

Mainstay Medical Announces Additional U.S. Patent Issued

Dublin – Ireland, 26 October 2016 – 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 neurostimulation system to treat disabling Chronic Low Back Pain (“**CLBP**”), today announced the issuance of a new U.S. Patent, which strengthens its intellectual property portfolio.

- U.S. Patent No. 9,474,906 “*Systems and Methods for Restoring Muscle Function to the Lumbar Spine*”

Corresponding applications have been made in other countries. Mainstay continues to add to its portfolio of issued patents and pending applications.

Peter Crosby, CEO of Mainstay, commented: “*This new U.S. patent bolsters our growing intellectual property portfolio, which now includes eight issued U.S. patents. We are proud of the continued development of the intellectual property underpinning ReActiv8, a medical device which offers a new approach to the treatment of CLBP, addressing cause and not simply symptoms.*”

ReActiv8 is designed to electrically stimulate the nerves responsible for contracting muscles which stabilize the lumbar spine. Activation of these muscles to restore functional stability has been shown to facilitate recovery from CLBP. Mainstay received CE Marking for ReActiv8 in May 2016 based on positive results from the ReActiv8-A Clinical Trial that demonstrated a clinically important, statistically significant and lasting improvement in pain, disability and quality of life in people with disabling CLBP and few other treatment options.¹

The ReActiv8-B Clinical Trial is intended to gather data in support of an application for pre-market approval (PMA) from the U.S. Food and Drug Administration (FDA), and the first subject in the Clinical Trial was implanted with ReActiv8 in October 2016.

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¹ Please refer to the Company’s web site for the Press Release of 20 September 2016 with details of results of the ReActiv8-A Clinical Trial and follow-up data after a one-year period.

About Mainstay

Mainstay is a medical device company focused on bringing to market an innovative implantable 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 and Germany, and its ordinary shares are admitted to trading on Euronext Paris (MSTY.PA) and the ESM of the Irish Stock Exchange (MSTY.IE).

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 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 utilisation 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

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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 commercialisation of ReActiv8, the progress and success of the ReActiv8-B Clinical Trial, 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, 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.