Mainstay Medical Announces Publication of Two-Year Patient Outcomes Data from ReActiv8-B Clinical Trial Demonstrating Long-Term Efficacy of ReActiv8® Restorative Neurostimulation™

Data shows compelling efficacy and safety, as well as improvement on all key measures of pain and disability as compared to the one-year study results

Dublin, Ireland – 6 January 2022 – Mainstay Medical Holdings plc today announced the publication of the two-year patient outcomes data from its pivotal ReActiv8-B clinical trial. The data, published in the journal of the International Neuromodulation Society, *Neuromodulation*, confirm the efficacy and safety of ReActiv8 Restorative Neurostimulation, and also demonstrate compelling long-term durability and improvement over time on key outcome measures in the treatment of intractable chronic low back pain.

On virtually all key efficacy measures, the 2-year data showed improvements over the data from the patients' 1-year visits. Of note:

Outcome measure	**2-year result (N = 156)**	**1-year result (N = 176)**
Patients reporting pain intensity (VAS score) reduced by 50% or more from baseline	71%	64%
Patients reporting a greater than 20-point reduction in Oswestry Disability Index	61%	57%
Patients reporting VAS score < 2.5	65%	52%
Patients taking opioids at baseline that voluntarily eliminated or reduced opioid use	60%	48%

Dr. Chris Gilligan, Director of the Brigham and Women's Spine Center at Brigham and Women's Hospital, and Assistant Professor of Anaesthesia, Harvard Medical School, said, "*The recently published data from the ReActiv8-B clinical trial showed clinically meaningful improvements in both pain and function for patients with refractory chronic low back pain who received two years of neurostimulation. Pain scores in patients have decreased substantially from an average of 7.3 to 2.4 and are sustained for the duration of 2 years and longer with ongoing data collection. These long-term data are extremely important and encouraging given the chronic and refractory nature of this condition."*

"These impressive results represent an important milestone for Mainstay, as the profound improvements in patient outcomes we observed from baseline to 1 year to 2 years validate the restorative nature of the therapy and represent a new paradigm among treatments available to patients with intractable chronic low back pain," **said Jason Hannon, CEO of Mainstay Medical**. *"We are proud to have the only commercially available device with a strong safety profile and long-term, peer-reviewed evidence supporting the rehabilitation of this severely affected patient population, evidence which continues to expand through multiple clinical trials."*

The full publication can be downloaded free of charge at https://www.sciencedirect.com/science/article/pii/S1094715921063868. The ReActiv8-B trial patient cohort continues to be evaluated to generate additional data on longer-term efficacy.

About ReActiv8®

ReActiv8 is an implantable medical device designed to treat adults with intractable chronic low back pain (CLBP) associated with multifidus muscle dysfunction. Multifidus muscle dysfunction may be evidenced by imaging or physiological testing in adults who have failed therapy including pain medications and physical therapy, and who are not candidates for spine surgery. ReActiv8 has received regulatory approval in several geographic areas, and is commercially available in the European Economic Area, Australia, the United Kingdom, and the United States.

About the ReActiv8-B Clinical Trial

The ReActiv8-B clinical trial is an international, multi-center, prospective, randomized, active sham-controlled, blinded trial with one-way cross-over, conducted under an Investigational Device Exemption (IDE) from the FDA. A total of 204 patients with chronic low back pain refractory to physical therapy and medical management were implanted with ReActiv8 at leading clinical sites in the U.S., Europe and Australia and randomized 1:1 to therapy or control. In the treatment group, the ReActiv8 pulse generator was programmed to deliver electrical stimulation expected to elicit episodic contractions of the multifidus muscle. In the control group, the ReActiv8 device was programmed to provide a low level of electrical stimulation. Following assessment of the primary endpoint at 120 days, patients in the control group crossed over to receive levels of electrical stimulation similar to those in the treatment group.

Clinical trial funded by Mainstay Medical. Dr. Chris Gilligan, Principal Investigator of the trial, is a consultant of Mainstay Medical. Information about the study can be found at https://clinicaltrials.gov/ct2/show/study/NCT02577354.

About Mainstay Medical

Mainstay Medical is a medical device company focused on commercializing its innovative implantable Restorative Neurostimulation™ system, ReActiv8®, for people with disabling mechanical CLBP. Mainstay

Medical is headquartered in Dublin, Ireland and has subsidiaries operating in Ireland, the United States, Australia, Germany and the Netherlands.

Further information can be found at www.mainstaymedical.com.

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Forward-Looking Statements

All statements in this announcement other than statements of historical fact are, or may be deemed to be, forward-looking statements. These forward-looking statements may include, without limitation, statements regarding the company's intentions, beliefs or current expectations concerning, among other things, the company's commercial efforts and performance, financial position, financing strategies, product design and development, regulatory applications and approvals, and reimbursement arrangements.

Forward-looking statements involve risk and uncertainty and are not guarantees of future performance. Actual results may differ materially from those described in, or suggested by, the forward-looking statements. A number of factors could cause results and developments to differ materially from those expressed or implied by the forward-looking statements herein, including, without limitation, the potential for future clinical results to not match past, reported results; the potential for commercial results to fall short of expectations; and other the risks and uncertainties included in the company's Annual Report for the year ended 31 December 2020, which should be read in conjunction with the company's public disclosures (available on the company's website, www.mainstaymedical.com). The forward-looking statements herein speak only as of the date of this announcement.