Mainstay Medical Announces Limited Commercial Launch of ReActiv8® in the U.S.

Official launch includes new website and marketing resources to support physician and patient education

Dublin – Ireland, 29 June 2021 – Mainstay Medical Holdings plc (the "Company") today announced the limited commercial launch in the U.S. of ReActiv8, its implantable Restorative Neurostimulation™ system to treat intractable chronic low back pain. The ReActiv8 system will be available in the U.S. through ReActiv8-certified physicians commencing in the summer of 2021.

"We are delighted to commercially launch ReActiv8 in the U.S. and make this innovative Restorative Neurostimulation therapy available to Americans suffering from intractable chronic low back pain. Supported by more than 10 years of clinical research, ReActiv8 is the only proven neurostimulation system to address mechanical intractable low back pain. Physicians will finally have access to a therapy to treat these patients beyond temporary treatments designed to merely mask the pain for a limited time," **said Jason Hannon, CEO of Mainstay Medical.** *"We are launching in a limited fashion to ensure we provide proper education to physicians and assist them in selecting the appropriate patients. We look forward to expanding the availability of ReActiv8 across the U.S. over the coming months and building on the momentum we have gained in Europe and Australia to continue to improve the quality of patients' lives."*

To support the U.S. commercial launch, Mainstay Medical has launched a new corporate website centered around patient and physician education. The new company website can be accessed at: https://www.mainstaymedical.com. In addition to the new website, the Company has introduced updated tools, guidance, and training materials to assist in identifying prospective patients for ReActiv8 therapy, educating physicians on the ReActiv8 system and becoming ReActiv8-certified, and helping patients access ReActiv8 in the U.S. Specific resources include physician training protocols and modules on ReActiv8, educational and marketing collateral, and informative videos that support and further physician education, patient identification, and appropriate product use.

"We are equipping ReActiv8-certified physicians with robust tools and information to enable proper patient identification and education. We expect that these resources will facilitate the identification of strong candidates for ReActiv8 and drive compelling patient outcomes," **added Mr. Hannon.**

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). The Company 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 the Company 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.