



## **Voluntis receives CE Mark for Oleena, key milestone to the future commercialization of its digital therapeutics for oncology**

- **First Digital Therapeutic for oncology based on the Theraxium platform to receive regulatory approval in the European Union**
- **Marketing authorization to commercialize Oleena now received both in the US and in the EU**
- **12<sup>th</sup> regulatory clearance (worldwide) obtained by Voluntis for a proprietary digital therapeutic**

**Cambridge, MA, and Paris, France – November 16 2020** - Voluntis (*Euronext Paris, Ticker: VTX - ISIN: FR0004183960*), a leader in digital therapeutics, today announced that it has received the CE mark for Oleena. This is a key first step ahead of the commercialization of its oncology solutions in the European Union.

### **Oleena, a digital therapy to support treatments of cancer patients**

Oleena is Voluntis' proprietary digital therapeutic that enables patients to self-manage symptoms across a wide range of cancer therapies, and also allows care teams to remotely monitor patients. Oleena is based on Voluntis' Theraxium platform, and its patented algorithm engine, which also serves as the foundation for digital therapeutics the company co-develops with life science partners.

Using embedded evidence-based clinical algorithms, Oleena delivers automated recommendations to patients in real-time. These recommendations are based on a personalized patient care plan. They focus on:

- self-management of symptoms (e.g. advice on dietary adjustments, use of symptomatic treatments over a certain period of time),
- personalized dosing of medication,
- guidance for the self-monitoring of relevant health indicators,
- and identifying the need for escalation of care.

### **Paving the way to commercialization of oncology digital therapeutics in the EU**

The CE mark of Oleena paves the way to the future commercialization of Voluntis' oncology digital therapeutics in the EU, where there are an estimated 3.9 million new cancer cases annually<sup>1</sup>. Recent real-world research has shown that up to 89% of patients experience side effects related to cancer treatments<sup>2</sup>. If not managed appropriately, these symptoms may result in hospitalizations and ER visits, which could have been partially avoided by delivering highly personalized, proactive real-time support for patients at home.

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<sup>1</sup> <https://canceratlas.cancer.org/the-burden/europe/>

<sup>2</sup> PLOS. 12(10). DOI: 10.1371/journal.pone.0184360.



This regulatory approval happens at a time when healthcare professionals and health systems are increasingly turning to remote patient monitoring solutions. This is currently illustrated during the Covid-19 pandemic with patient access to hospital services and oncology centers being significantly reduced. These solutions can support both patients and their care teams in the management of at-home treatments. Oleena enables healthcare providers to easily access patient data remotely so they can monitor patients' treatment and if necessary, intervene.

*"The CE mark of Oleena, a key milestone on our strategic roadmap, is an important step towards the commercial launch of our oncology digital therapeutics in Europe" said Pierre Leurent, Chief Executive Officer. "Following our groundbreaking marketing authorization received in the US last year, we look forward to supporting our partners in the future commercial rollout of our solutions on both sides of the Atlantic."*

*"This twelfth regulatory clearance obtained over the past seven years speaks to the maturity of Voluntis' proprietary platform and processes in the field of digital therapeutics." added Raffi Krikorian, SVP Global Quality and Regulatory Affairs. "Leveraging our ISO 13485 and MDSAP certified Quality Management System, we are glad to provide our partners with state-of-the-art capabilities to quickly design and bring to market digital therapeutics that make a difference for patients around the world."*

## About Voluntis

Voluntis creates digital therapeutics that empower people with chronic conditions to self-manage their treatment every day, thus improving real-world outcomes. Voluntis' solutions, combining mobile and web apps, use clinical algorithms to deliver personalized recommendations to patients and their care teams. For example, these recommendations are used to adjust treatment dosage, manage side effects or monitor symptoms. Leveraging its Theraxium technology platform, Voluntis has designed and operates multiple digital therapeutics, especially in oncology and diabetes. Voluntis has long-standing partnerships with leading life science companies. Based in Cambridge, MA, and Paris, France, Voluntis is a founding member of the Digital Therapeutics Alliance. For more information, please visit: [www.voluntis.com](http://www.voluntis.com)

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