FDA Approves Abbott's New Spinal Cord Stimulation Device; Provides Tailored Relief To Multiple Pain Areas And Adds More Treatment Options For Evolving Pain Conditions

- Abbott's new Proclaim™ Plus spinal cord stimulation (SCS) system offers the next generation of stimulation therapy, giving physicians the ability to treat multi-site and evolving pain
- The system builds on the company's proprietary therapy, BurstDR™ stimulation, that works by mimicking natural patterns found in the brain[1] to deliver superior pain relief[2,3] and is preferred to traditional "tingling" tonic stimulation by 87% of patients[4]
- The Proclaim Plus SCS System can be used in conjunction with Abbott's NeuroSphere™ Virtual Clinic, which allows people to connect with their doctor and receive remote programming adjustments from the comfort of their home*

ABBOTT PARK, Ill., Aug. 23, 2022 /PRNewswire/ -- Abbott (NYSE: ABT) today announced that the U.S. Food and Drug Administration (FDA) has approved its new Proclaim™ Plus spinal cord stimulation (SCS) system featuring FlexBurst360™ therapy. The next generation of Abbott's proprietary BurstDR™ stimulation, FlexBurst360 therapy offers pain coverage across up to six areas of the trunk and/or limbs and enables programming that can be adjusted as a person's therapeutic needs evolve.

Designed to fit within a person's life, the Proclaim Plus SCS system is recharge-free with a battery that can last up to 10 years.^ It can be used with Abbott's NeuroSphere™ Virtual Clinic connected care technology, which allows a person to both communicate with a physician through secure in-app video chat and remotely receive stimulation settings in real time regardless of location.*

More than 50 million people in the U.S. suffer from chronic pain[5] and 88% of those have pain in at least two or more different areas of their body.[6] SCS therapy, also known as neurostimulation, is an implanted device that sends mild electrical pulses to the nerves along the spinal cord, changing the way the body perceives pain signals, which can relieve chronic pain and improve quality of life. According to the U.S. Pain Foundation, chronic pain is the leading cause of people going to the doctor and costs the nation approximately $635 billion each year in healthcare, disability and lost productivity costs.[7]

"Spinal cord stimulation has provided tremendous relief for patients suffering from chronic pain. With its ability to mimic natural patterns found in the brain, the Abbott BurstDR platform has been a game-changer in this space, helping to not only improve a patient's ability to perform everyday activities but also relieve the emotional suffering[§] that pain can cause," said Steven Falowski, M.D., Argires Marotti Neurosurgical Associates of Lancaster, Lancaster, Pa. "However, despite the many benefits of BurstDR, such as being effective as a low-energy stimulation therapy, some patients continue to be burdened by pain because of multiple painful areas and evolving pain over time. Now, with Proclaim Plus and FlexBurst360, an already established platform has been improved to treat more patients who suffer from pain across different body parts and changing pain over time."

BurstDR therapy is Abbott's exclusive stimulation technology that delivers pulses – or bursts – of mild electrical energy to alter pain signals as they travel from the spinal cord to the brain. Clinical studies have shown that BurstDR technology delivers superior pain relief as compared to tonic stimulation[3], improves people's day-to-day life, and reduces the emotional suffering[§] associated with pain.[4] When compared to standard tonic stimulation technology, which provides a constant tingling sensation felt by the patient, 87% of people preferred BurstDR technology, which provides pain relief in a sub-sensory range not felt by the patient.[4]

Using FlexBurst360 therapy on the Proclaim Plus system, physicians can identify the lowest effective dose of stimulation for each patient and adapt it based on evolving pain needs. The system allows doctors control over multiple independent BurstDR stimulation areas to provide broader pain coverage without overstimulation risk.[8]

The Proclaim Plus system with FlexBurst360 therapy is designed to fit seamlessly within a person's life and therapy settings can be accessed using either a personal mobile device** or through an Abbott-provided mobile device. Patients can use the same device to access Abbott's proprietary NeuroSphere Virtual Clinic, a first-of-its-kind neurostimulation technology[9] in the U.S. that allows patients to communicate with physicians, ensure proper functionality of their device, and receive remote adjustments to their therapeutic settings as needed.

"At Abbott, we are deeply committed to advancing the field of neurostimulation, thus helping people address the challenges they face while managing their chronic pain," said Pedro Malha, vice president, neuromodulation, Abbott. "Our latest development, Proclaim Plus with FlexBurst360 therapy, is yet another testament of that commitment."

* Anywhere with a cellular or Wi-Fi connection and sufficiently charged patient controller.
^Up to 10 years of battery longevity at the lowest program setting: 0.6mA, 500 Ohms, duty cycle 30s on/360s off, single area BurstDR stimulation. Refer to the IFU for additional information.

§ Pain and suffering as measured by visual analog scale.
**For a list of compatible devices: https://www.neuromodulation.abbott/us/en/mobile-device-os-compatibility.html.
For U.S. important safety information on the Abbott Proclaim Plus with FlexBurst360, visit:

https://www.neuromodulation.abbott/us/en/important-safety-info.html.

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For further information: Abbott Media: Carolina Castaño, (512) 286-4021, Abbott Financial: Michael Comilla, (224) 668-1872

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