

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

- PMA submission for ReActiv8 expected this summer

DUBLIN--([BUSINESS WIRE](#))-- Regulatory News:

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 announces that on 25 June 2019 the Company completed a pre-submission meeting with the U.S. Food and Drug Administration regarding a Pre-Market Approval (PMA) application submission for ReActiv8.

Jason Hannon, CEO of Mainstay, said: “We believe in a rigorous, evidence-based approach to the evaluation of ReActiv8, and we appreciate the opportunity to meet with the FDA on the data we have generated to date relating to the efficacy and safety of this novel therapy. We expect to submit the final module of our PMA application to the FDA relating to ReActiv8 this summer, with a decision on approval expected around the end of 2020.”

Separately, Mainstay also announced that it has entered into an amendment to its agreement with IPF Partners relating to its existing debt facility. Under the amendment, the deadline for Mainstay to qualify to draw down a new tranche of €3.0 million (approximately \$3.34 million) in debt was extended from June 30, 2019 to July 31, 2019.

– End –

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 the ESM of Euronext Dublin (MSTY.IE).

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.

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 a PMA application with the FDA for ReActiv8, the timing of such filing and of the FDA's review of such 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 a 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.

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Source: Mainstay Medical International plc