Neural-Spinal Scaffold
A spinal cord Injury Regeneration Platform

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Topic

Spinal cord injury (SCI) is a devastating trauma in the life of a patient and has severe costs on our society. There are approximately 17,000 new acute SCI cases in the U.S. diagnosed each year[1]. Today there are about 285,000 people in the U.S living with SCI and the cost of care range from $350,000 to $1 million per patient for the first year and thereafter. Mortality rates in the first years after the injury, have fallen by some 50%, however beyond this period, there have not been significant improvements[2]. Older people have half of the life expectancy of younger people and people in their twenties have a life-expectancy of about 30 years or 15 years depending whether they are dependent on a ventilator[3].

People sustaining a spinal cord injury often have permanent and profound injury complications occurring in multiples (bladder, bowel, skin, movements, etc.) with functional loss or disability, and potential neurologic disorders (Multiple Sclerosis, Amyotrophic Lateral Sclerosis, Post-Polio, Spina Bifida, Transverse Myelitis, Syringomyelia, Brown-Sequard syndrome, Cauda Equina Syndrome).

Invivo Therapeutics develops a scaffold platform, the **Neural-Spinal scaffold**, and has completed single-arm clinical study for patients with a complete thoracic spinal cord injury. FDA has accepted the preclinical version of the Neural-Spinal scaffold. The company has started a two-arm clinical study looking for 20% or greater improvement in the treatment group compared to the control group on the Abbreviated Injury Scale (AIS) grade. The results of this study are expected in Q1 2023. This platform will be used in conjunction with stem cell therapies as drug screening and drug delivery tool opening the door to improved and novel therapies that will promote the recovery and quality of life of patients afflicted with SCI.

OPC1, **LineageTherapeutics** oligodendrocyte progenitor cell therapy, has received a regenerative medicine advanced therapy (RMAT) and Orphan drug designations from the FDA. OPC1 has been tested in two clinical trials; a Phase 1 safety trial and Phase 1/2a dose escalation trial ("SciStar" trial). Among the patients enrolled in the SciStat trial, 96% reported improved in motor functions with 32% at two or more levels.

Problem statement

As of today, there is no effective treatments for spinal cord injury (SCI) that can generate the spinal cord after injury. There is a need for tissue-engineered construct to provide an environment promoting environment and guidance cues for axonal regeneration.

The product is composed of two biocompatible and bioresorbable polymers which together form an adhesive matrix that can deliver the cells near the injury site for enhancing axon guidance in the spinal cord. This matrix is able to provide graded, spatially and temporarily

[1] National spinal cord injury statistical center.
[2] lifeexpectancy.org
[3] Using Life Expectancy Calculator tool at uab.edu/NSCISC.

neurotrophic factors, and other cues to improve cell survival and potential pro-generative drugs. The scaffold is surgically implanted into the gap in the spinal cord at the site of injury, and is resorbed over several weeks.
Strategies for cell transplantation within the conduit, should also include remyelination of non-damaged axons which has been established as an important mechanism for SCI recovery. Oligodendrocyte derived from oligodendrocyte progenitor cells (OPCs) produce the myelin sheath, remyelinate CNS lesions and by promoting to the production of neurotrophic factors, promote neuronal survival in SCI.
Oligodendrocyte progenitor cells (OPC1) in conjunction with Neurol-Spinal conduit could be the differentiator factor in spinal cord tissue regeneration.