Mainstay Medical Achieves Quality System Certification

Certification is an important step towards the commercialisation of ReActiv8.

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

Mainstay Medical International plc ("**Mainstay**" or the "**Company**") announces that its Quality Management System has been evaluated and found to be in compliance with the international quality standards ISO 13485:2003 and EN ISO 13485:2012. These international standards provide an accepted international framework for meeting medical device quality standards and compliance certification is an important step towards CE Mark and the commercialisation of ReActiv8. This certification granted by the Company's Notified Body, BSI Group-Medical Devices, covers the operational activities for developing and bringing to market implantable stimulation systems in the area of pain management.

Mainstay is focused on the development and commercialisation of ReActiv8, an innovative implantable neurostimulation device designed to treat people with Chronic Low Back Pain (CLBP) by helping to restore control to the muscles that stabilise the lumbar spine.

Mr. Peter Crosby, Mainstay's Chief Executive Officer, noted *"We are delighted that all the hard work of the Mainstay team was recognized with the ISO 13485 certification after passing the audits of our Quality Management System at all our facilities in Ireland, Australia and USA without any major observations. This is a testament to the quality and experience of the individuals in the team that made this happen, and an important step towards the commercialization of ReActiv8."*

The International Organization for Standardization (ISO) is the world's largest developer and publisher of international standards for the implementation of quality management systems and various other technical and operational procedures. In the "*full quality assurance"* conformity route the Company has chosen, the EU Active Implantable Medical Device Directive requires an evaluation of the Company's Quality Management System as a prerequisite to obtaining CE Mark. By achieving ISO 13485 certification, Mainstay has met this requirement.

Clinical trials with ReActiv8 are ongoing in Europe and Australia, and several sites continue to enrol subjects. The purpose of the clinical trial is to investigate ReActiv8 as a treatment for adults with CLBP who have few other treatment options.

About Mainstay

Mainstay is a medical device company which is developing an innovative implantable neurostimulation medical device, ReActiv8, for people with CLBP. Low Back Pain is a leading cause of activity limitation and work absence throughout much of the developed world, imposing a high economic burden on individuals, families, communities, industry, and governments.

The Company is headquartered in Dublin, Ireland. It has subsidiaries operating in Ireland, the United States and Australia, and is listed on Euronext Paris (MSTY.PA) and the ESM of the Irish Stock Exchange (MSTY.IE).

About Chronic Low Back Pain

One of the recognised root causes of CLBP is impaired control by the nervous system of the muscles that 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 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 spinal 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 economies.

Further information can be found at www.mainstay-medical.com

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” or “will”, 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 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 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 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, 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, currency fluctuations, changes in its business strategy, political and economic uncertainty. The forward-looking statements herein speak only at the date of this announcement.

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