

LivaNova Receives Approval from U.S. Centers for Medicare & Medicaid Services for RECOVER Clinical Study

Study to evaluate VNS Therapy for Treatment-Resistant Depression in accordance with agency's National Coverage Determination as part of its Coverage with Evidence Development Program

London, September 5, 2019 – LivaNova PLC (NASDAQ:LIVN), a market-leading medical technology and innovation company, today announced the U.S. Centers for Medicare & Medicaid Services (CMS) accepted the LivaNova protocol for “A Prospective, Multi-center, Randomized Controlled Blinded Trial Demonstrating the Safety and Effectiveness of VNS Therapy® System as Adjunctive Therapy Versus a No Stimulation Control in Subjects With Treatment-Resistant Depression” (RECOVER). In February, CMS modified the National Coverage Determination (NCD) from non-coverage to a Coverage with Evidence Development (CED) framework in which CMS will cover the LivaNova Vagus Nerve Stimulation Therapy (VNS Therapy) for Medicare beneficiaries enrolled in the approved study. Separate from the study, CMS is also covering device replacement for patients with a VNS Therapy device for Treatment-Resistant Depression (TRD).

“Now that the RECOVER study protocol has been finalized, we are ready to activate sites that will enroll patients in this important study. Those who suffer from depression that is difficult to treat may gain access through this study to a potentially life-altering treatment option,” said Damien McDonald, Chief Executive Officer of LivaNova. “We worked with CMS and leading experts in psychiatry to develop the study protocol in accordance with the agency’s NCD. With depression as the leading cause of disability in the U.S., Medicare coverage is vital for these patients.”

RECOVER is a double-blind, randomized, placebo-controlled study with a follow-up duration of at least one year. The CED also includes the possibility to extend the study to a prospective longitudinal study. Enrollment is expected to begin in late 2019 and will include up to 500 unipolar and up to 500 bipolar patients at a maximum of 100 sites in the United States.

“In previous studies, we have seen VNS Therapy for TRD be highly effective and significantly improve response and remission rates when used as an adjunctive therapy,” said Dr. Charles R. Conway, Director of the Washington University Center for Advancement of Research in Resistant Mood and Affective Disorders who will serve as Principal Investigator for RECOVER. “I am eager

to help facilitate this study to learn more about the effectiveness of VNS for TRD, and to begin helping more patients who desperately need better treatment. While the enrollment and study itself will take time, we have already created positive momentum that will have tremendous impact.”

More information about the protocol will be available at [ClinicalTrials.gov](https://clinicaltrials.gov).

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

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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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