

Mainstay Medical Starts Commercialization of ReActiv8® for the Treatment of Chronic Low Back Pain

First sale and implant in Germany following CE Marking

Dublin – Ireland, 1 February 2017 – 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 (“**CLBP**”), announces the first sale and implant of ReActiv8 in Germany.

The ReActiv8 implant was performed by Dr. med. Francis Kilian, Orthopedic and Neurosurgeon at the Catholic Hospital Koblenz-Montabaur in Koblenz Germany.

Dr. Kilian commented: *“As spine surgeons we are always looking to address the underlying cause of a patient’s condition but until now we had no effective option to offer to patients with Chronic Low Back Pain due to impaired control of their back muscles. ReActiv8 represents a significant breakthrough for this large group of patients who are not candidates for spine surgery and fills an important void in our restorative treatment portfolio.”*

ReActiv8 works by electrically stimulating the nerves responsible for contracting the key stabilizing muscles of the lumbar spine. Activation of these muscles to restore functional spine stability has been shown to facilitate recovery from CLBP.

Peter Crosby, CEO of Mainstay, commented: *“The first sale and implant of ReActiv8 in Germany is an important milestone for Mainstay. We are fully committed to working with our customers to integrate ReActiv8 into their routine clinical practice and provide a new option for many people suffering from chronic low back pain.”*

Mainstay’s European commercial activities for ReActiv8 are initially focused on Germany where the Company aims to drive adoption of ReActiv8 in a select number of high volume multi-disciplinary spine care centers. As the Company gains experience and momentum, it will expand to other sites and countries.

Mainstay received CE Marking for ReActiv8 supported by positive results from the ReActiv8-A Clinical Trial that demonstrated a clinically important, statistically significant and lasting improvement in pain, disability and quality of life in people with disabling CLBP and few other treatment options.

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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 its ordinary shares are admitted to trading 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 dynamically stabilise the spine in the low 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.

PR and IR Enquiries:**Consilium Strategic Communications (international strategic communications – business and trade media)**

Chris Gardner, Mary-Jane Elliott, Jessica Hodgson, Hendrik Thys
Tel: +44 203 709 5700 / +44 7921 697 654
Email: mainstaymedical@consilium-comms.com

FTI Consulting (for Ireland)

Jonathan Neilan
Tel: +353 1 663 3686
Email: jonathan.neilan@fticonsulting.com

NewCap (for France)

Julie Coulot
Tel: +33 1 44 71 20 40
Email: jcoulot@newcap.fr

AndreasBohne.Com/Kötting Consulting (for Germany)

Andreas Bohne
Tel : +49 2102 1485368
Email : abo@andreasbohne.com

Wilhelm Kötting
Tel: +49 69 75913293
Email: wkotting@gmail.com

Investor Relations:**LifeSci Advisors, LLC**

Brian Ritchie
Tel: + 1 (212) 915-2578
Email: britchie@lifesciadvisors.com

ESM Advisers:

Davy

Fergal Meegan or Barry Murphy

Tel: +353 1 679 6363

Email: fergal.meegan@davy.ie or barry.murphy2@davy.ie

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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”, “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 commercialisation of ReActiv8, the progress 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.