LivaNova

Health innovation that matters

NEWS RELEASE

LivaNova Enrolls First Patient in RECOVER Clinical Study

London, September 27, 2019 – LivaNova PLC (NASDAQ:LIVN), a market-leading medical technology and innovation company, today announced the first patient enrolled in "A P**r**ospective, 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" (RECOVER). The study will evaluate Vagus Nerve Stimulation Therapy (VNS Therapy) for Treatment-Resistant Depression (TRD) in accordance with the U.S. Centers for Medicare & Medicaid Services (CMS) National Coverage Determination as part of its Coverage with Evidence Development Program. The first patient was enrolled by Dr. Azfar Malik in St. Louis.

"Through the RECOVER study, we have the ability to help patients with TRD across the United States gain access to a potentially meaningful treatment option to improve depressive symptoms and their quality of life," said Dr. Malik, President and Chief Medical Officer for CenterPointe Behavioural Health Systems; Chairman and Chief Executive Officer of Psych Care; and Clinical Associate Professor of Psychiatry at St. Louis University. "I have had positive results treating depressed patients with VNS Therapy in the past. I look forward to gaining a greater understanding of TRD and evaluating how patients respond to VNS Therapy as an adjunctive treatment during this study."

The objectives of the RECOVER study are to determine whether active VNS Therapy treatment is superior to a no stimulation control in producing a reduction in baseline depressive symptom severity. The study will include up to 500 unipolar and up to 500 bipolar patients at as many as 100 sites in the United States. RECOVER is a double-blind, randomized, placebo-controlled study with a follow-up duration of at least one year. The CMS study framework also includes the possibility to extend to a prospective longitudinal study.

"With the enrollment of the first patient in RECOVER, we are on a pathway to better address treatment for depression, which is the leading cause of disability in the U.S.," said Damien McDonald, Chief Executive Officer of LivaNova. "We are committed to this journey and to the patients who seek and deserve better forms of treatment."

While VNS Therapy received CE Mark in 2001 and U.S. Food and Drug Administration (FDA) approval in 2005 for the treatment of depression, earlier this month, the FDA approved Symmetry™ as the latest VNS Therapy System for Depression. Symmetry is indicated 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 the first and only FDA-approved implantable device specifically designed for depression that is difficult to treat,” said Jonathan Walker, Vice President of Depression at LivaNova. “We are pleased that the latest model of our VNS Therapy System, Symmetry, is now available as an option for patients.”

More information about the RECOVER study protocol is available at ClinicalTrials.gov.

About VNS Therapy for Depression

The VNS Therapy System, Symmetry™, is indicated 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 decrease over time.

Safety information is available on the VNS Therapy website.

About LivaNova

LivaNova PLC is a global medical technology and innovation company built on nearly five decades of experience and a relentless commitment to improve the lives of patients around the world. LivaNova’s advanced technologies and breakthrough treatments provide meaningful solutions for the benefit of patients, healthcare professionals and healthcare systems. Headquartered in London, LivaNova has a presence in more than 100 countries worldwide. The Company currently employs approximately 4,000 employees. LivaNova operates as two businesses: Cardiovascular and Neuromodulation, with operating headquarters in Mirandola (Italy) and Houston (U.S.), respectively.

For more information, please visit www.livanova.com.

Safe Harbor Statement

This news release contains forward-looking statements within the meaning of Section 27A of the United States Securities Act of 1933, as amended, and Section 21E of the United States Securities Exchange Act of 1934, as amended. Forward-looking statements are not historical facts but are based on certain assumptions of management and describe LivaNova's future plans, strategies and expectations. Forward-looking statements can generally be identified by the use of forward-looking terminology, including, but not limited to, "may," "could," "seek," "guidance," "predict," "potential," "likely," "believe," "will," "expect," "anticipate," "estimate," "plan," "intend," "forecast," or variations of these terms and similar expressions, or the negative of these terms or similar expressions. Forward-looking statements contained in this news release are based on information presently available to LivaNova and assumptions that LivaNova believes to be reasonable, but are inherently uncertain. As a result, LivaNova's actual results, performance or achievements may differ materially from those expressed or implied by these forward-looking statements, which are not guarantees of future performance or actions that may be taken by LivaNova and involve known and unknown risks, uncertainties and other factors that are, in some cases, beyond LivaNova's control. You should carefully consider the risks and uncertainties that affect LivaNova, including those described in the "Risk Factors" section of LivaNova's Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and other documents filed from time to time with the United States Securities and Exchange Commission.

All information in this news release is as of the date of its release. LivaNova does not undertake or assume any obligation to update publicly any of the forward-looking statements in this news release to reflect actual results, new information or future events, changes in assumptions or changes in other factors affecting forward-looking statements, except to the extent required by applicable law. If we update one or more forward-looking statements, no inference should be drawn that we will make additional updates with respect to those or other forward-looking statements. We caution you not to place undue reliance on any forward-looking statements, which are made only as of the date of this news release.

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