



FOR IMMEDIATE RELEASE: July 31, 2019, 5:45 pm cest

## **Voluntis Announces Market Authorization for Oleena™, First Digital Therapeutic in Oncology**

***First FDA Class II Software-as-a-Medical Device to be Marketed for Use Across All Cancer Indications***

**CAMBRIDGE, Mass., and PARIS, France** - Voluntis (Euronext Paris, Ticker: VTX - ISIN: FR0004183960), a leader in digital therapeutics, today announced it has successfully completed a U.S. Food and Drug Administration (FDA) regulatory review of its Oleena™ software for oncology-related symptoms management and remote patient monitoring. Oleena™ is determined as Class II medical device falling under enforcement discretion per FDA Guidance.

With an estimated 1.7 million new cases of cancer diagnosed every year in the United States, cancer management is one of the country's leading health expenditure. Patients with cancer often experience distressing symptoms that impair daily functioning and quality of life. When manageable symptoms are left untreated or undertreated, they can lead to treatment interruptions, unscheduled ER visits and hospitalizations. New approaches based on the combination of self-management and remote monitoring have the potential to enhance the quality of care in oncology, improve clinical outcomes and reduce costs for health systems.

### **Oleena™ is a unique solution in cancer care:**

- Innovative digital approach with embedded clinical algorithms
- Patient self-management of cancer symptoms with actionable recommendations
- Combined with remote patient monitoring and care team supervision

Oleena™ is a care companion for the cancer patient journey based on mobile and web technologies that enables self-management of symptoms and remote monitoring by care teams. Oleena™ provides patients with personalized insights to self-manage the symptoms they experience over the course of their disease. Once Oleena™ has been prescribed by a care team, patients are guided with real-time and personalized recommendations on what to know and what to do, now and next. These recommendations include personalized coaching for symptom management as well as on-demand directions for initiation and dosing of supportive therapies based on the patient's individual care plan. Healthcare teams receive access to automated and adaptive insights on their patient's symptoms in order to support patients wherever they are, whenever they need it.

*"Beyond monitoring their symptoms, we believe that empowering patients via the digital delivery of real-time and personalized therapeutic interventions offers the opportunity for significant clinical and economic outcomes. We are delighted to introduce Oleena™, the first prescription digital therapeutic in oncology, to transform patients' experience throughout their cancer journey,"* said Pierre Leurent, CEO of Voluntis.

Oleena™ supports the self-management of common side effects experienced by patients with cancer such as diarrhea, pain and nausea. Powered by a comprehensive set of proprietary algorithms, Oleena™ is able to support patients across a wide range of cancer diagnoses and anticancer treatments (including chemotherapies, immunotherapies and targeted therapies, such as PARP, PI3K, CDK4/6 inhibitors).

*"Digital therapeutics like Oleena™ represent a critically important addition to the management of symptoms at oncology practices level. The plain language and the user-friendly interfaces simplify the patient self-management. The embedded clinical algorithms enable automated and proactive intervention that aid health care teams, both in terms of personalization and standardization,"* said Arvind Dasari, MD, University of Texas MD Anderson Cancer Center, Houston, TX.

Oleena™'s actionable insights and recommendations are provided in accordance with the treatment plan set up by a patient's care team and using evidence-based standards of symptom management and supportive care in U.S. and EU consensus guidelines that have been validated by a panel of clinical oncology experts. Oleena™ is powered by Theraxium Oncology, Voluntis' proprietary platform dedicated to the development of digital therapeutics in the oncology space.



### **About Theraxium Oncology**

Theraxium Oncology is the cornerstone software platform for all digital therapeutics developed by Voluntis in the field of cancer treatments. Theraxium Oncology embeds specific modules to design and simulate algorithms: medical rules are coded in domain specific language with a high level of granularity to reflect temporality and contextualization according to an expert methodology. Voluntis has leveraged these modules to design an off-the-shelf library of clinical algorithms, which can be further customized. Theraxium Oncology also integrates modules with predefined Ux templates and configurable / interoperable workflows. The platform offers a scalable architecture to develop a full suite of solutions. It enables elaborate data analytics and remote maintenance of digital therapeutics.

### **About Voluntis**

Voluntis creates digital therapeutics that empower people suffering from chronic conditions to self- manage their treatment every day, thus improving real-world outcomes. Combining mobile and web apps, Voluntis' solutions deliver personalized recommendations to the patient and the care team so that they can, for example, adjust treatment dosage, manage side effects or monitor symptoms. These real- time recommendations are based on digitized clinical algorithms. Leveraging its Theraxium technology platform, Voluntis has designed and operates multiple digital therapeutics, especially in diabetes and oncology. Voluntis has long-standing partnerships with leading life science companies. Based out of Boston 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)

### **Contacts**

#### **U.S. Media Relations**

**Lauren Kannry**

[lkannry@thorpesearl.com](mailto:lkannry@thorpesearl.com)

202.491.1001

#### **International Media Relations**

**Nicolas Merigeau**

[voluntis@newcap.eu](mailto:voluntis@newcap.eu)

+33 (0)1 44 71 94 98