Mainstay Medical Announces Acceptance For Filing by US FDA Of Pre-Market Approval (PMA) Application for ReActiv8

Dublin – Ireland, 1 October 2019 – Mainstay Medical International plc ("Mainstay" or the "Company", Euronext Paris: MSTY.PA and Euronext Growth of Euronext Dublin: MSTY.IE), a medical device company focused on bringing to market ReActiv8®, an implantable neurostimulation system to treat disabling Chronic Low Back Pain, today announces that the U.S. Food and Drug Administration (FDA) has accepted for filing the Company's Pre-Market Approval (PMA) application for ReActiv8.

Mainstay submitted the PMA to the FDA in August. By regulation, the FDA will notify the applicant whether the PMA has been accepted for filing within 45 days after submission. By accepting the Company's PMA for filing, the FDA has made a threshold determination that the application is sufficiently complete to begin an in-depth review. Mainstay continues to expect a decision on approval around the end 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 regulated market of the Euronext Paris (MSTY.PA) and the Euronext Growth market 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.

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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 FDA’s review of the Company’s PMA application for ReActiv8, the clinical data relating to ReActiv8, and the potential for the FDA to approve ReActiv8 for marketing in the United States.

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 trial, 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.