



Press release

## **Orexo acquires exclusive US rights to commercialize vorvida<sup>®</sup>, a digital therapy for alcohol use disorder with scientifically proven efficacy**

- Deal further strengthens Orexo's partnership with GAIA

- Orexo committed to digital health to address addiction

**Uppsala, Sweden – November 27, 2019.** Orexo AB (publ), the fully integrated specialty pharmaceutical company with the aim of becoming a leader within treatment of addiction, today announces it has acquired the exclusive US rights to vorvida<sup>®</sup>, a digital therapy for the treatment of Alcohol Use Disorder (AUD), from GAIA AG (GAIA), a global leader in digital therapeutics. Today's news follows an earlier agreement with GAIA in August 2019, for the exclusive global commercial rights to OXD01, a new digital therapy being developed for the treatment of Opioid Use Disorder (OUD).

Under the terms of the new agreement, Orexo will be responsible for the regulatory approval and commercialization of vorvida<sup>®</sup> in the US, whilst GAIA will be entitled to an upfront payment, milestone payments as well as royalties. Orexo and GAIA will initiate a dialog with the FDA about the regulatory pathway, the outcome of which will decide the launch timing and requirement for additional investments in the development of vorvida<sup>®</sup> for the US market.

Vorvida<sup>®</sup> (Orexo project no. OXD02) is a fully automated digital therapy developed by GAIA based on its proprietary artificial intelligence (AI)-expert system, broca<sup>®</sup>. Vorvida<sup>®</sup> is scientifically proven to reduce troublesome drinking patterns in adults with AUD. In a randomized controlled trial involving 608 adults with problematic alcohol intake, researchers found that participants in the intervention group with vorvida<sup>®</sup> significantly reduced their daily alcohol consumption over three and six months, with significant effect sizes.<sup>1</sup> Additionally, in comparison to the control group, vorvida<sup>®</sup> users reported fewer days of binge drinking and drunkenness while stating high acceptance and utility rates of vorvida<sup>®</sup> at the same time. Vorvida<sup>®</sup> has already been launched successfully in Germany and Switzerland in 2019 by GAIA.

Nikolaj Sørensen, CEO and President of Orexo AB, commented: *"We are delighted to extend our partnership with GAIA and proud that Orexo may also be able to address alcohol dependency,*

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<sup>1</sup> Jördis M. Zill, Eva Christalle, Björn Meyer, Martin Härter, and Jörg Dirmaier *The Effectiveness of an Internet Intervention Aimed at Reducing Alcohol Consumption in Adults: Results of a Randomized Controlled Trial (Vorvida)* Dtsch Arztebl Int 2019; 116: 127–33. DOI: 10.3238/arztebl.2019.0127



*another major addiction crisis. We see a significant unmet need in the treatment of alcohol use disorder and are impressed by the clinical effects that vorvida® can deliver for patients. As a company, we are making a commitment to the digital therapy space by building up a portfolio of products which I expect to turn into a sizeable business for Orexo in the medium term. As we will invest to enhance our capabilities in the digital space we will of course leverage our successful commercial infrastructure to make our digital therapies a success in the United States.”*

Dr. Mario Weiss, CEO and Founder of GAIA, commented: *“Working with the Orexo team on the first agreement showed us their dedication and vision of the potential for digital therapeutics in the field of addiction. Partnering with them on vorvida® therefore became an almost natural consequence for us. With its scientifically proven efficacy vorvida® has shown it can create an enormous health impact on its own - for patients, providers, payers and employers alike. We are convinced that Orexo is the right partner to bring this best-in-class product to the US.”*

AUD is a major health crisis affecting approximately 14.5 million people in the United States.<sup>2</sup> Each year, more than 88,000 people die from alcohol-related causes,<sup>3</sup> making it the third leading preventable cause of death in the country. Alcohol misuse costs the United States about USD 249 billion per year.<sup>4</sup>

The licensing of vorvida® further strengthens the alliance with GAIA, adding a second digital therapy to the group’s pipeline. Orexo intends to continue to broaden investments in digital therapies with a focus on digital products for addiction and adjacent disease spaces that have proven clinical efficacy from well-run patient trials and are demonstrating tangible value to patients, health care professionals and payors alike. For Orexo, it is important the digital therapies independently offer attractive commercial potential where Orexo can leverage its existing commercial infrastructure.

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<sup>2</sup> Centers for Disease Control and Prevention (CDC). Alcohol and Public Health: Alcohol-Related Disease Impact (ARDI). Average for United States 2006-2010 Alcohol-Attributable Deaths Due to Excessive Alcohol Use. <https://go.usa.gov/xKBjQ>.

<sup>3</sup> Sacks, J.J.; Gonzales, K.R.; Bouchery, E.E.; Tomedi, L.E.; and Brewer, R.D. 2010 National and state costs of excessive alcohol consumption. *American Journal of Preventive Medicine*49(5):e73–e79, 2015.

<sup>4</sup> Substance Abuse and Mental Health Services Administration (SAMHSA). Results from the 2017 National Survey on Drug Use and Health: Detailed Tables. Table 5.5A—Alcohol Use Disorder in Past Year Among Persons Aged 12 or Older, by Age Group and Demographic Characteristics: Numbers in Thousands, 2016 and 2017. <https://www.samhsa.gov/data/sites/default/files/cbhsq-reports/NSDUHDetailedTabs2017/NSDUHDetailedTabs2017.htm>.



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### **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](http://www.orexo.com). You can also follow Orexo on Twitter, @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](http://www.gaia-group.com). You can also follow GAIA on Twitter, @GAIA\_COM, and LinkedIn

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 3.30 pm CET on November 27, 2019.