InVivo Therapeutics is developing a resorbable biomaterial scaffold, the investigational Neuro-Spinal Scaffold, to treat patients with spinal cord injury (SCI). The Neuro-Spinal Scaffold is in clinical trials for acute SCI, and InVivo is also searching for synergistic pipeline expansion opportunities.

InVivo Therapeutics Holding Corp.
www.invivotherapeutics.com

Rapid intervention—pioneering technology: redefining spinal cord injury treatment

InVivo Therapeutics is a research and clinical-stage biotechnology company focused on the development of technologies for the treatment of spinal cord injuries (SCIs). InVivo’s mission is to develop treatment options that provide meaningful improvement in patient outcomes following SCIs and help to redefine a patient’s life. Based on pioneering research from Boston Children’s Hospital and the Massachusetts Institute of Technology, the company is advancing an investigational bioresorbable polymer scaffold designed for implantation at the site of injury within the spinal cord shortly after acute SCI.

“The most common cause of SCI is a compressive–contusive-type injury that displaces the vertebral column, causing mechanical injury that disrupts axons, blood vessels and cell membranes. The trauma induces rapid swelling of the spinal cord and hemorrhaging, resulting in reduced blood flow and ischemic necrosis. Over the first 24 hours, these processes trigger rapid and extensive demyelination and loss of gray matter. By contrast, loss of white matter occurs over a period of about 1 week and results in the formation of a cyst in the spine. Overall, the result of SCI is a loss of neurologic function below the injury level with outcomes including permanent paralysis, sensory impairment and autonomic (bowel, bladder and sexual) dysfunction.

Approximately 285,000 people in the United States live with paralysis due to SCI, so called by even one grade on the AIS is considered clinically significant. A conversion at least one grade on the AIS is considered clinically important. This 44% conversion rate substantially outperformed historic benchmarks, based on published natural history studies, of -15-25% improvement at 6 months post-injury. A second randomized, single-blind study is now underway.

A primer on SCI

The most common cause of SCI is a compressive–contusive-type injury that displaces the vertebral column, causing mechanical injury that disrupts axons, blood vessels and cell membranes. The trauma induces rapid swelling of the spinal cord and hemorrhaging, resulting in reduced blood flow and ischemic necrosis. Over the first 24 hours, these processes trigger rapid and extensive demyelination and loss of gray matter. By contrast, loss of white matter occurs over a period of about 1 week and results in the formation of a cyst in the spine.

Overall, the result of SCI is a loss of neurologic function below the injury level with outcomes including permanent paralysis, sensory impairment and autonomic (bowel, bladder and sexual) dysfunction.

Approximately 285,000 people in the United States live with paralysis due to SCI, so called chronic SCI, and each year, another approximately 17,000 individuals become fully or partially paralyzed following SCI, also termed acute SCI.

Since there is no effective treatment available for SCI, and current management of acute SCI consists of a surgical spine stabilization and external decompression procedure of uncertain value. This standard of care has remained largely unchanged for the past 30 years.

InVivo Therapeutics is advancing an investigational bioresorbable polymer scaffold designed for implantation at the site of injury within the spinal cord shortly after acute SCI, also termed acute SCI.

The investigational Neuro-Spinal Scaffold

InVivo’s approach to helping limit neuronal damage from the initial SCI focuses on providing structural support to the spared spinal tissue and creating a neuronomimetic matrix to facilitate the endogenous repair processes. The company’s Neuro-Spinal Scaffold is an investigational and patented bioresorbable, biocompatible poly(lactic-co-glycolic acid)–poly-l-lysine (PLGA–PLL) copolymer scaffold designed for implantation at the site of injury within the spinal cord contusion that degrades over several weeks after implantation. PLGA and PLL are two US Food and Drug Administered (FDA)-approved polymers that, respectively, provide structural support and a surface coating conducive to cellular attachment and neurite outgrowth (Fig. 1).

A robust response can lead to improved outcomes for patients with SCI by preserving white matter to enable signal transmission along the spinal cord, preventing cavity development, enabling neural regeneration, encouraging growth and tissue remodeling at the site of injury, and remyelinating white matter axons.

In a foundational study of patients with thoracic American Spinal Injury Association (ASIA) Impairment Scale (AIS) A traumatic SCI treated with the Neuro-Spinal Scaffold, 7 of 16 patients (44%) who could be evaluated at 6 months post-treatment (the primary endpoint of the study) converted at least one grade on the AIS. A conversion by even one grade on the AIS is considered clinically important. This 44% conversion rate substantially outperformed historic benchmarks, based on published natural history studies, of -15-25% improvement at 6 months post-injury. A second randomized, single-blind study is now underway.

Partnering in SCI

InVivo plans to further evaluate the performance of its Neuro-Spinal Scaffold implant through multiple combination strategies that could involve complementary technologies such as electrostimulation devices, additional biomaterials, drugs approved by the FDA or growth factors. The company has established a joint research collaboration with Q Therapeutics to evaluate the preclinical safety and feasibility of a stem cell–Neuro-Spinal Scaffold combination.

“At InVivo, we are laser-focused on redefining the treatment of spinal cord injury with our Neuro-Spinal Scaffold technology,” said Toselli. “We envision building on this advance by layering other cutting-edge modalities on top of the scaffold or in conjunction with the scaffold to accelerate and expand the potential benefits for patients with SCI.”

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