharma Australia has been a good partner in the approval process and we are confident that

¹ Opioid harm in Australia and comparisons between Australia and Canada. Australian Government, Australian Institute of Health and Welfare. <https://www.aihw.gov.au/getmedia/605a6cf8-6e53-488e-ac6e-925e9086df33/aihw-hse-210.pdf.aspx?inline=true>

² National Opioid Pharmacotherapy Statistics Annual Data collection (NOPSAD) 2018, AIHW. <https://www.aihw.gov.au/reports/alcohol-other-drug-treatment-services/nopsad-2018/contents/introduction>

³ Opioid harm in Australia and comparisons between Australia and Canada. Australian Government, Australian Institute of Health and Welfare. <https://www.aihw.gov.au/getmedia/605a6cf8-6e53-488e-ac6e-925e9086df33/aihw-hse-210.pdf.aspx?inline=true>

⁴ Opioid-, amphetamine-, and cocaine-induced deaths in Australia: August 2018. National Drug and Alcohol Research Centre. https://ndarc.med.unsw.edu.au/sites/default/files/newsevents/events/Drug%20Induced%20Deaths_August%202018_Drug%20Trends%20Bulletin.pdf.



their experience and infrastructure will create a strong foundation for the successful launch of Zubsolv®, providing important treatment options for patients where they are needed most,” said Nikolaj Sørensen, President and CEO of Orexo AB.

“Mundipharma has worked closely with clinicians across Australia for more than 20 years and these connections have helped highlight the growing need for treatments that help reduce harms associated with opioid misuse and abuse,” said Jane Orr, Managing Director of Mundipharma Australia and New Zealand. “Earlier this year we began providing the potentially life-saving opioid overdose reversal nasal spray, Nyxoid®, so I’m proud that we can also now help Australians access this important treatment for opioid dependence,” continued Jane Orr.

For further information, please contact

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About Orexo

Orexo develops improved pharmaceuticals based on innovative drug delivery technologies. The focus is primarily on opioid addiction and pain but the aim is to address therapeutic areas where our competence and technologies can create value. The products are commercialized by Orexo in the US or via partners worldwide. The main market today is the American market for buprenorphine/naloxone products, where Orexo sells the product Zubsolv®. Total net sales for 2018 amounted to SEK 783.1 million and the number of employees was 129. Orexo is listed on the Nasdaq Stockholm Mid Cap (ORX) and is available as ADRs on OTCQX (ORXOY) in the US. The head office, where research and development is also performed, is situated in Uppsala, Sweden.

For more information about Orexo please visit, www.orexo.com. You can also follow Orexo on Twitter, @orexoabpubl, LinkedIn and YouTube.

About Mundipharma Pty Limited

Mundipharma Australia is a member of a global network of independent associated companies which are engaged in research, development, production and marketing of prescription medicines and consumer healthcare products. Established as a leader in the development and provision of medicines for pain, we have expanded our portfolio to include treatments for cancer, glaucoma, asthma, burns, wounds, skin irritations and the common cold.

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