



Press release

## Orexo submits application for vorvida® to the FDA to enable commercialization in the US

- vorvida® clearance from FDA anticipated Q2 2020
- expects to launch its first digital therapy in the US for heavy alcohol use in H2 2020

**Uppsala, Sweden – March 6, 2020.** Orexo AB (publ), today announces it has submitted an application to the US Food and Drug Administration (FDA) for vorvida® to enable commercialization in the US. vorvida®, is a digital therapy with clinically proven efficacy for the treatment of bothersome or harmful alcohol consumption including diagnosed alcohol use disorder (AUD). Subject to hearing from the FDA, which is expected during the second quarter of 2020, Orexo intends to initiate the commercialization in the second half of 2020. vorvida® has already been launched successfully in Germany and Switzerland in 2019 by GAIA AG (GAIA).

Today's news follows the November 2019 announcement of Orexo's acquisition of the US commercialization rights of the therapy from GAIA. vorvida® (Orexo project no. OXD02) is a digital therapeutic designed to offer patients quality psychotherapy intervention based on cognitive behavioral therapy and motivational interviewing. It was developed by GAIA and is based on its proprietary artificial intelligence (AI)-expert system, broca®. vorvida® is scientifically proven to reduce troublesome drinking patterns in adults with harmful alcohol consumption. In a randomized controlled trial, conducted in Germany, involving 608 adults with problematic alcohol intake, researchers found that participants in the intervention group using vorvida®, saw a significant reduction in their daily alcohol consumption over three and six months, with significant effect sizes.<sup>1</sup> Additionally, in comparison to the control group, vorvida® users reported fewer days of binge drinking and drunkenness while stating high acceptance and utility rates of vorvida® at the same time.

**Nikolaj Sørensen, CEO and President of Orexo AB, commented:** *“Based on our deep understanding of treating addiction disorders, we are acutely aware of the need for better access to quality treatment options for all patients. We also recognize that the treatment of substance use disorder, such as alcohol, requires a multifaceted approach often including both medication and psycho-social support. Access to vorvida® will enable patients to treat heavy alcohol use in their homes, when they need it the most. This ease of use combined with the strong clinical evidence, suggests vorvida® could present an important treatment option for patients.”*

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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



**Dennis Urbaniak, Executive Vice President of Orexo Digital Therapeutics, commented:**

*“Since I joined Orexo in December last year, we have worked intensively to prepare an application for vorvida® with the FDA. I am proud we have been able to complete this process in a few months, which wouldn’t have been possible without leveraging the significant experience in Orexo from the substance use disorder market in the US. With the application to the FDA we have taken one important step forward. In anticipation of the ability to market vorvida® in H2, we will continue to build the commercialization team and to finalize the commercialization and pricing strategy. Our top priority is to make vorvida® available to patients as fast as possible to meet the significant need for new and efficacious treatment alternatives for the 16.6 million patients suffering from the challenges with unhealthy drinking habits in the US. <sup>1</sup>”*

Heavy alcohol use is a major health crisis affecting approximately 16.6 million people in the United States. <sup>1</sup> Each year, more than 88,000 people die from alcohol-related causes, <sup>2</sup> making it the third leading preventable cause of death in the country. Alcohol misuse costs the US about USD 249 billion per year. <sup>3</sup>”

Dennis Urbaniak, EVP Digital Therapeutics, will provide additional details and comments about the market for digital therapies in the US at the Capital Markets Day March 17, 2020, in Stockholm, Sweden. At the Capital Markets Day Dr. Mario Weiss, CEO and Founder of GAIA, a global leader in digital therapeutics, will present his perspectives on the importance and efficacy of digital therapies. The Capital Markets Day will take place at Helio GT30, Grev Turegatan 30, Stockholm, Sweden. For registration please use this link, [https://financialhearings.com/event/12588/register/live\\_event](https://financialhearings.com/event/12588/register/live_event), or visit the company’s website.

1. SSMHA, Substance Abuse and Mental Health Services Administration
2. 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.
3. 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 and digital therapies addressing unmet needs mainly within the growing space of addiction. 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 commercializes its lead product Zubsolv® for treatment of opioid use disorder. Total net sales for 2019 amounted to SEK 845 million and the number of employees was 128. 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](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 150 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

The information was submitted for publication, through the agency of the contact persons set out above, at 8.00 am CET on March 6, 2020.