Mainstay Medical Announces Positive Outcome of Interim Analysis

Jason Hannon, CEO, to host business update call

Dublin – Ireland, 11 December 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 restorative neurostimulation system to treat disabling Chronic Low Back Pain, announces a positive outcome of the Interim Analysis in its U.S. Pivotal ReActiv8-B Study (the "Study"), comprising a definitive size and an estimated completion date.

Key updates relative to the Study (and its design) are as follows:

- The Study utilizes an adaptive trial design, inclusive of an Interim Analysis, to determine the definitive size of the Study of up to 232 patients in the pivotal cohort. With this adaptive design, Mainstay commenced the Study with a sample size of 128 patients pending the Interim Analysis;
- The independent Data Monitoring Committee ("**DMC**") has completed the Interim Analysis, which is based on data from the first 58 patients in the pivotal cohort to complete the primary endpoint. The DMC has recommended continuation of the Study with a definitive size of 168 evaluable patients. The ultimate number of patients in the Study will be slightly higher than 168 due to the nature of the enrollment process;
- The DMC also reported that they have observed no safety concerns in the Study; and
- The Study is expected to be fully enrolled by the end of the second quarter of 2018, and the Company expects to announce full data readout towards the end of 2018.

133 patients have been implanted in the pivotal cohort in the Study to date and clinical study sites have continued to implant patients pending the outcome of the Interim Analysis.

The Study is intended to gather data in support of an application for pre-market approval (PMA) from the U.S. Food and Drug Administration (FDA), a key step towards commercialization of ReActiv8 in the U.S..

Richard Rauck MD, President and Founder, Carolinas Pain Institute, Medical Director for The Center for Clinical Research, Pain Fellowship Director at Wake Forest University School of Medicine and Chairman of the DMC said: *"The outcome of the Interim Analysis has validated the adaptive Study design agreed with the FDA, which provided for a sample size of up to 232 patients in the pivotal cohort. By following this course, we have been able to determine an appropriate sample size for the Study. We also reviewed the safety data and I am pleased to report there are no safety concerns in the Study thus far."*

Jason Hannon, CEO, said: *"We are pleased to now have a definitive enrollment goal for the Study, which compares favorably in total size to other neuromodulation studies. We will now push forward to the data collection point in a highly efficient manner, and I am confident we will complete the Study in the coming months and announce the full data readout towards the end of 2018."*

Chris Gilligan MD, Chief, Division of Pain Medicine, Department of Anesthesiology, Perioperative and Pain Medicine, Brigham & Women's Hospital, Assistant Professor of Anaesthesia, Harvard Medical School, and Principal Investigator for the ReActiv8-B Study said: *"The treatment of Chronic Low Back Pain is a significant challenge around the world with many patients experiencing disabling effects for large portions of their lives. These patients can be left with few treatment options. I'm proud to be part of a clinical study that is analyzing whether we can use ReActiv8 to help patients truly restore their muscle function and thereby reduce the effects of chronic pain, rather than rely on short term analgesics such as opioids. I look forward to the compilation of the data."*

Investor Conference Call and Business Update

Jason Hannon will host an investor conference call to discuss this positive news and will also provide a broader business update at 16:00 GMT (11:00 EST) on 11 December 2017 in English.

Dial-ins for the call are outlined below:

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In addition to the update on the Interim Analysis, the business update will include the following developments:

- The Company continues to advance the initial commercialization of ReActiv8 in Europe. Our European commercial activities are initially focused on Germany, where we are working to drive adoption in a select number of high volume spine care centers to develop reference sites. Four centers in Germany and Ireland have implanted patients with ReActiv8 to date, and several additional sites have been trained. We have begun recruiting an experienced sales team of direct Mainstay employees. The team currently consists of eight people, located in key regions in Germany and one person in Ireland.
- Mainstay is planning to add to its investment in commercial infrastructure to expand commercialization in Europe and in preparation for commercialization in other markets including Australia and the U.S. We will be building a market development team of clinical experts to drive market penetration, identify the right physician partners, help educate the market about Reactiv8, and support implants.
- We will also increase our investment in the training of physicians; the education of referring physicians regarding the potential of ReActiv8; and in the collection and dissemination of clinical data regarding the expanding use of ReActiv8.
- Cash on hand at 30 November 2017 was $12.7 million. The Company on an ongoing basis explores potential financing opportunities to fund the business.

- End –

This announcement contains inside information within the meaning of the EU Market Abuse Regulation 596/2014

About Mainstay

Mainstay is a medical device company focused on bringing to market an innovative implantable restorative 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, Germany and the Netherlands, 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 Study

The ReActiv8-B Study is an international, multi-center, prospective randomized sham controlled blinded trial with one-way crossover conducted under an Investigational Device Exemption (IDE). In summary, this means that eligible subjects will have baseline data collected and then following verification that the enrollment criteria are met, ReActiv8 will be implanted. At the 14-day post implant follow up visit, half the patients will be randomized to receive appropriately programmed stimulation (the treatment arm), and half will be randomized to receive sham stimulation/minimal stimulation (the control arm) .The ReActiv8-B Study is designed to generate data to form part of the Pre-Market Approval Application (PMAA) of ReActiv8 to the FDA.

About Chronic Low Back Pain

One of the recognized root causes of CLBP is impaired control by the nervous system of the muscles that dynamically stabilize 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 utilization 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.

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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 commercialization of ReActiv8®, the progress and success of the ReActiv8-B Clinical Study, the ability to raise additional capital to fund the Company’s business and the cost of such capital, general economic and business conditions, the global medical device market conditions, industry trends, competition, changes in law or regulation, changes in taxation regimes, 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.