ReActiv8-A Clinical Trial – Sustained Performance at One Year

One-year data confirm clinically important, statistically significant, and lasting improvement in pain, disability and quality of life for people with Chronic Low Back Pain and limited treatment options

Dublin – Ireland, 20 September 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 one-year results from the ReActiv8-A Clinical Trial, an international, multi-centre, prospective, single arm trial for ReActiv8 in people with disabling CLBP and few other treatment options.[1]

The one-year results show sustained performance in the ReActiv8-A Clinical Trial at the one-year follow-up with a clinically important, statistically significant and lasting improvement in the study's key endpoints for pain[2] (NRS), disability[3] (ODI) and quality of life[4] (EQ-5D).

Peter Crosby, CEO of Mainstay, said: *"We are very encouraged to see such strong and lasting benefits in this difficult to treat population. After one year of ReActiv8 treatment, 88% of subjects reported a clinically important improvement in one or more of the study endpoints, 81% were satisfied or very satisfied with the treatment and the majority continued to use the ReActiv8 treatment."*

The results presented are based on data from the first 47 subjects implanted in the ReActiv8-A Trial of whom 46 have completed the 90-day follow-up, 45 the 180-day follow-up and 41 the one-year follow-up.

To facilitate future comparison of results in the ReActiv8-A and the ReActiv8-B trial, all outcomes are presented relative to the data collected at the enrolment visit.

- Results for all subjects at 90 days, 180 days and 1 year respectively are:
  - **93%, 87%** and **88%** with clinically important improvement in one or more of the study's key endpoints.
  - **63%, 58%** and **56%** with clinically important improvement in low back pain NRS on the day.
  - **50%, 53%** and **59%** with clinically important improvement in ODI.
  - **89%, 82%** and **80%** with clinically important improvement in EQ-5D.
  - **61%, 67%** and **62%** reported>50% pain relief.
  - **89%, 84%** and **81%** were satisfied with ReActiv8 treatment.

The results for EQ-5D and ODI previously announced were relative to data collected at the pre-implant visit to 90 days and 180 days and were:

- 57% and 60% with clinically important improvement in ODI.
- 67% and 73% with clinically important improvement in EQ-5D.

Adverse Events (AEs) incidence and type were comparable to AEs in clinical trials reported for other neurostimulation devices, with no unanticipated AEs and no serious AEs related to the device, therapy or procedure.

---

1 Please refer to the Company's web site for the Press Release of 4 December 2015 with details of results of the ReActiv8-A Trial

2 Dworkin, R. H., Turk, D. C., Wyrwich, K. W., Beaton, D., Cleeland, C. S., Farrar, J. T., Zavisic, S. (2008). Interpreting the clinical importance of treatment outcomes in chronic pain clinical Trials: IMMPACT recommendations. The Journal of Pain: Official Journal of the American Pain Society, 9(2), 105–21.

3 Ostelo, R. W. J. G., Deyo, R. A., Stratford, P., Waddell, G., Croft, P., Von Korff, M., … de Vet, H. C. W. (2008). Interpreting change scores for pain and functional status in low back pain: towards international consensus regarding minimal important change. Spine, 33(1), 90–4.

4 Soer, R., Reneman, M. F., Speijer, B. L. G. N., Coppes, M. H., & Vroomen, P. C. A. J. (2012). Clinimetric properties of the EuroQol-5D in patients with Chronic Low Back Pain. Spine Journal, 12(11), 1035–1039.

- The observed lead migration incidence (<1%) demonstrates that the ReActiv8 lead mitigates the risk of lead migration identified with commercially available neurostimulation leads in the earlier Feasibility Trial.
- The Company previously announced a modification of the implant surgical approach to mitigate the risk of conductor fractures inside the lead, which had been observed in the ReActiv8-A Trial at that time. To date, no subject implanted with the currently used midline approach has required lead revision surgery.

Subjects continue to be enrolled in the ReActiv8-A Trial as part of a Post Market Clinical Follow Up to gather additional data on performance and safety.

ReActiv8 is for treatment of people who suffer from CLBP, have attempted most or all available treatment options, and are not candidates for back surgery or spinal cord stimulation. 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.

Further details can be found at https://clinicaltrials.gov/ct2/show/NCT01985230.

CAUTION – in the United States, ReActiv8 is limited by federal law to investigational use only.

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).

CAUTION – in the United States, ReActiv8 is limited by federal law to investigational use only.

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

PR and IR Enquiries:

Consilium Strategic Communications (international strategic communications – business and trade media)

Chris Gardner, Mary-Jane Elliott, Jessica Hodgson, Hendrik Thys
Tel: +44 203 709 5700 / +44 7921 697 654
Email: mainstaymedical@consilium-comms.com

FTI Consulting (for Ireland)

Jonathan Neilan
Tel: +353 1 663 3686
Email: jonathan.neilan@fticonsulting.com

NewCap (for France)

Julie Coulot
Tel: +33 1 44 71 20 40
Email: jcoulot@newcap.fr

Investor Relations:

LifeSci Advisors, LLC

Brian Ritchie
Tel: + 1 (212) 915-2578
Email: britchie@lifesciadvisors.com

ESM Advisers:

Davy
Fergal Meegan or Barry Murphy
Tel: +353 1 679 6363
Email: fergal.meegan@davy.ie or barry.murphy2@davy.ie

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 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 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.