LivaNova

Health innovation that matters

NEWS RELEASE

LivaNova Announces Publication Detailing the Design of the RECOVER Clinical Study Evaluating VNS Therapy for Treatment-Resistant Depression

London, July 7, 2020 – LivaNova PLC (NASDAQ:LIVN), a market-leading medical technology and innovation company, today announced a publication in *Contemporary Clinical Trials*[1], which details the design for "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" or the RECOVER clinical study. RECOVER is currently under way as part of a Coverage with Evidence Development framework of the U.S. Centers for Medicare & Medicaid Services' (CMS) National Coverage Determination process.

"VNS Therapy for treatment-resistant depression has proven to be a safe and effective adjunctive treatment that significantly improves patients' response and remission rates in this chronically ill population that is difficult to treat," said Dr. Charles R. Conway, Director of the Washington University Resistant Mood Disorders Center, who serves as Principal Investigator for RECOVER. "As we continue to gain momentum and recruit patients for this important research, we are pleased to share more detailed information on this ground-breaking study, with the goal of raising awareness among clinicians and patients who could benefit from VNS Therapy."

Major Depressive Disorder (MDD) is a leading cause of disability, morbidity and mortality worldwide.[2] Even after four adequate courses of antidepressant treatment, one in three patients are left with depressive symptoms that significantly impact their daily functioning.[3] The objectives of the RECOVER study are to confirm, in a randomized controlled blinded trial, the outcomes previously observed and published in a large registry[4] – that VNS Therapy has a significant positive effect on baseline depressive symptom severity for patients with treatment-resistant depression (TRD).

"Working with CMS, we designed RECOVER – the largest clinical study of its kind – to further evaluate and confirm the efficacy of VNS Therapy for TRD," said Bryan Olin, LivaNova Senior Vice President for Clinical, Quality and Regulatory Affairs. "The goal of the RECOVER study is to strengthen the results reported in previous studies, facilitating a positive National Coverage

Determination that improves access to VNS Therapy for TRD patients who do not respond to other antidepressant therapies, potentially transforming their quality of life."

More information about the RECOVER study is available at ClinicalTrials.gov and at recovervns.com.

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 only occur during stimulation and are less noticeable over time.

Safety information is available at symmetryvns.com.

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. 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" 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 our approach to treatment-resistant depression using VNS Therapy. 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, 2019, 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 *C.R. Conway, B. Olin, S.T. Aaronson, 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 (2019).*

2 *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.*

3 *Rush, Aaronson et al. Chronic Vagus Nerve Stimulation Significantly Improves Quality of Life in Treatment-Resistant Major Depression. J Clin Psychiatry. 2018.*

4 *Aaronson ST, Sears P, Ruvuna F, et al. A 5-Year Observational Study of Patients With Treatment-Resistant Depression Treated With Vagus Nerve Stimulation or Treatment as Usual: Comparison of Response, Remission, and Suicidality [published correction appears in Am J Psychiatry. 2017 Sep 1;174(9):907]. Am J Psychiatry. 2017;174(7):640-648.*

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