

Mainstay Medical Announces Participation at the American Association of Neurological Surgeons (AANS) Annual Meeting

Interactive panel session to be held Monday, August 23 at 1pm ET

Abstract by Dr. Chris Gilligan chosen for William H. Sweet Young Investigators Award

Dublin, Ireland – 23 August 2021 – Mainstay Medical Holdings plc today announced its participation in the American Association of Neurological Surgeons (AANS) Annual Scientific Meeting, to be hosted virtually on August 21-25, 2021. Mainstay Medical’s participation will focus on ReActiv8®, its implantable Restorative Neurostimulation™ system to treat intractable chronic low back pain. Notably, the abstract presentation titled “Long-Term Durability of Restorative Neurostimulation for Chronic Mechanical Low Back Pain – Two-Year Pivotal Trial Results” by Dr. Chris Gilligan, was selected to receive the William H. Sweet Young Investigators Award.

Mainstay Medical will also be sponsoring a virtual event regarding ReActiv8 featuring an interactive panel. The session titled “Targeting the Multifidus: A Paradigm Shift in Treatment Options,” will take place on August 23, 2021 from 1:00 pm – 2:00 pm ET and can be accessed through the AANS conference website at <https://virtual2021.aans.org/>. The panellists include Dr. Chris Shaffrey, Dr. Juan Uribe, Dr. Steven Falowski, Dr. Chris Gilligan and Dr. Robert Levy.

Regarding the William H. Sweet Young Investigators Award, **Dr. Chris Gilligan, Chief, Division of Pain Medicine, Department of Anaesthesiology, Perioperative and Pain Medicine, Brigham & Women’s Hospital, and Assistant Professor of Anaesthesia, Harvard Medical School,** said *“I am honored to receive this award and have the opportunity to share the long-term data from the pivotal ReActiv8-B Clinical trial, where I served as Principal Investigator. I am excited to inform my colleagues about this novel, restorative therapy and the compelling patient outcomes. ReActiv8 has the potential to change the treatment paradigm for those suffering from mechanical chronic low back pain.”*

“We are excited to introduce ReActiv8 to the AANS membership,” said Jason Hannon, CEO of Mainstay Medical. “With a mechanism-of-action that is intended to restore motor control of the multifidus muscle and thereby relieve pain in non-operative patients with severe mechanical CLBP, ReActiv8 is extremely well suited for a neurosurgery practice. Because historically no proven long-term treatments have been available for these patients, we look forward to the AANS community learning about the long-term outcomes we have achieved with ReActiv8 in multiple clinical studies.”

About Mainstay Medical

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

About ReActiv8®

ReActiv8 is an active implantable medical device designed to treat adults with intractable chronic low back pain associated with dysfunction of the lumbar multifidus muscle, a key stabilizing muscle of the low back, 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. ReActiv8 provides bilateral electrical stimulation of the L2 medial branch of the dorsal ramus nerve as it crosses the transverse process at L3. Stimulation of this nerve that supplies the multifidus muscle elicits contraction of the muscle which can lead to restoration of control over time, allowing the back to recover from CLBP.

ReActiv8 has a CE Mark allowing for commercialization in the European Economic Area. 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 Prostheses List of reimbursed products in Australia, effective as of 1 July 2020. The Prostheses List identifies implantable devices eligible for reimbursement from all private health insurance funds in Australia. In the U.S., ReActiv8 is FDA approved and Mainstay Medical commercially launched the ReActiv8 system in the summer of 2021.

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 their CLBP and the resulting days lost from work, disability benefits, and health resource utilization, exert a significant burden on individuals, families, communities, industry and governments.

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

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Forward Looking Statements

This announcement includes statements that are, or may be deemed to be, forward-looking statements 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, other variations or comparable terminology, or within 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 commercialization of ReActiv8 in the United States, the U.K., Australia and elsewhere; the commercial performance of 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 herein, including, without limitation, the successful launch and commercialization of ReActiv8, general economic and business conditions, global medical device market conditions, industry trends, competition, the availability and cost of capital, changes in law or regulation, changes in taxation regimes, the time required to commence and complete clinical trials, the time and process required to obtain regulatory approvals, currency fluctuations, changes in company’s business strategy, and political and economic uncertainty. The forward-looking statements herein speak only as of the date of this announcement.