LivaNova

Health innovation that matters

NEWS RELEASE

LivaNova and Verily Announce First Patient Enrolled in Study to Evaluate Treatment Effectiveness for Patients Living with Depression

London, April 26, 2021 – LivaNova PLC (NASDAQ:LIVN), a market-leading medical technology and innovation company, and Verily, a subsidiary of Alphabet focused on life sciences and healthcare, today announced that the first patient has been enrolled in their collaborative UNCOVER study or "The RECOVER Sub-Study, Which Leverages Quantitative and Credible Research Tools from Verily, Will Provide Assessment Measures for Depressive Episodes."

UNCOVER is an opt-in research study for patients taking part in the ongoing LivaNova clinical study RECOVER or "A Prospective, Multi-center, Randomized Controlled Blinded Trial Demonstrating the Safety and Effectiveness of VNS Therapy® as Adjunctive Therapy Versus a No Stimulation Control in Subjects with Treatment-Resistant Depression." The UNCOVER sub-study deploys technology-enabled research tools from Verily to evaluate the real-world effectiveness of VNS Therapy as an adjunctive treatment for difficult-to-treat depression (DTD). The first UNCOVER patient was enrolled by Dr. David L. Dunner, FACPsych, Director of the Center for Anxiety and Depression in Mercer Island, Wash., and Professor Emeritus at the University of Washington in Seattle.

Participants in the UNCOVER sub-study will use two Verily-developed digital tools – a wearable, multi-sensor device (Verily Study Watch) along with an Android smartphone application (Verily Mood App). The Verily tools measure passive and active data, such as the participant's pulse rate, activity levels and sleep quality. The Mood App also allows participants to record voice diaries to more accurately assess depressive episodes and their effect on daily living.

"After detailed planning with our colleagues at LivaNova, we are pleased to have launched the UNCOVER study and enrolled the first participant," said Dr. William Marks, Head of Clinical Science and Neurology at Verily. "These Verily tools will collect behavioral, environmental, and physiological data from study participants, with the goal of painting a clearer picture of depressive episodes and the impact depression has on individual's lives over the course of the study."

Quantitative data obtained from these Verily tools will supplement the clinical outcomes collected in the RECOVER study, providing clinicians a more comprehensive view of whether each patient's depression is improving, staying the same, or worsening.

Depression continues to be an important health concern globally and an area in need of more effective treatments. Research shows the number of adults experiencing depression in the U.S. has tripled in recent times. Before the pandemic, 8.5% of U.S. adults reported being depressed, whereas that number has risen to 27.8% as the country deals with COVID-19.[1]

"For as many as one in three patients, medication alone may not be enough to combat depression that is difficult to treat,"[2] said Damien McDonald, Chief Executive Officer of LivaNova. "As we re-confirm the effectiveness of VNS Therapy in treating depression through the RECOVER study, we hope to learn even more through the UNCOVER sub-study about each patient's journey and the daily improvements in their lives with the use of Verily tools so we can provide the most effective treatment for this disorder."

About the RECOVER Study and UNCOVER Sub-study

Launched in September 2019, RECOVER is studying up to 1,000 people ages 18 or older who have depression or bipolar depression that has been difficult to treat. The double-blind, randomized, placebo-controlled study is assessing how VNS Therapy can offer patients relief from their DTD symptoms and improve quality of life. Symmetry®, the LivaNova VNS Therapy System for depression, is the first and only FDA-approved implantable device specifically designed for DTD. RECOVER is being carried out at up to 100 leading hospitals and medical centers across the United States. RECOVER subjects from participating sites who own an Android smartphone are being offered the option to participate in the UNCOVER sub-study, with a maximum of 300 subjects to be enrolled. LivaNova and Verily announced their collaboration on UNCOVER in February 2020.

For more information on the RECOVER clinical study, please visit www.RecoverVNS.com. For more information on UNCOVER, please visit clinicaltrials.gov.

About VNS Therapy for Depression

The VNS Therapy System, Symmetry, is indicated in the U.S. for the adjunctive long-term treatment of chronic or recurrent depression for patients 18 years of age or older who are experiencing a major depressive episode and have not had an adequate response to four or more adequate antidepressant treatments. Symmetry is indicated outside the U.S. for the adjunctive long-term treatment of chronic or recurrent depression in patients that are in a treatment-resistant or treatment-intolerant major depressive episode. Commonly reported side effects are hoarseness, shortness of breath, sore throat and coughing. Side effects typically occur during stimulation and are less noticeable over time. Safety information is available at www.symmetryvns.com/resources.html.

About LivaNova

LivaNova PLC is a global medical technology and innovation company built on nearly five decades of experience and a relentless commitment to provide hope for patients and their families through innovative medical technologies, delivering life-changing improvements for both the Head and Heart. Headquartered in London, LivaNova employs approximately 4,000 employees and has a presence in more than 100 countries for the benefit of patients, healthcare professionals and healthcare systems worldwide. For more information, please visit www.livanova.com.

About Verily

Launched in 2015, Verily is a subsidiary of Alphabet focused on life sciences and healthcare. Verily's mission is to make the world's health data useful so that people enjoy healthier lives. Verily develops tools and devices to collect, organize, and activate health data, and creates interventions to prevent and manage disease. Verily partners with leading life sciences, medical device, and government organizations, using deep hardware, software, scientific, and healthcare expertise to enable faster development, meaningful advances, and deployment at scale. For more information, please visit www.verily.com.

Safe Harbor Statement

This news release contains "forward-looking statements" concerning our goals, beliefs, expectations, strategies, objectives, plans and underlying assumptions and other statements that are not necessarily based on historical facts. These statements include, but are not limited to, statements regarding VNS Therapy and its use for patients with difficult-to-treat depression. Actual results may differ materially from those indicated in our forward-looking statements as a result of various factors, including those factors set forth in Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2020, as supplemented by any risk factors contained in our Quarterly Reports on Form 10-Q and our Current Reports on Form 8-K. We undertake no obligation to update the information contained in this press release to reflect subsequently occurring events or circumstances.

References

1. *Ettman, C, Abdalla, S, Cohen G, et al. Prevalence of Depression Symptoms in U.S. Adults Before and During the COVID-19 Pandemic. JAMA Network Open. 2020;3(9):e2019686. doi:10.1001/jamanetworkopen.2020.19686.*

2. *STARD: Rush AJ, Trivedi MH, Wisniewski SR, et al. Acute and longer-term outcomes in depressed outpatients requiring one or several treatment steps: a STAR*D report. Am J Psychiatry. 2006;163(11):1905–1917.*

LivaNova Investor Relations and Media Contacts

Melissa Farina, +1 (281) 228-7262
VP, Investor Relations
InvestorRelations@livanova.com

Deanna Wilke, +1 (281) 727-2764
VP, Corporate Communications
Corporate.Communications@livanova.com

###