Mainstay Medical Applies for CE Mark for ReActiv8®

A key step towards European commercialisation of innovative treatment of chronic low back pain

Dublin – Ireland, 2 November 2015 – Mainstay Medical International plc (**Mainstay** or the **Company,** Euronext Paris: MSTY.PA and ESM of the Irish Stock Exchange: MSTY.IE), a medical device company focused on bringing to market ReActiv8®, an implantable neurostimulation system to treat disabling Chronic Low Back Pain, announces it has submitted an application for CE Mark for ReActiv8. The submission represents a further key step towards commercialisation of ReActiv8 in Europe.

Mainstay's application for CE Mark includes the results of the ReActiv8-A Clinical Trial which showed clinically important, statistically significant, and lasting improvement in pain, disability, and quality of life for people with Chronic Low Back Pain and limited treatment options[1].

Peter Crosby, CEO of Mainstay, said: *"The application for CE Mark approval is a significant milestone for Mainstay and follows the successful results of our ReActiv8-A trial. With FDA approval to start the ReActiv8-B Clinical Trial to gather data for an application for US approval, we are moving towards our goal of commercialisation of ReActiv8 in major world markets. We believe ReActiv8 has the potential to change the lives of millions of people who have no effective treatment for their chronic low back pain and we are now a step closer to selling ReActiv8 in Europe."*

ReActiv8-A (http://clinicaltrials.gov/show/NCT01985230) is an international, multi-centre, prospective single arm clinical trial that recruited subjects who were not candidates indicated for surgery or spinal cord stimulation, and who had attempted other therapies, including at least physical therapy.

Data have been reported for the first 46 subjects in the ReActiv8-A trial. After 90 days of treatment with ReActiv8, 63% of people showed a clinically important improvement in their low back pain, 57% showed a clinically important improvement in their disability and 67% showed a clinically important improvement in their quality of life. Improvements in low back pain, disability and quality of life were generally consistent or improved at 180 days.

In addition to the clinical results, the application for CE Mark includes extensive information about the design, testing, manufacturing, and quality system for ReActiv8, and is the culmination of several years' work.

Mainstay's notified body will review the application for CE Mark, and Mainstay will respond to questions and/or requests for additional data during the review process.

Mainstay Medical plans to establish its own direct sales force for commercialisation of ReActiv8 in key European markets starting in 2016, subject to CE Mark approval.

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CE Marking

CE Marking is a mandatory conformity marking for certain products sold within the European Economic Area since 1985, and is a declaration that the product meets the essential requirements of the applicable EC directives. 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 which is developing 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 and Australia, and is listed on Euronext Paris (MSTY.PA) and the ESM of the Irish Stock Exchange (MSTY.IE).

1 Please see Mainstay's website for a full description of the ReActiv8-A Results in the press release of 31 August 2015.

About Chronic Low Back Pain

One of the recognised root causes of CLBP is impaired control by the nervous system of the muscles that dynamically stabilise 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

ReActiv8 is an investigational device and is not approved for commercialisation anywhere in the world. CAUTION – in the United States, ReActiv8 is limited by federal law to investigational use only.

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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” 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 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 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, 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.