

Mainstay Medical Begins Clinical Trial of ReActiv8® for People with Chronic Low Back Pain

Dublin based medical device company hits key milestone.

Dublin – Ireland, 10th March 2014 – Mainstay Medical today announced that it has secured approval from Ethics Committees in Australia to start a clinical trial of ReActiv8, its innovative implantable neurostimulation device for the treatment of people with Chronic Low Back Pain (CLBP). Recruitment of subjects for the trial has commenced at three clinical sites in Australia.

The purpose of the clinical trial is to investigate ReActiv8 as a treatment for adults with debilitating Chronic Low Back Pain for whom surgery is not indicated.

One of the root causes of CLBP is impaired control by the nervous system of the muscles that stabilize the spine in the lower 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 spine stability, allowing the body to recover from chronic low back pain.

“Our novel approach of electrical stimulation to help restore the muscle control system is based on published scientific research, and the performance of the therapy was demonstrated in the recently completed European Feasibility Study.” said Peter Crosby, the CEO of Mainstay Medical. “The energy and experience of the Mainstay Medical team has enabled us to complete the development of our innovative, therapy-specific device and obtain approval to start the ReActiv8 clinical trial within a year after the Feasibility Study results.”

People with debilitating CLBP usually have a greatly reduced quality of life and score significantly higher on scales for disability, depression, anxiety and sleep disorders. Their pain and disability can persist despite the best available medical treatments, and most of these people have no indications for 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.

“Back pain specialists from all over the world have told us that they need a new approach to help the large group of people with CLBP who are stranded without a viable alternative. We believe, based on published research, that there are millions of such people in Europe and the USA today. The results of the European Feasibility Study encouraged us to believe that ReActiv8 can play an important role in helping these people,” Crosby mentioned.

Results from Mainstay Medical’s European Feasibility Study were presented at the meeting of the International Neuromodulation Society in Berlin in June 2013. Results showed a statistically significant and clinically important improvement in key outcome measures, including reduction in pain and disability from CLBP and an improved quality of life.

About Mainstay Medical Ltd

Mainstay Medical Limited is a medical device company which is developing an innovative implantable neurostimulation medical device, ReActiv8, for people with debilitating Chronic Low Back Pain (CLBP). Low Back Pain is the 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 and has subsidiaries operating in the United States and Australia. Mainstay Medical is backed by investors including Sofinnova Partners (France), Fountain Healthcare Partners (Ireland), Medtronic (US), Capricorn Venture Partners (Belgium), Seventure Partners (France) and Twin Cities Angels (Minneapolis, USA).

Further information can be found at www.mainstay-medical.com

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