



Press release

Orexo commences patent infringement litigation against Sun Pharmaceutical

Uppsala, Sweden – September 14, 2020 – Orexo AB (publ.), **(STO:ORX) (OTCQX:ORXOY)** today announces it has filed a patent infringement action in the United States District Court for the District of New Jersey, against Sun Pharmaceutical Industries Limited, Sun Pharma Global FZE, Sun Pharma Global, Inc., and Sun Pharmaceutical Industries, Inc. (collectively “Sun”).

The lawsuit was filed in response to an Abbreviated New Drug Application (“ANDA”) filed by Sun with the US Food and Drug Administration (“FDA”). In its ANDA, Sun seeks to market and sell generic versions of Orexo’s ZUBSOLV® products, (buprenorphine and naloxone) sublingual tablets (CIII), in the US prior to expiration of the patents listed in FDA’s Orange Book. In the lawsuit, Orexo asserts US Patent Nos. 8,470,361; 8,658,198; 8,940,330; 9,259,421 and 9,439,900 against Sun. The patents have expiration dates ranging from December 2027 to September 2032.

Since Orexo timely filed a lawsuit against Sun, FDA is statutorily precluded from approving Sun’s ANDA for 30 months, or until a district court decision finds the patents to be invalid or not infringed, whichever occurs first. The 30-month stay period began as of the date Orexo received the notice letter from Sun advising Orexo of their ANDA filing.

Nikolaj Sørensen, Orexo’s president and CEO, said: *“Today Orexo is much more well prepared to defend the exclusivity of ZUBSOLV® than when we started our previous patent litigation. We successfully defended the exclusivity for ZUBSOLV® in the past and we are well prepared to do so again by enforcing our patent rights against Sun.”*

Orexo expects increased legal expenses related to the litigation process, with the majority of the expenses expected in 2021 and 2022. The expenses in 2020 are expected to be non-material and any changes to OPEX guidance will be shared in quarterly reports.

For more information, please contact:

Orexo AB (publ.)

Nikolaj Sørensen, President and CEO

Tel: +46 18 780 88 00

E-mail: ir@orexo.com

Lena Wange, IR and Communications Director

Tel: +46 (0)18 780 88 00

E-mail: ir@orexo.com

About ZUBSOLV®

ZUBSOLV® (buprenorphine and naloxone) sublingual tablet (CIII) is indicated for the maintenance treatment of opioid use disorder and should be used as part of a comprehensive treatment plan, which includes counseling and psychosocial support. Treatment should be



initiated under the direction of physicians who are certified under the Drug Addiction Treatment Act of 2000, and who have been assigned a unique identification number ("X" number).

ZUBSOLV® sublingual tablets can be abused in a manner similar to other opioids, legal or illicit. Clinical monitoring appropriate to the patient's level of stability is essential. Liver function tests should be monitored before and during treatment. Children who take ZUBSOLV® sublingual tablets can have severe, possibly fatal, respiratory depression. Emergency medical care is critical. Keep ZUBSOLV® sublingual tablets out of the sight and reach of children.

Adverse events commonly observed with the sublingual administration of buprenorphine/naloxone sublingual tablets during clinical trials and post-marketing experience are headache, nausea, vomiting, hyperhidrosis, constipation, signs and symptoms of withdrawal, insomnia, pain and peripheral edema.

Further information on ZUBSOLV® can be found at www.ZUBSOLV.com

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.

The information was submitted for publication at 8:00 am CET, on September 14, 2020.