## New Quality Of Life And Functional Improvement Data From Abbott's BOLD And TRIUMPH Studies Reinforce Benefit Of Proclaim™ XR Neurostimulation System In People Living With Chronic Pain

- BOLD study found that BurstDR™ stimulation waveform reduced the negative psychological effects associated with a person's chronic pain at six-month follow up by 62%
- Data were presented at the 2020 North American Neuromodulation Society (NANS) annual meeting
- Proclaim XR uses Abbott's proprietary BurstDR technology to achieve chronic pain relief

LAS VEGAS, Jan. 23, 2020 / PRNewswire/ -- Abbott (NYSE: ABT) announced positive results from a prospective, multicenter study, providing the scientific basis for the company's Proclaim<sup>TM</sup> XR recharge-free neurostimulation system for people living with chronic pain. Data from the **B**urstDR micr**O**dosing stimu**L**ation in **D**e-novo patients (**BOLD**) study found that BurstDR<sup>TM</sup> reduced pain catastrophizing scale scores (PCS) by an average of 62%. PCS is a patient reported measure used to determine how pain affects the mental state of a person experiencing chronic pain.

The research, which was presented at the 2020 North American Neuromodulation Society (NANS) annual meeting, also found that 78% of people had a baseline, or initial, Oswestry Disability Index (ODI) score of "severe," "crippling" or "bed bound." After receiving treatment from a Proclaim XR implant for six months, 71% of people in the study had a minimal or moderate ODI score, with 29% of people having a "severe" or "crippling" ODI score. ODI is a diseases specific measurement that is used to determine the patient's physical level of disability and measure change over a period of time.

"Chronic pain is a broad term that doesn't accurately capture the variety of issues and symptoms people experience as a result of it," said Timothy Deer M.D., DABPM, president and chief executive officer of The Spine and Nerve Center of the Virginias in Charleston, W.Va. "Whether the individual is worrying about being bedridden or experiencing severe pain for the rest of their lives, when we tell people about Proclaim XR, we can share with them the science behind the system to address physical and psychological aspects of pain."

Additional data were also presented at NANS from the TRIUMPH study, a prospective, multi-center, single-arm, international study of 269 patients, which found significant improvements in physical, mental and emotional function were sustained for up to one-year, post-permanent implant. Patients also reported a reduction in the impact of pain on daily life, which resulted in patients becoming more active when measured at one year.

"These collective data illustrate the important and promising physical and mental health benefits of the BurstDR stimulation waveform for people living with chronic pain," said Steven M. Falowski, M.D., director of Functional Neurosurgery at Neurosurgical Associates of Lancaster in Pennsylvania. "We now have clinical evidence that Proclaim XR, using the BOLD dosing protocol, shows reductions in two standard measures of characterizing pain. The improvements in these two areas are critical factors in creating personalized care plans that help individuals feel better overall and treating the multiple aspects of pain."

It is estimated that 50 million Americans live with chronic pain, which is defined as pain that lasts longer than six months. About 30% of those living with chronic pain develop depression or psychological effects when patients develop a preoccupation with pain that makes it difficult to live a normal life.

Abbott's Proclaim XR system allows physicians to identify the lowest effective dose of BurstDR stimulation customized to each patient, optimizing system longevity while maintaining effective pain and symptom relief, and eliminating the need for recharging (for up to 10 years at low-dose settings\*). This patient-centric innovation is possible because of Abbott's proprietary stimulation waveform and advanced battery technology that is integrated into Proclaim XR.

"We're still only scratching the surface of what spinal cord stimulation can do in patients experiencing chronic pain," saidKeith Boettiger, vice president of Abbott's neuromodulation business. "The more we learn and study the BurstDR stimulation waveform and low intermittent dose stimulation, the more we are able to apply this technology to real world situations. Abbott is proud to be at the forefront of this new way of thinking about neurostimulation and developing truly life-changing therapies for people with debilitating conditions like chronic pain."

## **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. The Proclaim XR system is the latest advancement from Abbott, featuring upgradeable software and consumer-friendly technology that is compatible with Apple devices such as the iPad<sup>®</sup> or iPod Touch<sup>®</sup>.

## **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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www.facebook.com/Abbott and on Twitter @AbbottNews and @AbbottGlobal.

\*Up to 10 years of battery longevity at the lowest dose setting: 0.6mA, 500 Ohms, duty cycle 30s on/360s off. NOTE: In neurostimulation therapy, 'dose' refers to the delivery of a quantity of energy to tissue. Safety comparisons and specific dose-response curves for each dosage have not been clinically established. Refer to the IFU for additional information. Hassle-free means recharge-free.

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