Mainstay Medical Gains Approval to Start US Clinical Trial of ReActiv8®

DUBLIN--(BUSINESS WIRE)-- Mainstay Medical International plc ("**Mainstay**" or the "**Company**" listed on Euronext Paris: MSTY.PA and ESM of the Irish Stock Exchange: MSTY.IE) has received approval from the United States Food and Drug Administration (FDA) to begin a clinical trial of ReActiv8® under an Investigational Device Exemption (IDE). ReActiv8 is an innovative implantable neurostimulation system designed to reduce the pain and disability of Chronic Low Back Pain (CLBP) by helping to restore control to the muscles that dynamically stabilise the lumbar spine.

"The FDA approval to start a US clinical trial of ReActiv8 is a major step towards our goal of bringing ReActiv8 to the US market," said Peter Crosby, the CEO of Mainstay Medical*. "We are impressed with the FDA's responsiveness during the development and review of this trial. It helped us to develop a clinical trial to meet the needs of the Company, the FDA, and the millions of people who could potentially benefit from ReActiv8."*

The FDA approval is for the planned ReActiv8-B trial, an international, multi-centre, prospective randomized sham-controlled trial designed to evaluate the safety and efficacy of ReActiv8 for the treatment of adults with CLBP and no prior back surgery.

The approval is to conduct the ReActiv8-B trial at up to 40 clinical trial sites and for 128 randomized subjects to be implanted with ReActiv8 in the pivotal cohort. The IDE approval allows the Company to engage with investigators, clinical trial sites, and Institutional Review Boards (IRBs or Ethics Committees) leading towards the first subject recruitment and implant. Upon successful completion of the ReActiv8-B Trial and if the results support it, the Company plans to submit an application for a Pre-Market Approval (PMA) which is required to allow the start of commercialization in the United States.

In the approval letter, the FDA provided some helpful study design recommendations which the Company is considering, and it is possible that one or more IDE supplements may be submitted in the coming months.

Protocol details will be published on www.clinicaltrials.gov before the start of the ReActiv8-B Trial.

The Principal Investigator for the trial is Dr Christopher Gilligan, Chief, Division of Pain Medicine at Beth Israel Deaconess Medical Center in Boston, and Assistant Professor of Anaesthesiology at Harvard Medical School. Dr Gilligan is head of the Data Monitoring Committee of the ongoing ReActiv8-A Trial.

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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 disabling Chronic Low Back Plan (CLBP). Low Back Pain is a 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 the ReActiv8-A Trial

The ReActiv8-A clinical trial, is a prospective single arm clinical trial with up to 96 subjects at sites in Australia and Europe. Outcome measures for the ReActiv8-A clinical trial are assessed at a three month endpoint after activation of stimulation and compared to baseline prior to implant. Further details can be obtained at https://clinicaltrials.gov/show/NCT01985230.

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 economies.

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.

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 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, currency fluctuations, changes in its business strategy, political and economic uncertainty. The forward-looking statements herein speak only at the date of this announcement.

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