Richard T Layer, PhD. Development and Clinical Translation of Biomaterial Technologies for Spinal Cord Injury. Presented at: 4th International Neural Regeneration Symposium; 2014 Sep 6-8, Nanjing, China.

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Abstract:

InVivo Therapeutics Corporation is developing novel biomaterial platform technologies for the treatment of spinal cord injuries (SCI). Despite promising preclinical research in many laboratories, treatments that successfully restore function following a spinal cord injury remain elusive. Severe spinal cord injury is accompanied by cystic cavitation and tissue loss, which reduce the potential for functional recovery after spinal cord injury. Biomaterial scaffolds implanted into the injured spinal cord can serve as a locus for tissue remodeling as well as a supportive matrix promoting the survival of seeded neural stem cells. Previously, InVivo's scientific founders showed that implantation of multi-layer biomaterial scaffolds composed of a porous and biodegradable block copolymer of Poly(lactic-co-glycolic acid) and Poly(L-lysine), both with and without seeded neural stem cells, reduced spinal cord tissue damage and improved functional recovery after spinal hemisection injury in rats. Subsequently, we evaluated the safety and efficacy of porous, single-layer scaffolds in African green monkeys after an incomplete and complete lateral hemisection of the thoracic spinal cord. Detailed analyses of kinematics revealed that fully hemisected monkeys implanted with scaffolds exhibited significantly improved recovery of locomotion compared to control subjects. To identify some of the mechanisms by which the scaffolds increased recovery, the spinal cords were subjected to histological analysis. The spinal cords of monkeys with hemisection injury implanted with scaffolds were characterized by a significant increase in remodeled tissue in the region of the hemisection compared to non-implant controls, and the presence of unphosphorylated neurofilament H or myelin basic protein positive fibers inside the remodeled tissue. ISO-10993 Biocompatibility testing of the PLGA-PLL scaffold demonstrated acceptable safety from contact of the component materials with the body. Based on these safety and efficacy results, InVivo intends to develop its novel, investigational Neuro-Spinal Scaffold to treat acute SCI and Neuro-Spinal Scaffold seeded with neural stem cells to treat chronic SCI. InVivo has initiated an early feasibility pilot IDE study of the Neuro-Spinal Scaffold investigational device in patients with a thoracic level AISA A acute spinal cord injury. The study currently has opened enrollment at 3 US sites, with an additional 3 US sites planned, and intends to enroll 5 subjects. Concurrently, preclinical research and development efforts are focused on the Neuro-Spinal Scaffold with attached neural stem cells for the treatment of chronic spinal cord injury. This next generation combination product has the potential to boost the efficacy and safety of neural stem cell transplantation.