Mainstay Medical Achieves CE Marking for ReActiv8® and Prepares for Commercial Launch in Germany

ReActiv8® is the only approved implantable neurostimulation system addressing cause, not just symptoms, of chronic low back pain

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

Mainstay Medical International plc (Euronext Paris: MSTY.PA and ESM of the Irish Stock Exchange: MSTY.IE), today announced that it has received CE Mark approval for ReActiv8®, its innovative and proprietary implantable neurostimulation system to treat disabling chronic low back pain. CE Marking enables commercialization of ReActiv8 in Europe.

The CE Mark approval is based on positive results from the ReActiv8-A clinical trial which demonstrated a clinically important, statistically significant and lasting improvement in pain, disability and quality of life in people with disabling chronic low back pain and few other treatment options.[1]

“CE Marking is a pivotal milestone for Mainstay. Our team has been working tirelessly towards making ReActiv8 commercially available to physicians and their patients,” Peter Crosby, CEO of Mainstay, commented. “We believe ReActiv8 has the potential to change the lives of millions of people who currently have limited treatment options for their chronic low back pain.”

ReActiv8 is indicated as an adjunct to medical management of chronic low back pain for relief of pain in adults who have attempted at least medical management and physical therapy. During patient-controlled treatment sessions, ReActiv8 stimulation causes repetitive contractions of the key stabilizing muscles in the back to support recovery from chronic low back pain and related symptoms.

Dr. Robert Pflugmacher, orthopedic surgeon at the University Hospital in Bonn, Germany said “We see several new chronic low back pain patients every week who are not indicated for surgery and who meet the indications for ReActiv8. Rather than sending them home untreated, we now have an exciting new option we can offer them. As orthopedic surgeons, ReActiv8 meets our objective of addressing the underlying functional causes of chronic low back pain, and the straightforward implant procedure utilizes skills and techniques familiar to us.”

Mainstay will initially focus its sales and marketing efforts for ReActiv8 on Germany. The launch will primarily target hospitals with a multi-disciplinary approach to back pain and a large patient population. The Company has a direct sales force which is supported by its team of experienced field clinical specialists. As Mainstay gains experience and momentum, the Company will consider expanding to additional customers and countries.

“ReActiv8 is an innovative use of neurostimulation for the treatment of chronic low back pain and the clinical data from the ReActiv8-A trial are compelling,” said Dr. Stefan Schu, neurosurgeon and neurostimulation expert at the Sana Hospital in Duisburg, Germany. “Neurosurgeons in Germany have a track record of embracing important innovations and we are looking forward to offering ReActiv8 to patients who until now were facing the prospect of disabling chronic low back pain for the rest of their lives.”

Mainstay will conduct a Post Market Clinical Follow-up to gather additional long term data. In the US, subject to the availability of sufficient financial resources, the Company plans to launch the ReActiv8-B clinical trial in support of an application for Premarket Approval (PMA) which is required for commercialization in the United States.

CE Marking

CE Marking allows companies to legally market and distribute products within the European Market, and declares the product complies with all applicable European Directives and Regulations. For Active Implantable Medical Devices (AIMDs) like ReActiv8, CE Marking is granted by a Notified Body after review of the design dossier and other information for conformity to the AIMD Directive. Following CE Marking, a product can be sold in the EEA, and certain other countries.

About Mainstay

Mainstay is a medical device company focused on bringing to market an innovative implantable 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 and Germany, and is listed on Euronext Paris (MSTY.PA) and the ESM of the Irish Stock Exchange (MSTY.IE).

About the ReActiv8-A Trial

The ReActiv8-A clinical trial is a prospective single arm clinical trial with up to 96 subjects at sites in Australia and Europe. Outcome measures for the ReActiv8-A clinical trial are assessed at a three-month endpoint after activation of stimulation and compared to baseline prior to implant. Further details can be obtained at https://clinicaltrials.gov/show/NCT01985230.

About Chronic Low Back Pain

One of the recognized root causes of CLBP is impaired control by the nervous system of the muscles that dynamically stabilize the spine in the lower back, and an unstable spine can lead to back pain. ReActiv8 is designed to electrically stimulate the nerves responsible for contracting these muscles and thereby help to restore muscle control and 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 utilisation 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 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.

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, and the development of its main product, 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 successful launch and commercialization of ReActiv8, the initiation and success of the ReActiv8-B Clinical Trial, general economic and business conditions, the 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, political and economic uncertainty. The forward-looking statements herein speak only at the date of this announcement.

[1] Please refer to the Company’s web site for the Press Release of 4 December 2015 with details of results of the ReActiv8-A Trial

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