Press release

Orexo announces first patient enrolled in pivotal study evaluating the efficacy of modia™ in combination with sublingual buprenorphine/ naloxone for the treatment of OUD

- **The digital therapeutic can be a valuable addition to clinician supervised medication-assisted treatment programs for individuals with opioid use disorder (OUD)**
- **The study is designed to enroll an estimated 400 participants at 35 sites across the US**
- **Orexo brings deep category expertise to the research effort, having served the US OUD market extensively over the last eight years**

Uppsala, Sweden – July 1, 2021 – Orexo AB (publ.), **(STO:ORX) (OTCQX:ORXOY**), today announces the enrollment of the first participant in the pivotal study of digital therapeutic modia™, in combination with sublingual buprenorphine/naloxone, as part of a clinician-supervised medication-assisted treatment program for the treatment of opioid use disorder (OUD).

The randomized, open-label, parallel-group study will evaluate whether the use of modia™ in combination with sublingual buprenorphine/naloxone background therapy is superior to sublingual buprenorphine/naloxone alone to reduce illicit opioid use. The study is designed to enroll an estimated 400 participants at 35 sites across the US who are voluntarily seeking treatment for documented moderate to severe OUD.

Orexo brings deep category expertise to the research effort, having served the US OUD market extensively over the last eight years through its efforts with ZUBSOLV® (buprenorphine and naloxone) sublingual tablets, among other things.

“When it comes to treating OUD, research has proven time and time again that we need to take a whole-person approach by addressing both the physical withdrawal symptoms and the mental health issues associated with addiction,” **said Nikolaj Sørensen, President and CEO, Orexo**. “Yet, all too often, the resources needed to effectively do so just aren’t available. The enrollment of our first patient in the pivotal study of modia™ is a significant milestone toward closing that treatment gap and allowing more people easy access to a tool designed to support them in the battle against addiction.”

The opioid epidemic has continued to grow during the COVID-19 pandemic, with the number of fatal opioid overdoses reaching more than 67,500, an increase of 36 percent, from December 1,

2019, to November 30, 2020.[1] Improving access to new, innovative treatments like modia™ may help reverse the epidemic's continued development.

"A great deal of work went into designing and building modia™ to deliver a unique digital therapeutic for patients struggling with OUD," **said Mike Sumner, Chief Medical Officer, Orexo**. "We fully anticipate that the outcomes of the study will prove that modia™ can be a valuable addition to existing treatment plans for patients with OUD when paired with medications like buprenorphine/naloxone."

modia™ has been co-developed with GAIA, a leading global DTx company based in Hamburg, Germany, which has over two decades of industry leading DTx evidence development across multiple therapeutic categories. In addition to GAIA's significant research experience and Orexo's expertise in OUD, patients with OUD were also included in the development and initial product testing of modia™, offering a highly unique patient perspective that drives the therapeutic experience.

For more information about the study, please visit www.clinicaltrials.gov.

For further information, please contact:

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About modia™
modia® is intended to provide digital cognitive behavioral therapy for patients with opioid use disorder (OUD), 18 years of age or older, as part of a clinician supervised medication-assisted treatment program for opioid use disorder (OUD). In addition, modia™ helps users develop a customized relapse prevention plan based on the responses collected from the exercises throughout the program.

About the Pivotal modia™ Study
The pivotal, randomized, open-label, parallel-group study will evaluate whether the use of modia™ in combination with sublingual buprenorphine/naloxone background therapy is superior to sublingual buprenorphine/naloxone alone to reduce opioid use. The study is designed to enroll an estimated 400 participants aged 18 to 65 across the US who are voluntarily seeking treatment for documented moderate to severe OUD. Participants will be evaluated over the course of 24 weeks, including a screening period where they will be stabilized on buprenorphine/naloxone, with a

[1] Centers for Disease Control and Prevention. (2021, June 16). *Products - Vital Statistics Rapid Release - Provisional Drug Overdose Data*. Centers for Disease Control and Prevention. https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm#dashboard.

primary endpoint defined as the subject having ≥80 percent of urine drug tests negative for opioids and negative self-reports for illicit opioid use during the study period.

About Orexo

Orexo develops improved pharmaceuticals and digital therapies addressing unmet needs within the growing space of substance use disorders and mental illness. The products are commercialized by Orexo in the US or via partners worldwide. The main market today is the US market for buprenorphine/naloxone products, where Orexo commercializes its lead product, ZUBSOLV®, for treatment of opioid use disorder. Total net sales for Orexo in 2020 amounted to SEK 664 million and the number of employees was 138. Orexo is listed on the Nasdaq Stockholm Mid Cap (ORX) and is available as ADRs on OTCQX (ORXOY) in the US. The company is headquartered in Uppsala, Sweden, where research and development activities are performed.

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 a.m. CET, on July 1, 2021.