Abbott Enrolls First Patient In Study To Investigate BurstDR™ Stimulation To Treat Non-Operative Low Back Pain

- Low back pain affects one in 10 Americans and often impacts the patient physically, emotionally and economically

- The multicenter, randomized, controlled DISTINCT study represents an Abbott collaboration with both spine surgeons and pain specialists to amass post-market evidence for its BurstDR™ spinal cord stimulation therapy for patients who have limited surgical options

ABBOTT PARK, Ill., Sept. 30, 2020 – Abbott today announced the first patient has been enrolled in the DISTINCT study (**D**orsal sp**I**nal cord **STI**mulatio**N** vs medi**C**al management for the **T**reatment **of low back pain**). The study will investigate the efficacy of the company's BurstDR™ spinal cord stimulation (SCS) compared with conventional medical management (CMM) in people with chronic low back pain that cannot be managed with standard medical care. The study will evaluate improvement in pain, physical function and emotional well-being in people living with chronic low back pain, who have not had lumbar spine surgery or for whom surgery is not an option.

It is estimated that more than 30 million Americans experience low back pain at any given time, and low back pain is one of the most common reasons people see a doctor.[1] Low back pain may range in intensity from a constant ache to a sharp or shooting pain.[2]

"Unlike other spinal conditions, there is a lack of clear treatment guidelines for people living with severe low back pain who are ineligible for back surgery and are unresponsive to traditional medical treatments and rehabilitation methods. The lack of evidence-based guidelines leads to an imbalance of care for this specific subset of patients," said James J. Yue, M.D., Associate Clinical Professor in the Department of Surgery, Frank H. Netter School of Medicine, Quinnipiac University, Conn., and co-principal investigator of the trial. "These patients need more treatment alternatives, and we look forward to researching BurstDR as an important therapeutic option in lower back pain treatment."

DISTINCT is a prospective, multi-center, randomized, controlled clinical study designed to evaluate the efficacy of Abbott's BurstDR SCS in the treatment of chronic low back pain with a neuropathic (unrelenting, severe and constant pain) component, compared to conventional medical management – using medication and other non-surgical methods to treat the patient's pain.

Primary and secondary endpoints of the study will capture participant's improvement in physical function and pain relief. Additional endpoints will be used to evaluate quality of life measures including depression, sleep, emotional distress, medication usage and overall participant satisfaction with the therapy. The DISTINCT study will enroll 270 subjects at up to 30 sites in the United States and then randomize for SCS treatment and CMM, respectively. Following six months of treatment in either arm, all participants will have an option to cross over – presenting an opportunity for those in the medical management arm of the study to opt for BurstDR stimulation in the open label part of the study.

"The DISTINCT study will provide important data in our clinical development program for intermittently dosed BurstDR stimulation," said Keith Boettiger, vice president, Neuromodulation, Abbott. "Conducting this study is another example of how Abbott is listening to patients, physicians and the pain community to address current unmet needs in pain management. For the patients, we see this as a unique opportunity to address their suffering as well as their pain."

For more information about the DISTINCT clinical study, please visit www.clinicaltrials.gov.

About Abbott's Chronic Pain Portfolio

Chronic pain can negatively impact personal relationships, work productivity and a person's daily routine.Abbott is a global leader in the development of chronic pain therapy solutions, offering radiofrequency therapy and spinal cord stimulation therapy solutions, including BurstDR stimulation, and dorsal root ganglion stimulation in the portfolio of chronic pain treatments.

BurstDR stimulation works to reduce pain by altering by the pain signals as they travel to the brain. BurstDR stimulation is clinically proven to improve peoples' ability to perform everyday activities* and reduce emotional suffering associated with pain.[3]

About Abbott

Abbott is a global healthcare leader that helps people live more fully at all stages of life. Our portfolio of life-changing technologies spans the spectrum of healthcare, with leading businesses and products in diagnostics, medical devices, nutritionals and branded generic medicines. Our 107,000 colleagues serve people in more than 160 countries.

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* Based on PGIC scores of moderately better improvement or higher.

1. Jensen M, Brant-Zawadzki M, Obuchowski N, et al. Magnetic Resonance Imaging of the Lumbar Spine in People Without Back Pain. *N Engl J Med* 1994; 331: 69-116.

2. National Institute of Health. "Back Pain Fact Sheet", NINDS, Publication date March 2020. https://www.ninds.nih.gov/Disorders/Patient-Caregiver-

Education/Fact-Sheets/Low-Back-Pain-Fact-Sheet

3. Deer T, Slavin KV, Amirdelfan K, et al. Success Using Neuromodulation With BURST (SUNBURST) Study: Results From a Prospective, Randomized Controlled Trial Using a Novel Burst Waveform. Neuromodulation. 2017;20(6):543-552.

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