



Press release

MODIA™ paper published in the Journal of Medical Internet Research Mental Health

Uppsala, Sweden – October 18, 2021 – Orexo AB (publ.), (STO:ORX) (OTCQX:ORXOY) today announced the publication of a manuscript, “A Personalized, Interactive, Cognitive-Behavioral Therapy-Based Digital Therapeutic (MODIA™) for Adjunctive Treatment of Opioid Use Disorder: Development Study,” in the Journal of Medical Internet Research (JMIR) Mental Health. The paper outlines the development and features of the company’s new digital therapeutic, MODIA™. (Link to the article: <https://mental.jmir.org/2021/10/e31173>).

MODIA™ was developed by Orexo in collaboration with GAIA AG, and, in July, Orexo was pleased to announce the enrollment of the first participant in a clinical evaluation of MODIA™ for the treatment of opioid use disorder (OUD) as part of a clinician-supervised medication assisted treatment (MAT) program. Over the next year, MODIA™ will be assessed relative to the current MAT approach as well as gauging its ability to provide sustainable positive outcomes for OUD patients.

“For more than a decade, our main focus has been on improving the lives of patients suffering from opioid addiction, an experience which has given us important and unique insights that have been instrumental in the development of MODIA™,” **said Mike Sumner, Chief Medical Officer, Orexo.** “We know that the ability to combine medication with psychosocial support improves the lives of those struggling with opioid dependence. This paper outlines our innovative new tool that is designed to help advance that treatment and make it more accessible, independent of time or geographical location.”

OUD patients face a multitude of barriers to receiving treatment, including geographic location, a shortage of qualified health providers, and the heavy weight of stigma, all of which impede access to adequate counseling and the psychosocial support necessary for long-term recovery. MODIA™ is a cognitive behavioral therapy (CBT) based digital therapy that was developed to provide adjunct counseling support. MODIA™ uses an artificial intelligence approach providing tailored content, messaging, and tone to meet the patient’s unique needs and circumstances. The patient only requires basic computer skills and internet access.

Nikolaj Sørensen, President and CEO of Orexo AB, said: “I am delighted that well-renowned JMIR has published this report to inform the scientific community about the development and features of MODIA™. Digital therapies have the potential to significantly improve efficiency and quality in the treatment of multiple disease spaces, particularly mental health. Obtaining strong clinical evidence is our key focus and requires us to apply similar scientific rigor to our digital therapies as we do to our pharmaceuticals.”



MODIA™ was developed in close collaboration with OUD specialists and OUD patients at various stages of recovery. The paper sets forth some of the program content, techniques, and innovative features of MODIA™. It includes some of the attributes and features specifically developed for the OUD patient as a supplement in the MAT therapeutic approach and to support positive patient outcomes. The paper is authored by Bjorn Meyer, Ph.D. (GAIA AG), Geri-Lynn Utter, Psy.D. (Orexo US), and Catherine Hillman, Psy.D.

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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 primary endpoint defined as the subject having ≥80% of urine drug tests negative for opioids and negative self-reports for illicit opioid use during the study period. For more information about the study, please visit www.clinicaltrials.gov.

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 8.00 am CET, on October 18, 2021.