

## **LivaNova Announces 150th Bipolar Depression Patient Randomized in RECOVER Clinical Study**

**London, June 13, 2023** — LivaNova PLC (Nasdaq: LIVN), a market-leading medical technology and innovation company, today announced the 150th bipolar depression patient has been randomized in the [RECOVER clinical study](#), “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.” The RECOVER protocol allows for a minimum of 150 and a maximum of 500 bipolar depression patients to be randomized into the study. Now, having randomized the 150th bipolar patient, a series of interim analyses will be conducted by an independent Statistical Analysis Committee to assess if predictive probability of success has been reached for the bipolar cohort of the study.

“The RECOVER study is progressing well having completed enrollment for the unipolar patient cohort at 500 and now achieving a major milestone with 150 bipolar patients randomized 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. “As we move through the major milestones of this study, we are taking incremental steps toward offering another treatment option for this significantly impaired patient population.”

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.

“Through RECOVER, we are evaluating the effectiveness of VNS Therapy as a treatment for patients who suffer from depression that is difficult to treat,” said William Kozy, Interim Chief Executive Officer and Board Chair of LivaNova. “We look forward to analyzing each cohort in the study – bipolar and unipolar – once enrollment concludes and patients complete their 12-month follow-up visit. From there, we will conduct a final analysis and publish study results for each cohort.”

Launched in September 2019, RECOVER is being carried out at up to 100 leading hospitals and medical centers across the United States. The trial, if successful, will be used to support a peer-reviewed article and reconsideration of reimbursement for VNS Therapy by U.S. Centers for Medicare & Medicaid Services (CMS) for the treatment of depression that is difficult to treat. 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](http://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 2,900 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](http://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.

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