FDA Approves Abbott's Spinal Cord Stimulation For People Living With Painful Diabetic Peripheral Neuropathy

- The new indication for Abbott's Proclaim™ XR SCS system provides a non-medication option for people with painful diabetic peripheral neuropathy
- Spinal cord stimulation is proven to be more effective than conventional medical management in the treatment of chronic pain[1,2]

ABBOTT PARK, Ill., Jan. 26, 2023 /PRNewswire/ -- Abbott (NYSE: ABT) announced today that the U.S. Food and Drug Administration (FDA) has approved its Proclaim™ XR spinal cord stimulation (SCS) system to treat painful diabetic peripheral neuropathy (DPN), a debilitating complication of diabetes. The Proclaim XR SCS system can provide relief to DPN patients in need of alternatives to traditional treatment approaches, such as oral medication. People who receive therapy from the Proclaim XR SCS system will also be able to use Abbott's NeuroSphere™ Virtual Clinic, a connected care app that allows people to communicate with a physician and receive treatment adjustments remotely.

Roughly 34.2 million Americans, or 10.5% of the U.S. population, have diabetes.[3] Diabetic neuropathy, one of the complications of diabetes, is a type of damage seen predominately in nerves running to the feet.[4] During their lifetime, approximately 50% of adults with diabetes will develop peripheral neuropathy, which may include symptoms such as pain and numbness in the legs, feet and hands.[5]

Currently, there are no disease modifying treatments for DPN, only symptom management and behavioral modifications to mitigate further nerve damage that can result from high blood sugar (glucose) levels.[6] Spinal cord stimulation is a non-opioid approach that has been used for more than 50 years to help manage chronic pain and is proven to be more effective than conventional medical management in the treatment of this type of chronic pain.[1,2] As a global leader in diabetes care, Abbott is committed to bringing life-changing solutions, including diagnostics, nutritionals, medicines and medical devices such as spinal cord stimulation to help better the lives of people living with diabetes.

Approved for the treatment of chronic pain in 2019, the Proclaim XR SCS system now offers DPN patients relief from chronic pain by delivering traditional “tingling” tonic stimulation.** People experiencing DPN can engage with their healthcare provider to be referred to a pain management specialist or spine surgeon to discuss the details of this treatment to determine the best course of care.

"Diabetic peripheral neuropathy has long plagued people affected by type 1 and type 2 diabetes, often adding another area of disease management on top of their ongoing monitoring of their glucose levels to manage this challenging disease," said Jason E. Pope, MD, DABPM, FIPP, president of Evolve Restorative Center in Santa Rosa, Calif. "Abbott’s Proclaim XR spinal cord stimulation system provides patients with painful diabetic peripheral neuropathy the opportunity to obtain a better quality of life while more seamlessly fitting into their current lifestyles."

Following a successful minimally invasive trial and undergoing an implant with the Proclaim XR SCS device, patients will have the ability to control their therapy through an Apple device. The device can also be programmed using the company’s proprietary NeuroSphere Virtual Clinic technology, a first-of-its-kind remote patient care technology in U.S. that allows users to communicate with physicians, ensure proper settings and functionality, and receive new treatment settings/adjustments remotely, as needed.*

"As a leader in diabetes care, Abbott is intimately familiar with the challenges people with diabetes encounter daily. This new indication for Proclaim XR will drive meaningful change in the treatment of pain associated with diabetic peripheral neuropathy and will be an important tool for physicians and patients in managing this debilitating condition," said Pedro Malha, vice president, neuromodulation, Abbott.

*Anywhere with a cellular or Wi-Fi connection and sufficiently charged patient controller.

**Clarification: Abbott has updated the original release issued on Jan. 26, 2023. The original release referenced incorrect settings used for diabetic peripheral neuropathy and has been updated to indicate the approval is for tonic stimulation mode only.

For U.S. important safety information on the Abbott Proclaim™ XR SCS system, visit:Important Safety Information (neuromodulation.abbott).

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 115,000 colleagues serve people in more than 160 countries.

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[1] Slangen, R., et al. (2014). "Spinal cord stimulation and pain relief in painful diabetic peripheral neuropathy: a prospective two-center randomized controlled trial." Diabetes Care 37(11): 3016-3024.

[2] de Vos, C. C., et al. (2014). "Spinal cord stimulation in patients with painful diabetic neuropathy: a multicentre randomized clinical trial." Pain 155(11): 2426-2431.

[3] Center for Disease Control & Prevention. National Diabetes Statistics Report 2022 - Estimates of Diabetes and Its Burden in the United States. https://diabetesresearch.org/wp-content/uploads/2022/05/national-diabetes-statistics-report-2020.pdf. Accessed November 9, 2022.

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[6] Petersen, E., Stauss, T., Scowcroft, J., Brooks, E., White, J., Sills, S., et. al (2022). Durability of High-Frequency 10-kHz Spinal Cord Stimulation for Patients With Painful Diabetic Neuropathy Refractory to Conventional Treatments: 12-Month Results From a Randomized Controlled Trial. *Diabetes Care*, 45 (1): e3–e6. https://doi.org/10.2337/dc21-1813.

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