

FDA Approves VNS Therapy Treatment for Drug-Resistant Epilepsy in Children as Young as Four Years Old

Expanded access to VNS Therapy treatment offers new hope for children with drug-resistant epilepsy

London, June 29, 2017 – LivaNova PLC (NASDAQ:LIVN) (“LivaNova” or the “Company”), a market-leading medical technology company, today announced it received FDA approval of its [VNS Therapy®](#) system (“VNS Therapy”) in patients as young as four years of age with partial onset seizures that are refractory to antiepileptic medications. This groundbreaking achievement makes VNS Therapy the first and only device that is FDA approved for drug-resistant epilepsy in this pediatric population. Previously, VNS Therapy was FDA approved for patients ages 12 and older. With this new indication, many children living with devastating drug-resistant seizures will have the opportunity for treatment beyond medication.

“Epilepsy can be a very trying and debilitating disease that can hold a child back from reaching his or her full potential,” said Damien McDonald, LivaNova’s Chief Executive Officer. “Children with frequent seizures require urgent and careful treatment to prevent further delay in their development. The data from several studies show that earlier use of VNS Therapy is proven to offer better long-term outcomes for children at a critical time in their development.”^{1,2,3}

VNS Therapy—a minimally invasive treatment option designed to prevent seizures before they start and stop them if they do—has been used to date by more than 100,000 patients globally.⁴ Every day in the U.S., 30 children will experience seizures for the first time, and ultimately will not be able to control them with medication alone.^{5,6,7} That means, every year more than 10,000 children under the age of 18 years old with drug-resistant epilepsy will face the consequences of seizures, including head trauma, emergency room visits, fractures and hospitalizations.⁸ Without treatment beyond medication, these children may miss developmental milestones and face potential cognitive decline.⁹

- more -

“Bringing VNS Therapy to children as young as age four in the U.S. is a huge opportunity to expand patient wellness and improve overall quality of life,” adds Jason Richey, LivaNova’s President of North America and General Manager of the Neuromodulation franchise. “We strive to provide value to patients, caregivers and healthcare professionals across the globe. Today’s announcement, along with the recent [FDA approval for our expanded MRI labeling](#), exemplifies how we continue to deliver on that promise.”

Jayden is one of many children living with drug-resistant epilepsy. He lives in Australia where VNS Therapy is approved for all ages.

“Growing up, Jayden was just like any other kid, before his epilepsy, anyway,” said Leah, Jayden’s mother. “His development stopped. He stopped progressing. He was seizing up to 300 times a day. Life was just a whirlwind of seizures and recoveries and appointments and medications.”

“Next month, we’ll be three years seizure free with VNS Therapy,” continued Leah. “He could never talk before and now, I’m having conversations with him. Now, we get to go and play. We get to go and do stuff. I don’t have to worry if I want to take him to the grocery store. It’s going to make me cry, thinking about just how far he’s come.”

Being able to offer VNS Therapy to younger patients in the U.S. is a game changer, according to Dr. Deborah Holder, Director of the Comprehensive Epilepsy Program for Children’s Hospital Los Angeles.

“Epilepsy affects one in 26 Americans, and 35 percent of these patients fail to respond to medications,” said Dr. Holder. “VNS Therapy offers many of these patients a chance for improved seizure control and a better quality of life. Controlling seizures in young children is life changing, allowing for improved development and educational successes that impact a child’s entire life.”

- more -

About VNS Therapy® for Epilepsy

VNS Therapy® is the first and only FDA-approved device for drug-resistant epilepsy that is clinically proven safe and effective for adults and children as young as four years of age. VNS Therapy is designed to prevent seizures before they occur and stop them if they do. It is a unique treatment approach developed specifically for people with drug-resistant epilepsy—a condition that affects one in three people with epilepsy. For more information, visit VNSTherapy.com or SeizureControl.com.

INTENDED USE/INDICATIONS – UNITED STATES

The VNS Therapy System is indicated for use as an adjunctive therapy in reducing the frequency of seizures in patients four years of age and older with partial onset seizures that are refractory to antiepileptic medications.

Individual results may vary. Common side effects include hoarseness or changes in voice tone, prickling feeling in the skin, shortness of breath, sore throat and coughing. Visit www.VNSTherapy.com/important-safety-information to view safety and full prescribing information.

1. Renfroe JB, Wheless JW. Earlier use of adjunctive vagus nerve stimulation therapy for refractory epilepsy. *Neurology*. 2002;59(6 Suppl 4):S26-30.
2. Berg AT, Zelko FA, Levy SR, Testa FM. Age at onset of epilepsy, pharmacoresistance, and cognitive outcomes: a prospective cohort study. *Neurology*. 2012;79(13):1384-91.
3. Otsuki T, Kim HD, Luan G, et al. Surgical versus medical treatment for children with epileptic encephalopathy in infancy and early childhood: Results of an international multicenter cohort study in Far-East Asia (the FACE study). *Brain Dev*. 2016;38(5):449-60.
4. Data on file, LivaNova PLC, Houston, TX.
5. U.S. Census Bureau, www.census.gov/quickfacts/table/PST045216/00, accessed 5/22/2017
6. Wirrell EC et al. *Epilepsy Res*. 2011 June; 95(1-2):110-118.
7. Mohanraj R et al. *Eur J Neurology*. 2006; 13:277-282.
8. Helmers SL et al. *Eur J of Paed Neuro*. 2012; 16(5): 449-458.
9. Otsuki T et al. *Brain & Development*. 2016; 38:449-460.

- more -

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 and with a presence in more than 100 countries worldwide, the company employs more than 4,500 employees. LivaNova operates as three business franchises: Cardiac Surgery, Neuromodulation and Cardiac Rhythm Management, with operating headquarters in Mirandola (Italy), Houston (U.S.A.) and Clamart (France), respectively.

For more information, please visit www.livanova.com.

Safe Harbor Statement

This press release contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended and Section 21E of the Securities Exchange Act of 1934, as amended. These statements can be identified by the use of forward-looking terminology, including "may," "believe," "will," "expect," "anticipate," "estimate," "plan," "intend," "forecast," or other similar words. Statements contained in this press release are based on information presently available to us and assumptions that we believe to be reasonable. We are not assuming any duty to update this information if those facts change or if we no longer believe the assumptions to be reasonable. Investors are cautioned that all such statements involve risks and uncertainties. Important factors that may cause actual results to differ include, but are not limited to: continued market acceptance of the VNS Therapy System and sales of our products; adverse changes in coverage or reimbursement amounts by the Centers for Medicare & Medicaid Services, state Medicaid agencies and private insurers; the presence or absence of intellectual property protection and potential patent infringement claims; maintaining compliance with government regulations; product liability claims and potential litigation; reliance on single suppliers and manufacturers for certain components; the accuracy of management's estimates of future expenses and sales; and other risks detailed from time to time in our filings with the Securities and Exchange Commission ("SEC"). For a detailed discussion of these and other cautionary statements, please refer to our most recent filings with the SEC, including our Annual Report on Form 10-K for the year ended December 31, 2016, and our Quarterly Report on Form 10-Q for the quarter ended March 31, 2017.

- more -

LivaNova PLC Media

Deanna Wilke, +1 (281) 727-2764
Corporate External Communications Manager
corporate.communications@livanova.com

Melissa Rieger, +1 (412) 251-2172
Havas PR
melissa.rieger@havas.com

###