Mainstay Medical's ReActiv8-B Clinical Trial for Treatment of Chronic Low Back Pain Enrolls First Subject

Trial to gather data in support of an application for US pre-market approval (PMA)

Dublin – Ireland, 14 September 2016 – 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 enrolment of the first subject in the ReActiv8-B Clinical Trial ("**the Clinical Trial**"), which is intended to gather data in support of an application for pre-market approval (PMA) from the US Food and Drug Administration (FDA), a key step towards commercialization of ReActiv8 in the US.

The first subject was enrolled at the Genesis Research Services center in Newcastle, NSW, Australia by Dr. Marc Russo, and if all eligibility criteria are met, will be implanted with ReActiv8 within a few weeks. As more investigational sites are activated, the information at https://clinicaltrials.gov/show/NCT02577354 will be updated.

ReActiv8 is designed to electrically stimulate the nerves responsible for contracting muscles which stabilize the lumbar spine. Activation of these muscles to restore functional stability has been shown to facilitate recovery from CLBP. Mainstay received CE Marking for ReActiv8 in May 2016 based on positive results from the ReActiv8-A clinical trial which demonstrated a clinically important, statistically significant and lasting improvement in pain, disability and quality of life in people with disabling Chronic Low Back Pain and few other options.[1]

Dr Chris Gilligan, Chief of the Division of Pain Medicine and Co-Director of the Spine Center at Beth Israel Deaconess Medical Center in Boston, MA, and Principal Investigator for the ReActiv8-B Clinical Trial said: *"Chronic Low Back Pain is a major global challenge and many patients have been suffering from the condition for many years and are left with few treatment options. ReActiv8 offers a unique new approach which addresses cause and not simply symptoms. We look forward to gathering the clinical evidence required for Mainstay to make an application for PMA approval which would make ReActiv8 also commercially available to patients in the US."*

Peter Crosby, CEO of Mainstay, commented: *"The enrolment of the first subject in the ReActiv8-B Clinical Trial is yet another significant step for Mainstay this year following the CE Marking for ReActiv8 in May, triggering the start of commercialization activities in our first European market, Germany, and the raising of €30m new capital in June."*

ReActiv8-B Clinical Trial

1 Please refer to the Company's web site for the Press Release of 4 December 2015 with details of results of the ReActiv8-A Trial

The ReActiv8-B Clinical Trial is an international, multi-center, prospective randomized sham controlled blinded trial with one-way crossover, conducted under an Investigational Device Exemption (IDE). The statistical design of the Clinical Trial requires data from the pivotal cohort of 128 randomized subjects at the 120-day primary outcome assessment visit.

The primary efficacy endpoint of the ReActiv8-B Clinical Trial is a comparison of responder rates between the treatment and control arms. The Clinical Trial will be considered a success if there is a statistically significant difference in responder rates between the treatment and control arms. The Clinical Trial, if successful, will provide what is referred to as Level 1 Evidence of safety and efficacy of ReActiv8, which may be used to support applications for favourable reimbursement in the USA. Evidence from the ReActiv8-B Trial will also be used to support market development activities worldwide.

Based on experience with enrolment in the ReActiv8-A Clinical Trial, it is estimated that full enrolment of the pivotal cohort in the ReActiv8-B Clinical Trial will take 12 to 18 months, with results anticipated to be available approximately six months following full enrolment.

Further details can be found at https://clinicaltrials.gov/show/NCT02577354.

CAUTION – in the United States, ReActiv8 is limited by federal law to investigational use only.

- End -

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 the ReActiv8-B Clinical Trial

The ReActiv8-B Clinical Trial is an international, multi-center, prospective randomized sham controlled blinded trial with one-way crossover conducted under an Investigational Device Exemption (IDE). The ReActiv8-B Clinical Trial is designed to generate data to form part of the Pre-Market Approval Application (PMAA) of ReActiv8 to the FDA. Further details can be found at https://clinicaltrials.gov/show/NCT02577354

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

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

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

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.