



Press release

Orexo receives paragraph IV Notice Letter for ZUBSOLV® in the US

Uppsala, Sweden – August 10, 2020 – Orexo AB (publ.), (STO:ORX) (OTCQX:ORXOY), today announces it has received a “paragraph IV” patent certification notice from Sun Pharmaceutical Industries Limited (“Sun”). The Notice Letter advises Orexo of Sun’s filing of an Abbreviated New Drug Application (“ANDA”) with the US Food and Drug Administration (FDA) seeking approval of generic versions of ZUBSOLV® before the expiration of Orexo’s patents listed in the Orange Book. Orexo currently has five patents listed in the Orange Book (US Patent Nos. 8,470,361; 8,658,198; 8,940,330; 9,259,421 and 9,439,900) with expiration dates ranging from December 2027 to September 2032.

Nikolaj Sørensen, Orexo’s president and CEO, said: *“We are working closely with our external lawyers 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. We intend to vigorously enforce our intellectual property rights around ZUBSOLV®. While every case is unique, we will benefit from the work and efforts from previous cases. ZUBSOLV® is important to Orexo, and we are confident our new digital therapies and pharmaceutical pipeline, including four US product launches in the coming two years, represent a significant value opportunity and will not be impacted by this and our other legal process.”*

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About Orexo

Develops improved pharmaceuticals and digital therapies addressing unmet needs within the growing space of substance use disorders and mental health. 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 commercialize its lead product ZUBSOLV® for treatment of opioid use disorder. Total net sales for 2019 amounted to SEK 844,8 million and the number of employees was 127. 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.



This information is information that Orexo AB (publ.) is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact persons set out above, at 8.00 am CET on August 10, 2020.