

## **LivaNova Comments on Proposed Decision Memo from the U.S. Centers for Medicare & Medicaid Services Regarding National Coverage Determination for VNS Therapy for Treatment-Resistant Depression**

*Final decision to be rendered by CMS in 90 days*

**London, November 20, 2018** – LivaNova PLC (NASDAQ:LIVN), a market-leading medical technology company, today commented on the U.S. Centers for Medicare & Medicaid Services (CMS) Proposed Decision Memo regarding its National Coverage Determination (NCD) for the LivaNova Vagus Nerve Stimulation Therapy® (VNS Therapy) System for Treatment-Resistant Depression (TRD).

Within the Proposed Decision Memo, CMS proposes to change the NCD for VNS Therapy for TRD to expand Medicare coverage. CMS could initiate coverage for Medicare beneficiaries through Coverage with Evidence Development (CED) when offered in a CMS-approved, double-blind, randomized, placebo-controlled trial with a follow-up duration of at least one year, with the possibility of extending the study to a prospective longitudinal study.

LivaNova intends to commence a clinical study that meets these requirements, once the NCD decision is finalized by CMS on or before Feb. 17, 2019.

LivaNova remains committed to providing additional treatment options for patients with depression and finds the Proposed Decision Memo from CMS to be a positive step toward increased access to important therapies for these patients. Over the last decade, a significant body of new evidence has emerged showing that the addition of VNS Therapy is effective in reducing symptoms in patients with chronic or recurrent depression.

With the release of its Proposed Decision Memo, CMS opened a 30-day public comment period. LivaNova encourages interested parties to [comment on the proposed decision memo](#) by Dec. 19, 2018 to be considered by CMS. All relevant information related to this process is available on the [CMS website](#).

LivaNova looks forward to the final decision from CMS regarding Medicare coverage of VNS Therapy for TRD. This would be a positive outcome for patients and physicians.

## **Conference Call Instructions**

The Company will host a conference call for interested parties commencing at 2 p.m. London time (9 a.m. Eastern Standard Time) on Tuesday, Nov. 20, 2018. To listen to the conference call, dial (844) 601-5111 (if dialing from within the U.S.) or (647) 253-8650 (if dialing from outside the U.S.). The conference ID is 7786437.

## **About LivaNova**

LivaNova PLC is a global medical technology 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](http://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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