

LivaNova VNS Therapy System, Symmetry, Granted CE Mark for Difficult-to-Treat Depression

Two UK patients receive innovative VNS Therapy implantable device through new pathway

London, March 9, 2020 – LivaNova PLC (NASDAQ:LIVN), a market-leading medical technology and innovation company, today announced its Vagus Nerve Stimulation Therapy® (VNS Therapy) System, Symmetry™, earned CE Mark approval for Difficult-to-Treat Depression (DTD). Two patients in the United Kingdom were implanted at the Musgrove Park Hospital in Taunton, England, making them the first patients to receive Symmetry devices outside the United States. The ability to treat these patients with Symmetry was the result of a collaborative effort to develop a VNS Therapy for depression treatment pathway by the [Somerset Partnership National Health Service \(NHS\) Foundation Trust](#), [the Taunton and Somerset NHS Foundation Trust](#) and LivaNova.

“With depression affecting so many people in the UK and so many patients suffering from symptoms despite traditional therapy, we were excited to develop a treatment pathway that can be replicated throughout the country, giving more patients with Difficult-to-Treat Depression access to VNS Therapy and Symmetry,” said Andreas Papadopoulos, MD, Clinical Director at Somerset Partnership NHS Foundation Trust, who served as the referring psychiatrist. “Working with Ear, Nose and Throat (ENT) surgical services enabled us to achieve swift and expert implantation of Symmetry devices for both patients.”

Now available in Europe, Symmetry is a small implantable device that stimulates the vagus nerve to improve symptoms of depression and quality of life. Symmetry sends mild electric pulses to the vagus nerve, which is connected to areas of the brain that control mood. While previous models of VNS Therapy have received CE Mark for the treatment of depression, Symmetry is specifically designed for the treatment of depression and is the newest VNS Therapy System. Symmetry also received U.S. Food and Drug Administration (FDA) approval in September 2019.

“As a surgeon, it is so gratifying to be able to help patients get access to new treatments like Symmetry given its benefit to patients’ daily lives,” said Edward Chisholm, MD, the ENT surgeon who led the implant surgery.

Major depressive disorder (MDD) is a leading cause of disability, morbidity and mortality worldwide.¹ In fact, for as many as one in three patients, medication alone may not be enough,

leading them to struggle daily with persistent feelings of sadness, hopelessness, thoughts of death or suicide and overall poor health.²

“For the many patients around the world with depression that is difficult to treat, VNS Therapy may transform their lives by giving them relief from the symptoms they struggle with every day,” said Damien McDonald, Chief Executive Officer of LivaNova. “We truly appreciate the dedication and commitment it took across the NHS teams to develop a pathway connecting ENT surgical services and mental health to give more patients with depression that is difficult to treat access to this innovative therapy.”

About VNS Therapy for Depression

The VNS Therapy System, Symmetry™, is 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. Symmetry is indicated outside the U.S. for the adjunctive long-term treatment of chronic or recurrent depression in patients that are in a treatment-resistant or treatment-intolerant major depressive episode. 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 at www.symmetryvns.com/resources.html.

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 treating Difficult-to-Treat Depression. 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 *The economic burden of treatment-resistant depression. Olchanski N, McInnis Myers M, et al. Clin Ther. 2013 Apr;35(4):512-22.*
- 2 *STAR*D: Rush AJ, Trivedi MH, Wisniewski SR, et al. Acute and longer-term outcomes in depressed outpatients requiring one or several treatment steps: a STAR*D report. Am J Psychiatry. 2006;163(11):1905–1917*

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