News Release

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SynerFuse™ Announces First Two-Level Integrated Spinal Fusion & DRG Neuromodulation Procedure by Solo Surgeon in Proof-of-Concept Study

--10th Patient Implanted in PoC Study Evaluating Safety & Feasibility of the Integrated Procedure

EDEN PRAIRIE, Minn. – June 26, 2023 – Justin Zenanko, CEO of SynerFuse, Inc., a Minnesota-based medical device company, is pleased to announce that for the first time in the world, a solo spine surgeon performed the SynerFuse procedure in a two-level spinal fusion patient. Dr. Rohan Lall performed a two-level spinal fusion procedure and implanted a neurostimulator system in the 10th patient in the proof-of-concept study evaluating the safety and feasibility of this investigational integrated procedure.

"So far in the study, the SynerFuse procedure has been efficient and straightforward to perform, including in the context of a two-level fusion," said Lall. "It is very exciting to study the integration of DRG stimulation to the fusion surgery for patients with chronic pain earlier in the treatment process in an attempt to reduce their pain levels and need for opioids."

See photo taken after the 10th surgery, left to right: SynerFuse Chief Scientific Officer Greg Molnar, Dr. Rohan Lall, SynerFuse CEO Justin Zenanko.

The SynerFuse proof-of-concept study involves combining spinal fusion with the implant of a neurostimulator to provide stimulation of the dorsal root ganglion (DRG), a key nerve structure along the spine that can be targeted with neuromodulation to treat neuropathic pain in patients suffering from chronic lower back pain (cLBP).

"The implantation of the 10th patient in our proof-of-concept study is an important milestone for SynerFuse and our goal of commercialization," said Zenanko. "With each new patient, we hope to be one step closer to demonstrating the viability of our non-narcotic therapy concept for spinal fusion patients with chronic lower back pain. We are looking forward to seeing the long-term outcomes as the data will be used to inform our next clinical trial using our novel device."

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"Bringing this patient-focused therapy from concept to the 10th implant is a testament to the collaboration between SynerFuse and our clinician partners at the University of Minnesota Medical School and M Health Fairview University of Minnesota Medical Center," said SynerFuse Chief Scientific Officer Gregory F. Molnar, Ph.D.

Previously, there had been nine single-level fusion procedures in this proof-of-concept study conducted by Michael C. Park, MD, Ph.D., Rohan Lall, MD, and Jonathon Sembrano, MD, at M Health Fairview University of Minnesota Medical Center. The first solo-surgeon SynerFuse procedure was performed by Rohan Lall, MD, in the eighth patient.

More information about SynerFuse is available at www.synerfuse.com.

About Chronic Lower Back Pain (cLBP)

cLBP is defined as lower back pain that continues for 12 weeks or longer, even after an initial injury or underlying cause of acute lower back pain has been treated.[1] With more than 500,000 procedures performed annually, spinal fusion remains a common treatment for spinal instability, albeit with a high incidence of residual neuropathic pain[2]. Up to 40% of patients who undergo spinal fusion end up with Failed Back Surgery Syndrome (FBSS), a condition resulting in significant, lingering neuropathic pain, costing the U.S. healthcare system $20B per year and significantly affecting the quality of life of patients[3].

About SynerFuse

SynerFuse is a Delaware corporation based in Minnesota—the heart of Medical Alley and the cradle of neuromodulation and medical device innovation. SynerFuse believes that individuals with cLBP/FBSS and their providers deserve an alternative option than spinal fusion alone. Even when spinal fusion is successful, it can often result in residual chronic neuropathic pain and use of addictive opioids. The company is working to create a non-narcotic pain management for chronic low back pain with a patented therapy that integrates spinal fusion hardware and an active neuromodulation system. For more information on the company, please visit www.synerfuse.com.

This communication contains information about an investigational product. This product is limited by Federal (U.S.) law to investigational use only. SynerFuse makes no claims regarding the safety or effectiveness of the unapproved investigational product. The intent of providing this information is to convey research and development initiatives underway at SynerFuse.

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[1] *See* "Low Back Pain Fact Sheet." National Institute of Neurological Disorders and Stroke, https://www.ninds.nih.gov/low-back-pain-fact-sheet#:~:text=Chronic%20back%20pain%20is%20defined, back%20pain%20has%20been%20treated, *accessed* October 17, 2022.

[2] Karen L. Saban et al., "Health-Related Quality of Life of Patients Following Selected Types of Lumbar Spinal Surgery: A Pilot Study," Health and Quality of Life Outcomes 5 (2007), https://doi.org/10.1186/1477-7525-5-71.

[3] Farber SH, Han JL, Elsamadicy AA, Hussaini Q, Yang S, Pagadala P, Parente B, Xie J, Lad SP. Long-term Cost Utility of Spinal Cord Stimulation in Patients with Failed Back Surgery Syndrome. Pain Physician. 2017 Sep;20(6):E797-E805. PMID: 28934786; PMCID: PMC8358894.