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

Data continue to show compelling efficacy and safety, including improvement on all key measures of pain and disability, as compared to the one-year and two-year study results

Dublin, Ireland – 28 September 2022 – Mainstay Medical Holdings plc today announced the publication of the three-year patient outcomes data from its pivotal ReActiv8-B clinical trial. The data, published in the journal of the International Neuromodulation Society, *Neuromodulation*, further establish the efficacy and safety of ReActiv8 Restorative Neurostimulation, including compelling long-term durability and improvement over time on key outcome measures in the treatment of intractable chronic low back pain.

The three-year data show improvements over results from the patients' one-year and two-year visits on virtually all key efficacy measures. Of note:

Outcome measure	**1-year result (N = 176)**	**2-year result (N = 156)**	**3-year result (N = 133)**
Patients reporting pain intensity (Visual Analog Scale (VAS) score) reduced by 50% or more from baseline	64%	71%	**77%**
Patients reporting a greater than 20-point reduction in Oswestry Disability Index	57%	61%	**63%**
Patients reporting VAS score < 2.5	52%	65%	**67%**
Patients taking opioids at baseline that voluntarily eliminated or reduced opioid use*	48%	60%	**71%**

*Percent of patients that were on opioids at baseline: (1-year=31/65), (2-Year= 34/57), (3-Year= 36/51).

Overall, 83% of patients experienced substantial and clinically meaningful improvements in pain or disability, or both, at three years.

Chris Gilligan, Director of the Brigham and Women's Spine Center at Brigham and Women's Hospital, assistant professor of Anesthesia at Harvard Medical School (Boston, USA), and Principal Investigator of the study, said: *"The recently published data from the ReActiv8-B clinical trial continued to show clinically meaningful improvements in both pain and function for patients with refractory chronic low back pain who received three years of neurostimulation. The long-term trajectory and durability of clinical*

benefits are consistent with the restoration of neuromuscular control and muscle rehabilitation, which gives us confidence that we are able to treat the underlying cause of chronic low back pain in these patients."

*"Multifidus dysfunction in patients with chronic low back pain has historically been a challenging etiology for the spine surgeon community to properly treat," **said*** **Frank Schwab, Chair of Orthopedic Spine Surgery at Lenox Hill Hospital, and Chief of Orthopedic Spine Surgery for Northwell Health System.** "*These patients are not indicated for surgery, with existing treatment options being temporary and palliative. ReActiv8 therapy has proven to maintain effectiveness long-term and provides this challenging patient population with a safe and restorative solution."*

Jason Hannon, CEO of Mainstay Medical, **said**: *"These 3-year results further validate ReActiv8's restorative mechanism of action, which treats a primary underlying cause of mechanical chronic lower back pain, multifidus dysfunction. 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, and we look forward to continuing to generate clinical and other research to compel physicians and their patients to further utilize the therapy."*

The full publication can be downloaded free of charge at Three-Year Durability of Restorative Neurostimulation Effectiveness in Patients With Chronic Low Back Pain and Multifidus Muscle Dysfunction - ScienceDirect

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 UK, and the US.

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 future research studies, 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 risks and uncertainties included in the company's Annual Report for the year ended 31 December 2021, 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.