Mainstay Medical Announces Commercial Launch of ReActiv8® in Australia

Dublin – Ireland, 8 March 2021 – Mainstay Medical Holdings plc ("**Mainstay**" or the "**Company**") today announced the commercial launch in Australia of ReActiv8®, its implantable neurostimulation system to treat chronic low back pain.

"Launching ReActiv8, our Restorative Neurostimulation therapy, commercially in Australia is a significant milestone for our global commercial expansion. Several top Australian physicians have been part of our clinical studies since inception and are among the most experienced globally in selecting and treating patients with ReActiv8. We are excited to make ReActiv8 commercially available to Australian physicians and their patients suffering from mechanical chronic low back pain," **said Jason Hannon, CEO of Mainstay.**

The first commercial ReActiv8 implant in Australia was conducted by Associate Professor Bruce Mitchell, Sports and Interventional Pain Physician and Director of Metro Pain Group in Melbourne, Australia.

"Having been involved in both the ReActiv8-A and -B Clinical Trials, I am excited to be able to expand this restorative therapy to other patients in my practice. The launch in Australia is a great milestone for ReActiv8 and, ultimately, the patients that suffer from chronic mechanical low back pain who now have a new treatment option," **said Associate Professor Bruce Mitchell.**

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.

The ReActiv8 Restorative Neurostimulation therapy 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. 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 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 plans to commercially launch in early 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 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.

About Mainstay

Mainstay 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 the United States, Australia, Germany, and the Netherlands.

Further information can be found at 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, 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, 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 its business strategy, and political and economic uncertainty. The forward-looking statements herein speak only at the date of this announcement.