Mainstay Medical Announces Pre-IDE Submission for ReActiv8® to FDA

Mainstay Medical continues progress towards the commercialisation of ReActiv8.

Dublin – Ireland, 7th July 2014 – Mainstay Medical International plc *(Euronext Paris: MSTY.PA and ESM of the Irish Stock Exchange: MSTY.IE)* announces that it has submitted a Pre-Investigational Device Exemption ('IDE') information package to the US Food and Drug Administration ('FDA' or the 'Agency') for ReActiv8, its innovative implantable neurostimulation device for the treatment of people with Chronic Low Back Pain.

Under the Pre-IDE Submission Program of the FDA, Mainstay can request feedback from the Agency on its planned ReActiv8 IDE submission. The FDA states that *"Receiving and incorporating FDA feedback on various elements of a future IDE submission, such as the proposed study design or statistical analysis plan, can facilitate the IDE review process and reduce the number of review cycles needed to reach full IDE approval."*[1]

Mr. Peter Crosby, Mainstay's Chief Executive Officer, noted *"The pre-IDE submission to the FDA is a significant step on the path to regulatory approval and commercialization of ReActiv8. We will consider the FDA's feedback in our planned IDE submission. When available, ReActiv8 has the potential to change the lives of the millions of people who suffer from Chronic Low Back Pain."*

Clinical trials with ReActiv8 are ongoing in Europe and Australia, and several sites have been actively enrolling subjects since March 2014. The purpose of the trial is to investigate ReActiv8 as a treatment for adults with debilitating Chronic Low Back Pain who have few other treatment options.

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About Mainstay

Mainstay is a medical device company which is developing an innovative implantable neurostimulation medical device, ReActiv8, for people with debilitating Chronic Low Back Pain (CLBP). Low Back Pain is the 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 debilitating 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.

[1] Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff. Guidance for Industry and Food and Drug Administration Staff. Document issued on: February 18, 2014.

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” 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.