Mainstay Medical Announces Regulatory Approval from Australian Therapeutic Goods Administration (TGA) for ReActiv8

- *Next step is applying for inclusion on Australian Prostheses List for private reimbursement; decision expected in the third quarter of 2020.*

DUBLIN--(BUSINESS WIRE)-- Regulatory News:

Mainstay Medical International plc (“Mainstay” or the “Company”, Euronext Paris: MSTY.PA and Euronext Growth operated by Euronext Dublin (MSTY.IE), today announced that it has received regulatory approval from the Australian Therapeutic Goods Administration (TGA) for ReActiv8, its implantable restorative neurostimulation system to treat disabling Chronic Low Back Pain. This approval confirms inclusion of ReActiv8 in the Australian Register of Therapeutic Goods (ARTG), enabling commercialization throughout Australia.

Jason Hannon, CEO of Mainstay, said: *“We are excited to receive TGA approval and take the next step toward making ReActiv8 available to patients in Australia. Australian physicians who have been part of our clinical studies to date are among the most experienced globally in selecting and treating patients with ReActiv8 therapy. The clinical data in support of ReActiv8 continues to build and was instrumental in demonstrating to TGA that ReActiv8 is a valuable therapy that should be available to Australian patients. We are moving to the next step in the process, which is applying for inclusion of ReActiv8 on the Prostheses List. We plan to launch ReActiv8 commercially after securing a place on the Prostheses List.”*

The Company plans to submit an application for ReActiv8 to be included in the Prostheses List of reimbursed products, with a reimbursement decision expected in the third quarter of 2020. The Prostheses List identifies implantable devices eligible for reimbursement from all private health insurance funds in Australia.

About ReActiv8

ReActiv8 is an active implantable medical device designed to treat people with chronic low back pain (CLBP). ReActiv8 electrically stimulates the nerves that supply the lumbar multifidus muscle, a key stabilizing muscle of the low back, to elicit contraction of the muscle which can lead to restoration of control over time, allowing the back to recover from CLBP.

Low back pain is the number one cause of years lived with disability worldwide and is 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 predmoniantly nociceptive (or mechanical) in nature there are few therapies beyond drugs and injections, both of which offer temporary relief at best. 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 estimates that there are approximately two million people in the EU and the U.S. alone who could be candidates for ReActiv8 today.

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. The Company submitted the final module of its Pre-Market Approval (PMA) application to the U.S. FDA relating to ReActiv8 in August 2019, and it expects an approval decision around the end of 2020.

About Mainstay

Mainstay 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. It has subsidiaries operating in Ireland, the United States, Australia, Germany and the Netherlands, and is listed on the regulated market of Euronext Paris (MSTY.PA) and Euronext Growth operated by Euronext Dublin (MSTY.IE).

About the ReActiv8-B Study

The ReActiv8-B Study is an international, multi-center, prospective, randomized, sham-controlled, blinded trial with one-way crossover conducted under an Investigational Device Exemption (IDE). In summary, this means that eligible patients had baseline data collected and then following verification that the enrollment criteria were met, ReActiv8 was implanted. At the 14-day post implant follow up visit, half the patients were randomized to receive appropriately programmed stimulation (the treatment arm), and half were randomized to receive sham stimulation/low stimulation (the control arm). 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 the body to recover from CLBP.

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.

CAUTION – in the United States, ReActiv8 is limited by federal law to investigational use only.

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 file an application for inclusion on the Australian Prostheses List, the timing of such filing and of the review of such application; the Company’s plans to commercialize ReActiv8; the commercial performance of ReActiv8 in the EU, Australia or elsewhere; the clinical data relating to ReActiv8; the potential for the FDA to approve ReActiv8 for marketing in the United States; 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 the actual results of the Company’s operations, the development of its main product, and the markets and the industry in which the Company operates may differ materially from those described in, or suggested by, the forward looking statements contained in this announcement. In addition, even if the Company’s results of operations, financial position and growth, and the development of its main product and the markets and the industry in which the Company operates 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 final outcome of the Company’s ReActiv8-B clinical study, the outcome of the Company’s interactions with the FDA on a PMA application for ReActiv8, 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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