

# ANALYSIS OF DATA FROM SUNBURST STUDY CONFIRMS THE BENEFITS OF ABBOTT'S BURSTDR™ STIMULATION

- Data from two separate analyses highlight key benefits of BurstDR™
- BurstDR stimulation was preferred by more than 70 percent of patients compared to tonic stimulation
- Optimal programming options demonstrated additional improvement in patient-reported pain scores

**Abbott Park, Ill, Jan. 23, 2017** — A new analysis that includes full results from the SUNBURST study has confirmed the superiority of Abbott's proprietary BurstDR™ stimulation over traditional tonic (mild pulses of energy) spinal cord stimulation (SCS) for patients suffering from chronic pain. An additional sub-study analysis from SUNBURST presented today also suggested that the benefits of standardizing BurstDR stimulation programming (a process of optimizing the therapy a patient receives) could further improve patients' clinical outcomes and demonstrate additional symptom improvement for patients suffering from chronic pain.

Abbott's proprietary BurstDR stimulation works differently from other stimulation designs, utilizing intermittent "burst" pulses designed to mimic the body's natural nerve impulse patterns. While other companies have tried to mimic burst patterns, BurstDR stimulation from Abbott is the only approved form of burst stimulation to have been evaluated in a large scale, multicenter randomized controlled clinical trial.

The analysis of the SUNBURST study and the programming optimization sub-study were presented at the 2017 North American Neuromodulation Society (NANS) annual meeting. Results from the SUNBURST study were originally presented at the 2015 NANS annual meeting.

Based on the SUNBURST study's intent-to-treat (ITT) analysis, BurstDR stimulation met both non-inferiority and superiority endpoints compared to tonic SCS for pain relief.

In addition:

- With BurstDR stimulation, 89 percent of patients reported less paresthesia (a tingling sensation that accompanies tonic stimulation) than was experienced with tonic SCS.
- More than 61 percent of patients experience no paresthesia at all with BurstDR stimulation.
- Overall, more than 70 percent of patients selected BurstDR stimulation as their preferred therapy.

"Results from the full data cohort of the SUNBURST study provide important confirmation of the clinical value of BurstDR stimulation in the treatment of chronic pain, a condition for which new therapeutic options have been urgently needed for some time," said Konstantin V. Slavin, M.D., professor and head of stereotactic and functional neurosurgery at the University of Illinois College of Medicine at Chicago and member of the SUNBURST steering committee. "BurstDR stimulation is a highly effective new tool in the management of chronic pain while reducing and even eliminating paresthesia in many patients. Importantly, since the launch of the therapy in the U.S. we have seen positive clinical outcomes nationwide that have reinforced and even built on the results of the SUNBURST study."

According to the National Institutes of Health (NIH), chronic pain is typically defined as pain lasting longer than 12 weeks. The condition, which affects approximately 1.5 billion people

worldwide, can take a physical and emotional toll on patients, many of whom try many different types of treatment options on their path to finding pain relief.

## **Optimizing Programming to Improve Clinical Outcomes**

In a second presentation today, building on the full analysis of the SUNBURST study, Steven Falowski, M.D., a neurosurgeon at St. Luke's University Health Network in Easton, Pa., reported on a SUNBURST sub-study examining programming optimization for BurstDR stimulation. The sub-study suggested that optimized BurstDR stimulation programming can offer patients even better pain relief while further reducing paresthesia.

When patients receive a new spinal cord stimulator implant, devices are programmed to deliver therapy based on a patient's condition, anatomy and stimulation needs. During programming, patients work with their physician to ensure the device delivers optimal therapy. By optimizing BurstDR programming, overall patient outcomes can be improved.

Of 32 patients in this sub-study:

- A total of 59 percent of patients achieved approximately 60 percent reduction in the Visual Analog Scale (VAS) scoring, a measurement of pain intensity from their pre-implant baseline.
- Researchers also reported that 91 percent of these sub-study patients were paresthesia free with the standardized BurstDR therapy.

"The clinical experience with BurstDR stimulation in Europe made it clear that we could further improve patient outcomes with the therapy by optimizing programming to generate strong pain relief while reducing or eliminating paresthesia," said Allen Burton, M.D., medical director of neuromodulation at Abbott. "This sub-study shows that we can continue to maximize patient benefits with BurstDR stimulation and build upon the superior pain relief delivered by the therapy over traditional tonic spinal cord stimulation therapy."

### About the SUNBURST Study

The SUNBURST study was a U.S. investigational device exemption (IDE) trial designed to support U.S. approval of BurstDR stimulation. The study enrolled 100 patients from 20 centers across the U.S., and found BurstDR stimulation provided superior pain relief for patients over traditional tonic SCS. The study also found patients preferred BurstDR stimulation to traditional tonic SCS.

### **About Abbott's Chronic Pain Portfolio:**

Chronic pain affects approximately 1.5 billion people worldwide, more than heart disease, cancer and diabetes combined. The condition can negatively impact personal relationships, work productivity and a patient's daily routine. Abbott is a global leader in the development of chronic pain therapy solutions and the only medical device manufacturer in the world to offer radiofrequency ablation (RFA) and spinal cord stimulation (SCS) therapy solutions including BurstDR stimulation and stimulation of the dorsal root ganglion (DRG) for the treatment of chronic pain.

### **About Abbott:**

At Abbott, we're committed to helping people live their best possible life through the power of health. For more than 125 years, we've brought new products and technologies to the world -- in nutrition, diagnostics, medical devices and branded generic pharmaceuticals -- that create more possibilities for more people at all stages of life. Today, 74,000 of us are working to help people live not just longer, but better, in the more than 150 countries we serve.

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