



Press release

Orexo signs partnership agreement with GAIA to develop and commercialize a new digital therapy for the treatment of Opioid Use Disorder

Uppsala, Sweden – August 20, 2019. Orexo AB (publ), the fully integrated specialty pharmaceutical company addressing opioid addiction and pain, today announces it has entered into an exclusive agreement with GAIA AG (GAIA), a global leader in digital therapeutics that successfully launched its first digital health product in 2001, for a new digital therapy (DTx) for the treatment of Opioid Use Disorder (OUD). Orexo will have the exclusive global commercial rights to the product and intends to launch it in the US in 2022, subject to regulatory approval.

The medically assisted treatment of OUD requires a complete treatment plan, including effective medication, such as Orexo's commercially available Zubsolv[®], and counseling and psychosocial support. The access and quality of counseling and psychosocial support remain one of the main barriers to successful treatment in many areas of the US. Orexo believes that the fully-automated DTx (Orexo project no. OXD-01) can become a valuable addition to existing treatment plans, which will improve patients' access to treatment and overall treatment outcomes.

OXD-01 will be powered by GAIA's technology platform broca[®], which has been the backbone of more than 70 products and been tested on more than 10,000 patients during clinical trials to date. Based on an artificial intelligence (AI)-expert system, broca[®] engages users in highly individualized, simulated 1:1 interactions, guiding patients step-by-step towards specific goals and therapeutic targets. This individualization makes GAIA's products unique and has proven to have a significant positive impact on patients' treatment outcomes during both multiple clinical trials and actual treatment in various healthcare settings and indications around the world. GAIA's broca[®] platform has the flexibility to run the highly individualized products on nearly all web compatible devices, including virtual reality applications.

Nikolaj Sørensen, CEO and President of Orexo AB, commented: *"We are delighted to sign this partnership with GAIA, which reinforces the need for a complete treatment plan for OUD patients. GAIA's technology and expertise in digital therapeutics are impressive and makes them an ideal partner for Orexo to develop this new treatment. I am convinced that DTx will become an integral and natural part of addiction treatment in the future. This digital therapy for OUD patients is perfectly positioned with Orexo's competences and commercial organization in the US. GAIA's technology and products can potentially be applied to several other disease areas relevant to Orexo's current customers and we look forward to continuing our dialogue with GAIA on other possible DTx that can be commercialized by Orexo."*



Dr. Mario Weiss, CEO and Founder of GAIA, commented: *“Orexo brings everything to the table we are looking for in a partnership for digital therapeutics: comprehensive expertise in the field, focus on evidence and science, and last but not least a dedicated, committed team that is open for innovation. I’m also very happy to see we both share the same vision – helping the ones in need by leveraging the full potential of proven effective treatments and technology. With GAIA’s almost 20 years of experience in the development of effective digital therapies and the great Orexo team on our side, I’m very positive that our new product will have a true health impact on many patients’ lives around the world.”*

Under the terms of the agreement, Orexo will be responsible for the clinical development, regulatory approval and commercialization. GAIA will be entitled to royalties, milestone payments as well as financial compensation during the development phase. Orexo will provide an updated cost guidance for 2019 in connection with the Q3 report release, the increase in the operational expenses for 2019 is expected to be non-material. Future expenses related to OXD-01 will be incorporated into Orexo’s overall cost guidance.

For further information, please contact

Orexo AB (publ.)

Nikolaj Sørensen, President and CEO

Tel: +46 (0)18 780 88 00

E-mail: ir@orexo.com

Lena Wange, IR and Communications Manager

Tel: +46 (0)18 780 88 00

E-mail: ir@orexo.com

GAIA AG

Dr. Mario Weiss, CEO

Tel: +49.40.3510520

E-mail: press@gaia-group.com

Dr. Matthias Zenker, SVP Business Development DTx

Tel: +49.40.3510520

E-mail: bd@gaia-group.com

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](https://twitter.com/orexoabpubl), LinkedIn and YouTube.



About GAIA

GAIA is a global leader in digital therapeutics (DTx), launching its first product successfully in 2001. With its stringent focus on research and development of evidence based, fully-automated online interventions the company continuously shifts benchmarks when it comes to effect sizes and safety profiles for digital therapeutics in neuroscience, immunology, oncology, or behavioral health. With more than 140 experts in the field of Medicine, Psychology, Behavioral Medicine, Software Engineering as well as Regulatory and Market Access, GAIA is one of the most experienced and largest global players in the development of next generation digital solutions to support and treat patients with a broad variety of medical conditions.

For more information about GAIA please visit www.gaia-group.com. You can also follow GAIA on Twitter, @GAIA_COM, and LinkedIn

About Opioid Use Disorder

Opioid Use Disorder is a problematic pattern of opioid use that causes significant impairment and distress to patients. Symptoms of the disorder include a strong desire to use opioids, increased tolerance to opioids, failure to fulfill day to day obligations, trouble reducing use, and withdrawal symptoms upon discontinuation. Individuals with an opioid use disorder are often treated with medication assisted treatment as part of a complete treatment plan that includes counseling and psychosocial support. Even on treatment and/or after detoxification patients are often at high risk of relapse as certain psychological and social factors can be powerful triggers that lead to relapse.

The information was submitted for publication at 08:00 am CET on August 20, 2019