

Mainstay Medical Expands Clinical Trial of ReActiv8® for People with Chronic Low Back Pain to the United Kingdom

Mainstay Medical continues progress towards the commercialisation of ReActiv8.

Dublin – Ireland, 28th July 2014 – Mainstay Medical International plc (*Euronext Paris: MSTY.PA and ESM of the Irish Stock Exchange: MSTY.IE*) announces that it has received authorization from the Medicines and Healthcare Products Regulatory Agency (MHRA) and the Central Ethics Committee to expand the clinical trial of ReActiv8, its innovative implantable neurostimulation device for the treatment of people with Chronic Low Back Pain, to include clinical trial sites in the United Kingdom. Enrolment of subjects is commencing in these additional sites. Two of these sites also participated in the European Feasibility Study, results of which were presented in mid-2013.

Mr. Peter Crosby, Mainstay's Chief Executive Officer, noted *"We are pleased to expand the clinical trial to the UK sites as planned. This continues our steady progress towards regulatory approval and commercialization of ReActiv8. When available, ReActiv8 has the potential to change the lives of the millions of people who suffer from Chronic Low Back Pain."*

The clinical trial of ReActiv8 started in March 2014, and several sites in Australia and Belgium continue to actively enrol subjects. The purpose of the clinical trial is to investigate ReActiv8 as a treatment for adults with debilitating Chronic Low Back Pain who have few other treatment options. More details of the clinical trial, including identification of active investigation sites, can be found at www.clinicaltrials.gov/show/NCT01985230.

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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 and the ESM of the Irish Stock Exchange.

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.

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

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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, and political and economic uncertainty. The forward-looking statements herein speak only at the date of this announcement.