LivaNova

Health innovation that matters

NEWS RELEASE

LivaNova Announces 250th Unipolar Depression Patient Implanted in RECOVER Clinical Study

London, March 14, 2022 — LivaNova PLC (Nasdaq: LIVN), a market-leading medical technology and innovation company, today announced the 250th unipolar depression patient has been implanted in the RECOVER clinical study, "A **P**rospective, Multi-c**e**nter, Randomized **C**ontrolled Blinded Trial Dem**o**nstrating the Safety and Effectiveness of **V**NS Therapy® System as Adjunctiv**e** Therapy Versus a No Stimulation Control in Subjects With Treatment-**R**esistant Depression." The study is designed with frequent interim analyses to be conducted by an independent Statistical Analysis Committee. The interim analyses will assess if predictive probability of success has been reached for the unipolar cohort of the study.

"Implanting our 250th unipolar patient marks a major milestone in this groundbreaking depression study," said Dr. Charles R. Conway, Director of the Washington University Resistant Mood Disorders Center, who serves as Principal Investigator for RECOVER. "From here, a series of interim analyses is likely to occur as we collect follow-up data from these patients over time. When we reach a successful interim analysis for the unipolar cohort, we will inform the U.S. Centers for Medicare & Medicaid Services."

As interim analyses are conducted for the unipolar cohort, unipolar and bipolar depression patients will continue to be enrolled into the randomized controlled trial (RCT). If any analysis reveals that the predictive probability of success has been reached, the results will be shared with the U.S. Centers for Medicare & Medicaid Services (CMS) with the intent that RCT enrollment for that patient population will cease and future patients will be enrolled into the prospective open-label longitudinal study for that cohort. After the last patient enrolled into the RCT has completed 12 months of follow-up, a final analysis will be conducted on the complete dataset for that respective cohort. The trial, if successful, will be used to support a peer-reviewed article and reconsideration of reimbursement for VNS Therapy by CMS for the treatment of depression that is difficult to treat.

Depression continues to be an important health concern globally and an area in need of more effective treatments. Major Depressive Disorder (MDD) is the leading cause of disability, morbidity and mortality worldwide.[1] Of patients with MDD, approximately 15-20 percent have TRD or difficult-to-treat depression (DTD), meaning they have not been responsive to multiple antidepressant treatments.[2]

"An effective, safe and accessible long-term treatment is needed for the large population of patients worldwide who suffer from their depressive symptoms and who struggle to get and stay well with current treatment options," said Damien McDonald, Chief Executive Officer of LivaNova. "A positive outcome from the RECOVER study will help more patients gain access to Symmetry™, our VNS Therapy device for DTD. We look forward to the day when there will be widespread availability of Symmetry to allow patients and psychiatrists access to another treatment option in the battle with this debilitating disease."

Launched in September 2019, RECOVER is the largest clinical study of its kind, examining up to 1,000 patients ages 18 or older who have unipolar or bipolar depression that is difficult to treat. The double-blind, randomized controlled study is assessing how VNS Therapy can offer patients relief from their depressive symptoms and improve quality of life. RECOVER is being carried out at up to 100 leading hospitals and medical centers across the United States. RECOVER is currently under way as part of a Coverage with Evidence Development framework per the CMS National Coverage Determination process. For more information on the RECOVER clinical study, please visit www.RecoverVNS.com.

About VNS Therapy for Depression

The VNS Therapy System, Symmetry, is FDA approved and 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. 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 here.

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 3,000 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.

Safe Harbor Statement

This news release contains "forward-looking statements" concerning the Company's 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 progress relating to the RECOVER study and our VNS Therapy System, Symmetry. Actual

events may differ materially from those indicated in forward-looking statements as a result of various factors, including those factors set forth in Item 1A of the Company's most recent Annual Report on Form 10-K, as supplemented by any risk factors contained in Quarterly Reports on Form 10-Q and Current Reports on Form 8-K. LivaNova undertakes no obligation to update the information contained in this press release to reflect subsequently occurring events or circumstances.

References

1. *Rush, Trivedi, Wisniewski et al. Acute and longer-term outcomes in depressed outpatients requiring one or several treatment steps: a STAR*D report. Am J Psychiatry. 2006.*

2. *Conway et al. A prospective, multi-center randomized, controlled, blinded trial of vagus nerve stimulation for difficult to treat depression: A novel design for a novel treatment. Contemporary Clinical Trials. August 2020; Volume 95. doi:10.1016/j.cct.2020.106066.*

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