CyberLiver's CirrhoCare granted Breakthrough Designation by FDA for improved clinical outcomes of cirrhosis patients

Improvement in clinical outcomes of acutely decompensated cirrhosis patients with CirrhoCare, a novel digital therapeutic, leads to FDA Breakthrough Designation

LONDON, UK, September 26, 2022 /EINPresswire.com/ -- Cyberliver Ltd., a digital health company focusing on delivering cutting edge solutions for liver care, today announced that the U.S. Food and Drug Administration (FDA) has granted Breakthrough Device Designation (BDD) to the company's CirrhoCare device for out-of-hospital, specialist hepatology management of cirrhosis patients, who are at risk of new acute complications of cirrhosis (decompensation events).

CirrhoCare is a multi-modal monitoring and management system and is comprised of monitoring sensors, a mobile application which receives inputs from each sensor, a novel brain dysfunction monitoring App, and a proprietary algorithm which combines this data with patient inputs and assimilates this on a clinician dashboard. CirrhoCare is intended for out-of-hospital specialist hepatology management follow-up of adult cirrhosis patients. CirrhoCare is intended to identify new preventable decompensation events [such as dehydration (acute kidney injury), new accumulation of ascites, infection, or hepatic encephalopathy] for a health care provider to take immediate clinical action, allowing the opportunity for early outpatient-based, specialist interventions.

This BDD is based on the results of a recently published controlled clinical trial in the Journal of Hepatology (https://www.sciencedirect.com/science/article/pii/S0168827822030665?via%3Dihub) that compares the outcomes of a group of cirrhosis patients managed using CirrhoCare or standard of care over a 3-month period, following their discharge from the hospital. The study showed evidence of good CirrhoCare compliance in 85% patients. Re-hospitalization due to cirrhosis complications was reduced markedly by 38% in the CirrhoCare managed patients, whilst unscheduled therapeutic paracentesis was reduced by 80%. There were also trends

towards improved cirrhosis prognostic markers measured using the MELD score and the CLIF-AD scores, whilst patients reported positive user feedback.

“These preliminary results from our pilot study published in journal of Hepatology re-affirm that CirrhoCare is feasible for community management of decompensated cirrhosis patients. They demonstrate the potential to reduce re-hospitalizations, whilst enabling management of these patients at-home, with a data-driven, physician-assistance tool, that enables prompt intervention to clinical alerts, thereby reducing the morbidity in these patients”, said Prof Raj Mookerjee, Consultant Hepatologist and Chief investigator of the CirrhoCare study, from the Institute for Liver and Digestive Health, University College London.

FDA’s Breakthrough Device Program is intended to help patients receive more timely access to technologies that have the potential to provide more effective treatment or diagnosis for life-threatening or irreversibly debilitating diseases or conditions. Breakthrough device designation will enable CyberLiver to interact with FDA more collaboratively and will expedite FDA’s regulatory review of CyberLiver’s marketing submission.

"Liver disease is a significant and rapidly growing public health crisis with few treatment options. CirrhoCare is the first digital therapeutic for patients with cirrhosis to demonstrate impressive, clinically relevant results. The BDD designation by the FDA will allow completion of necessary studies to obtain regulatory approval and access of CirrhoCare for patients. Based on initial clinical data, we believe that CirrhoCare can address this unmet need and ultimately become part of the standard of care " said Prof. Rajiv Jalan, Chief Medical Officer and co-founder of CyberLiver.

"We thank the FDA for recognizing this significant unmet medical need, as well as the critical importance of providing innovative new diagnostic tools to patients with advanced cirrhosis. This breakthrough designation, and the peer-reviewed publication of our pilot study results, provides us with a remarkable opportunity to expedite the development of our digital therapeutic device, and move forward with developing partnerships, that will help take CirrhoCare into the clinic”, said Ravi Kumar, CEO and Co-founder of CyberLiver.

About CyberLiver
CyberLiver is a digital therapeutics company committed to developing its breakthrough technology, CirrhoCare, as a prescription digital therapeutic (DTx) aimed at halting or reversing the progression of end-stage liver disease, characterized as decompensated cirrhosis, as well as providing effective means of managing the very ill cohort of patients already at this stage. CyberLiver's CirrhoCare is a novel, multi-model, non-invasive and transformational medical device that remotely detects cirrhosis decompensation events in patients with cirrhosis, who are at-risk of acute cirrhosis decompensation.

CirrhoCare is a patent pending technology with the potential to greatly improve the management of advanced liver disease, specifically decompensated cirrhosis. Liver disease

affects 80-100 million adults in the U.S. and results in 51,642 deaths annually (CDC 2022). Decompensated cirrhosis describes the serious progression of complications of advanced liver disease. Patients with decompensated cirrhosis are nearing end-stage liver failure and have an average life expectancy of between months and 2 years, depending on age, overall health, and potential complications, such as the severity of decompensation or development of acute-on-chronic liver failure, and other comorbid diseases, with few patients having the opportunity for receiving a liver transplant. There are limited treatment options for decompensated cirrhosis, and, at this later stage of liver disease, it's usually not possible to reverse the condition.

CirrhoCare is a critical enabler of early therapeutic intervention when patients can most benefit from disease modifying treatments and non-pharmacological interventions. CyberLiver is currently fundraising a Series A round to extend its pivotal clinical studies to the USA in 2023 and achieve FDA approval in 2024/2025 timeframe.

For more on CyberLiver, please visit: https://cyberliver.com

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