FDA clears Oleena, first digital therapeutic in oncology

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Voluntis has announced that 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.

Features of Oleena™:

- 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.

Pierre Leurent, CEO of Voluntis said, "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."

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, immuno-therapies and targeted therapies, such as PARP, PI3K, CDK4/6 inhibitors.

Arvind Dasari, MD, University of Texas MD Anderson Cancer Center, Houston, TX said, "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."

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.