

## **Mainstay Medical Announces U.S. FDA Approval of ReActiv8® Neurostimulation System for Chronic Low Back Pain**

- U.S. commercialization expected to begin in the first half of 2021
- Continues positive momentum for Mainstay, with increasing commercial footprint in Europe and expected launch in Australia in early 2021

**Dublin – Ireland, 22 June 2020** – Mainstay Medical Holdings plc (“Mainstay” or the “Company”) today announced that the U.S. Food and Drug Administration (FDA) has approved the Company’s Premarket Approval (PMA) application for ReActiv8®, its implantable neurostimulation system to treat intractable chronic low back pain.

**Jason Hannon, CEO of Mainstay, said:** *“I am so proud of our team and the dedicated physicians who managed our clinical trials and cared for their patients. We are thrilled to receive FDA approval of ReActiv8, which is designed to be a restorative treatment and represents a new option for patients suffering with chronic low back pain. This disease affects millions of people around the world, and our clinical data demonstrates that ReActiv8 therapy provides progressive improvements in pain and disability over time, both in magnitude of effect and the proportion of patients who benefit from the treatment. This therapy has the potential to improve quality of life for the most severely-affected patients, and we look forward to making it available to U.S. patients and physicians beginning in the first half of 2021. This will build upon our growing business in Europe and our upcoming launch in Australia.”*

*“This milestone is the culmination of a development process over many years,” continued Mr. Hannon. “I would like to thank every member of our team, past and present, and in particular our clinical investigators, their teams and clinical study patients for their support and contributions.”*

**Dr. Chris Gilligan, Chief, Division of Pain Medicine, Department of Anaesthesiology, Perioperative and Pain Medicine, Brigham & Women’s Hospital, Assistant Professor of Anaesthesia, Harvard Medical and Principal Investigator of the pivotal ReActiv8-B study, said:** *“ReActiv8 fills an important unmet clinical need of patients suffering from chronic low back pain. Patients indicated for ReActiv8 therapy have generally tried numerous other treatments, including physical therapy and pain medications, and many are on long-term opioids to manage their pain. I have seen ReActiv8 provide durable improvements in back pain, the disabling effects of back pain, and quality of life. I am proud to have served as Principal Investigator of this landmark trial, and I look forward to sharing this experience with my physician colleagues who want to start using ReActiv8 in their patients.”*

**Dr. Robert Levy, a prominent neurosurgeon and pioneer in the field of neuromodulation, commented:** *“ReActiv8 represents a new treatment category for this severely-affected patient population. The use of neuromodulation to target underlying functional and motor-control issues in patients with musculoskeletal back pain can address a large unmet clinical need. ReActiv8 is designed*

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*as a restorative therapy for those suffering from musculoskeletal pain and does not compete with other forms of neuromodulation such as spinal cord stimulation. These patients are difficult for clinicians to treat with current therapy options, which is why so many of them take opioids to manage their pain. Having been part of the neuromodulation field for so long, I am really impressed by this particular innovation and I look forward to its adoption in clinical practice.”*

The FDA approval grants Mainstay the right to market ReActiv8 in the United States as an aid in the management of intractable chronic low back pain associated with multifidus muscle dysfunction, as evidenced by imaging or physiological testing in adults who have failed therapy, including pain medications and physical therapy, and are not candidates for spine surgery.

The FDA approval of ReActiv8 is primarily based on results from the ReActiv8-B clinical study, a pivotal 204-patient, international, multi-center, prospective, randomized, active sham-controlled, blinded trial with one-way cross-over, conducted under an Investigational Device Exemption (IDE) from FDA.

Based on the FDA approval, Mainstay is refining its commercial launch plans for ReActiv8 in the U.S., including the build out of the commercial team, inventory procurement and related matters, as well as evaluating the financial resources necessary to fund its planned activities. Mainstay intends to host an investor event later this year to provide an update on its commercial plans for ReActiv8.

#### **About ReActiv8®**

ReActiv8 is an active implantable medical device designed to treat people with chronic low back pain (CLBP). ReActiv8 provides bilateral electrical stimulation of the L2 medial branch of the dorsal ramus nerve as it crosses the transverse process at L3. This nerve supplies the lumbar multifidus muscle, a key stabilizing muscle of the low back. ReActiv8's stimulation of the nerve elicits contraction of the muscle, which can lead to improvement in CLBP and its disabling effects.

Low back pain is the number one cause of years lived with disability worldwide and a leading cause of activity limitation and work absence throughout much of the world, imposing a high economic burden on individuals, families, communities, industry and governments. While treatment options exist for patients with CLBP of a predominantly neuropathic origin, for the large portion of patients whose pain is predominantly nociceptive (or mechanical) in nature there are few therapies beyond drugs and injections, both of which merely mask the pain. ReActiv8 is intended for those patients without indications for spine surgery or spinal cord stimulation and who have continuing pain despite medical management. The Company currently estimates that there are approximately two million people in the EU and the U.S. who could be candidates for ReActiv8.

ReActiv8 has a CE Mark allowing for commercialization in the European Economic Area and has been focused on building clinical validation in Germany in select centers ahead of wider commercial availability in the future. ReActiv8 has also been admitted to the Australian Register of Therapeutic Goods (ARTG),

enabling commercialization throughout Australia, and has been approved for inclusion on the Protheses List of reimbursed products in Australia, effective as of 1 July 2020. The Protheses List identifies implantable devices eligible for reimbursement from all private health insurance funds in Australia. In the U.S., ReActiv8 is FDA approved, and the Company plans to commercially launch in early 2021.

### **About Mainstay Medical Holdings**

Mainstay Medical Holdings is a medical device company focused on commercializing an innovative implantable restorative neurostimulation system, ReActiv8®, for people with disabling Chronic Low Back Pain (CLBP). The Company is headquartered in Dublin, Ireland and has subsidiaries operating in Ireland, the United States, Australia, Germany and the Netherlands.

### **About the ReActiv8-B Clinical Trial**

Mainstay submitted the PMA application to the FDA based upon the totality of its clinical data for ReActiv8. The pivotal clinical trial upon which the PMA submission was based is the ReActiv8-B study. 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. Information about the study can be found at <https://clinicaltrials.gov/ct2/show/study/NCT02577354>.

### **About Chronic Low Back Pain**

One of the root causes of CLBP is impaired control by the nervous system of the muscles that dynamically stabilize the spine. ReActiv8 is designed to electrically stimulate the nerves responsible for contracting these muscles to improve dynamic spine stability, allowing for improvement in CLBP and its disabling effects.

People with CLBP usually have a greatly reduced quality of life and score significantly higher on scales for pain, disability, depression, anxiety and sleep disorders. Their pain and disability can persist despite the best available medical treatments, and only a small percentage of cases result from an identified pathological condition or anatomical defect that may be correctable with spine surgery. Their ability to work or be productive is seriously affected by the condition and the resulting days lost from work, disability benefits and health resource utilization put a significant burden on individuals, families, communities, industry and governments.

Further information can be found at [www.mainstay-medical.com](http://www.mainstay-medical.com)

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### **Forward looking statements**

This announcement includes statements that are, or may be deemed to be, forward looking statements. These forward looking statements can be identified by the use of forward looking terminology, including the terms “anticipates”, “believes”, “estimates”, “expects”, “intends”, “may”, “plans”, “projects”, “should”, “will”, or “explore” or, in each case, their negative or other variations or comparable terminology, or by discussions of strategy, plans, objectives, goals, future events or intentions. These forward looking statements include all matters that are not historical facts. They appear throughout this announcement and include, but are not limited to, statements regarding the Company’s intentions, beliefs or current expectations concerning, among other things, the Company’s plans to commercialize ReActiv8 in the United States, Australia and elsewhere; the commercial performance of ReActiv8; the clinical data relating to ReActiv8; and the Company’s results of operations, financial position, prospects, financing strategies, expectations for product design and development, regulatory applications and approvals, reimbursement arrangements, costs of sales and market penetration and other commercial performance.

By their nature, forward looking statements involve risk and uncertainty because they relate to future events and circumstances. Forward looking statements are not guarantees of future performance, and actual results may differ materially from those described in, or suggested by, the forward looking statements contained in this announcement. In addition, even if future results and developments are consistent with the forward looking statements contained in this announcement, those results or developments may not be indicative of results or developments in subsequent periods. A number of factors could cause results and developments of the Company to differ materially from those expressed or implied by the forward looking statements, including, without limitation, the successful launch and commercialization of ReActiv8, general economic and business conditions, global medical device market conditions, industry trends, competition, changes in law or regulation, changes in taxation regimes, the availability and cost of capital, the time required to commence and complete clinical trials, the time and process required to obtain regulatory approvals, currency fluctuations, changes in its business strategy, and political and economic uncertainty. The forward-looking statements herein speak only at the date of this announcement.

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