Voluntis receives CE Mark for new version of Oleena with expanded clinical intelligence

- **New regulatory approval in the European Union for an enhanced version of Oleena extending its patient decision support algorithms**
- **New version now authorized for marketing in the United States and the European Union**
- **13th regulatory clearance (worldwide) obtained by Voluntis for a digital therapeutic**

Cambridge (USA), Paris (France), May 12, 2021, 8:00 a.m. CET - Voluntis (Euronext Growth Paris, Ticker: ALVTX - ISIN: FR0004183960), a leader in digital therapeutics, today announced that it has received the CE mark for a new version of Oleena featuring expanded clinical intelligence.

Oleena, digital therapeutic for people with cancer

Oleena is Voluntis' proprietary digital therapeutic that supports patients in the self-management of their symptoms in combination with a wide range of cancer treatments, while allowing healthcare teams to remotely monitor the progress of the disease. It is based on the Theraxium platform developed by Voluntis, which also serves as the foundation for the digital therapeutics the company is co-developing with pharmaceutical partners.

As a reminder, Oleena was the first digital therapeutic in oncology based on the Theraxium platform to receive regulatory approval in the European Union as announced in the November 16, 2020 press release.

Oleena's new version sets a new standard for digital therapeutics in oncology

The new version of Oleena embeds new clinical algorithms that provide decision support recommendations to patients. It is designed to facilitate self-management of an increased number of symptoms that people with cancer may experience along their treatment journey.

This new CE-marked version of Oleena, a Class IIa medical device in Europe, is also authorized for marketing in the United States. The new symptom management modules are also available to Voluntis' pharmaceutical partners through the Theraxium platform.

"Thanks to this CE mark, the thirteenth regulatory clearance obtained by Voluntis, we are once again demonstrating our ability to rapidly conform our innovations, supported by our ISO 13485 and MDSAP certified quality management system, to the regulatory requirements of the markets in which we intend to increase our presence," said Pierre Leurent, CEO. "*Through this continuous effort of innovation, we are proud to enable people with cancer to benefit from increasingly personalized and efficient day-to-day support along the way of their treatment.* »

"*Clinical algorithms are the active ingredients of our digital therapeutics*" said Genevieve d'Orsay, MD, Chief Medical Officer. "*With this new version of Oleena, we are delighted to introduce a smarter daily companion for people with cancer that also aims to help care teams*

by simplifying treatment management. We believe patient-centric digital solutions can go beyond electronic PROs[1], by promoting self-management and individualized interventions."

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

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[1] Patient Reported Outcomes

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