Mainstay Medical Announces Completion of Day 100 Meeting with FDA Regarding Pre-Market Approval (PMA) Application for ReActiv8

Dublin – Ireland, 11 December 2019 – Mainstay Medical International plc ("Mainstay" or the "Company", Euronext Paris: MSTY.PA and Euronext Growth operated by Euronext Dublin (MSTY.IE), a medical device company focused on bringing to market ReActiv8, an implantable restorative neurostimulation system to treat disabling Chronic Low Back Pain, today announced that on 10 December 2019 the Company completed a Day 100 meeting with the U.S. Food and Drug Administration (FDA) regarding a Pre-Market Approval (PMA) application submission for ReActiv8.

Jason Hannon, CEO of Mainstay, said: *"We appreciate the opportunity to meet with FDA to discuss their review of the data we included in the PMA. The productive dialogue will help us submit an amendment to the PMA to reflect FDA's feedback. We continue to expect a decision regarding approval around the end of 2020."*

FDA generally meets with the PMA sponsor approximately 100 days after filing of the PMA for the purpose of discussing the status of the review of the application. Prior to the meeting, FDA provided Mainstay with its initial feedback on the PMA, consisting of questions regarding the data included in the PMA and the interpretation of such data. The Company currently has no plans to conduct another premarket pivotal IDE trial for ReActiv8.

Mainstay will include the information requested by FDA in an amendment to the PMA, which the Company expects to file in the first quarter of 2020.

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About Mainstay

Mainstay is a medical device company focused on commercializing 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 is listed on the regulated market of Euronext Paris (MSTY.PA) and Euronext Growth operated by Euronext Dublin (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 patients had baseline data collected and then following verification that the enrollment criteria were met, ReActiv8 was implanted. At the 14-day post implant follow up visit, half the patients were randomized to receive appropriately programmed stimulation (the treatment arm), and half were randomized to receive sham stimulation/low stimulation (the control arm). Information about the study can be found at https://clinicaltrials.gov/ct2/show/study/NCT02577354.

About Chronic Low Back Pain

One of the root causes of CLBP is impaired control by the nervous system of the muscles that dynamically stabilize the spine. ReActiv8 is designed to electrically stimulate the nerves responsible for contracting these muscles to 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 plans to file an amendment to its PMA application with the FDA for ReActiv8, the timing of such filing and of the FDA’s review of such amended application, the clinical data relating to ReActiv8, the potential for the FDA to approve ReActiv8

for marketing in the United States, and 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 and other commercial performance.

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, the development of its main product, and 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 final outcome of the Company's ReActiv8-B clinical study, the outcome of the Company's interactions with the FDA on the PMA application for ReActiv8, the successful launch and commercialization of ReActiv8, general economic and business conditions, 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, and political and economic uncertainty. The forward-looking statements herein speak only at the date of this announcement.