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MEDTRONIC ANNOUNCES FIRST IMPLANT IN STUDY TO EVALUATE INVESTIGATIONAL, CLOSED LOOP NEUROSTIMULATOR FOR THE TREATMENT OF CHRONIC PAIN

Prospective study will evaluate the long-term performance of the closed-loop algorithm and overall patient experience with Medtronic's next generation, rechargeable spinal cord stimulation device

Medtronic plc, a global leader in healthcare technology, today announced the first patient implant in a clinical study of its investigative, closed-loop, implantable neurostimulator. The Evaluation of Long-term Patient Experience with a Medtronic Closed-Loop SCS System study is being conducted in Australia. The objective is to characterize the efficacy of the next-generation, rechargeable neurostimulator for the treatment of overall pain in back and limb pain subjects. Medtronic's closed-loop feature uses the spinal cord's physiological response to stimulation, known as an evoked compound action potential (ECAP), to automatically deliver a consistent therapeutic dose at the precise moment it is needed. *The next-generation closed-loop neurostimulator is investigational in Australia and not approved for sale or distribution.*

ECAPs are signals generated by the spinal cord in response to an electrical stimulus. They are a direct measure of how many nerve fibers are activated in the spinal cord and provide a metric that can be used to inform real-time, patient-specific control of spinal cord stimulation (SCS) therapy.

"As SCS patients go about their daily lives, their dosage needs vary," said Dr. Vahid Mohabbati, MD, director of the Sydney Pain Research Centre in Sydney, Australia and the first physician to implant a patient with the investigational device for the study. "Maintaining the right intensity of stimulation is essential for treating patients with spinal cord stimulation. It is our hope that the closed-loop feature will enable more personalized and real-time stimulation adjustments that reduce pain while minimizing variances that fall outside of the optimal therapeutic dose."

Enrolling up to 90 patients across 10 centers in Australia, this prospective, multi-center, randomized, investigational feasibility study will evaluate the long-term performance of the closed-loop algorithm and overall patient experience with the study device. Following device implant and optimization, subjects will be randomized to a sequence of Closed-Loop On and Closed-Loop Off for in-clinic testing. They will then continue being followed

for a total study duration of up to 24 months.

“This study serves as another example of Medtronic’s continued commitment to ensuring that chronic pain patients receive the best possible care through clinically-validated treatment options,” said Charlie Covert, Vice President and General Manager, Pain Therapies at Medtronic. “Closed-loop technology represents a tremendous opportunity to create a more personalized therapy that offers durable, consistent and effective pain relief.”

This study is independent of Medtronic’s submission to FDA for approval of its closed-loop rechargeable neurostimulator. This device is not approved or cleared in the U.S. for commercial use.

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