

## Mainstay Medical Applies to Start US Clinical Trial of ReActiv8®

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

Mainstay Medical International plc ("**Mainstay**" or the "**Company**" listed on Euronext Paris: MSTY.PA and ESM of the Irish Stock Exchange: MSTY.IE) has submitted an application to the United States Food and Drug Administration (FDA) to begin a clinical trial of ReActiv8® under an Investigational Device Exemption (IDE). ReActiv8 is an innovative implantable neurostimulation device designed to treat people with disabling Chronic Low Back Pain (CLBP) for whom conventional therapy has not been successful and for whom surgery is not indicated.

The goal of ReActiv8 is to reduce pain and disability by addressing the root cause of CLBP in many people by helping to restore control to the muscles that dynamically stabilise the lumbar spine.

The clinical trial protocol submitted to the FDA as part of the IDE submission is for an international, multi-centre, prospective randomized controlled trial designed to show safety and efficacy of ReActiv8. The IDE submission includes details of the extensive preclinical and clinical testing conducted on ReActiv8. Upon successful completion of the trial and if the results support it, the Company plans to submit an application for a Pre-Market Approval (PMA) which is the final step to allow start of commercialization in the United States.

*"The submission of the IDE application to start a US clinical trial of ReActiv8 marks a significant milestone in our journey to bring ReActiv8 to the US market," said Peter Crosby, the CEO of Mainstay Medical. "As with all IDE applications, we anticipate that there may be one or more rounds of review by the FDA as we work together to develop a clinical trial that meets the needs of the Company, the FDA, and the millions of people who could potentially benefit from ReActiv8."*

Currently, ReActiv8 is an investigational device and is not approved for commercialisation anywhere in the world. The ReActiv8-A Trial is ongoing in Europe and Australia to gather data to support an application for a CE Mark which, if granted, would allow start of commercialization in Europe.

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### About Mainstay

Mainstay is a medical device company which is developing an innovative implantable neurostimulation medical device, ReActiv8, for people with CLBP. Low Back Pain is a leading cause of activity limitation and work absence throughout much of the developed world, imposing a high economic burden on individuals, families, communities, industry, and governments.

The Company is headquartered in Dublin, Ireland. It has subsidiaries operating in Ireland, the United States and Australia, and is listed 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 lower back, and a dynamically 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 disabled by 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 economies.

Further information can be found at [www.mainstay-medical.com](http://www.mainstay-medical.com)

### 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” or “will”, 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 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 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, 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, currency fluctuations, changes in its business strategy, political and economic uncertainty. The forward-looking statements herein speak only at the date of this announcement.

## Contacts

### Media:

FTI Consulting

Jonathan Neilan, +353 1 663 3686

[jonathan.neilan@fticonsulting.com](mailto:jonathan.neilan@fticonsulting.com)

or

FTI Consulting (French language enquiries)

Astrid Villette, +33 1 47 03 69 51

[Astrid.Villette@fticonsulting.com](mailto:Astrid.Villette@fticonsulting.com)

or

### Investor relations:

The Trout Group LLC

Jillian Connell, +1 646 378 2956 / +1 617 309 8349

[jconnell@troutgroup.com](mailto:jconnell@troutgroup.com)

or

### ESM Advisers:

Davy

Fergal Meegan or Barry Murphy, +353 1 6796363

[fergal.meegan@davy.ie](mailto:fergal.meegan@davy.ie) or [barry.murphy2@davy.ie](mailto:barry.murphy2@davy.ie)

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