Mission

BioAxone BioSciences Inc. has a mission to complete clinical development and commercialization of Cethrin, a biologic drug that has shown remarkable promise in human clinical studies to reduce paralysis after spinal cord injury.

BIOAXONE MANAGEMENT

Lisa McKerracher, PhD., CEO
Dr. McKerracher is Founder of BioAxone and inventor of Cethrin. She has received numerous awards and international recognition for her work on spinal cord injury. She was co-recipient of the Christopher Reeve Research Medal for Spinal Cord Repair in 2000 with Dr. Albert Aguayo. Dr. McKerracher is past CEO of Emerillon Therapeutics, past CSO of BioAxone (Canada) and currently holds positions of Adjunct Professor at McGill University (Dept. Neurology and Neurosurgery) and Université de Montréal.

Michael Cornelius, CPA., CFO
Mr. Cornelius has over 20 years of corporate finance experience. He was previously the CFO of Stiefel Labs prior to its sale to GSK in 2009.

Ken Rice, MBA, JD, LLM., Bus Dev.
Mr. Rice is Executive VP at Alseres Pharmaceuticals, and a partner helping advance development of Cethrin.

www.bioaxonebio.com

Cethrin™ is a protein therapeutic that blocks signaling from myelin debris present at the site of injury in the injured spinal cord. Cethrin promotes regeneration of cut axons and remodeling of damaged circuits. Cethrin is delivered topically during decompression surgery by a neurosurgeon.

CETHIN IS POSITIONED TO BE A TRANSFORMATIVE TREATMENT FOR SPINAL CORD INJURY

We are entering a new era in translational spinal cord injury (SCI) research, with a number of clinical trials in progress or being planned. The possibility of effective, approved, treatments that are widely available is approaching reality in the foreseeable future and BioAxone’s therapeutic protein, Cethrin, is at the leading edge of this wave. Cethrin is a drug that promotes axon regeneration and neuroprotection, and also has beneficial effects of modifying the adverse immune reaction that follows SCI. The ability to promote axon regeneration is likely to be the most important mechanism of action of Cethrin. Neuroprotection is important in CNS trauma, but saving neurons is not enough. Remodeling of neuronal pathways to replace damaged circuitry is likely to be critically important to improve recovery. Drugs that promote axon regeneration have the potential to stimulate and enhance plasticity, and to repair broken neuronal circuits.

Treatment of patients with Cethrin during clinical trials has elicited promising recovery. Cethrin has Fast-track status and Orphan Drug status from FDA. Cethrin is positioned to be the first drug approved to treat acute SCI that will truly make a difference to patient recovery, and also has potential help people already living with SCI. Chronic SCI is more complex, and combination therapy is expected to provide the best response. Cethrin is expected to act synergistically in combination with cell-based therapies, such as stem cell treatment. Treatments must be shown to be safe individually before proceeding to combinations, and Cethrin has achieved the first step in this process.
CLINICAL ADVISORY BOARD

Dr. Michael Fehlings, MD, PhD.
Dr. Fehlings, the Principal Investigator for the Cethrin trial, is a Professor of Neurosurgery, and Heads the Spinal Program at Toronto Western Hospital. Dr. Fehlings combines an active clinical practice in complex spinal surgery with a translationally oriented research program focused on discovering novel treatments for spinal cord injury. He has received many international prizes and honors for his work.

Dr. Robert Grossman, MD.
Chairman of the Depart. Neurology, Methodist Hospital, Houston Texas. Dr. Grossman has practiced medicine for over 40 years, and as a young doctor he was one of two neurosurgeons who examined President John F. Kennedy after he had been shot. Dr. Grossman has participated in many clinical trials for SCI and advises the Christopher Reeve Foundation as a member of the Advisory Panel.

Dr. James Guest MD PhD
Dr. Guest is Associate Professor of Neurosurgery at the Miami Project to Cure Paralysis., and practices medicine at the Miller School of Medicine, University of Miami. He has an interest in complications of chronic spinal cord injury.

Dr. John W. McDonald, MD, PhD. Dr. McDonald is Director of the Center for Spinal Cord Injury, Kennedy Krieger Institute and a Professor at Johns Hopkins University School of Medicine. Dr. McDonald developed the activity-based restoration therapies to help patients with long-term spinal cord injuries, and the therapy that produced the substantial and delayed recovery of actor/activist Christopher Reeve.

Dr. Wise Young, MD, PhD. Dr. Young holds the Richard H Shindell Chair in Neuroscience at Rutgers University and is Founding Director of the W.M. Keck Center for Collaborative Neuroscience and founder of China SCI Net, which is conducting clinical trials for cell based therapies. Dr. Young has received many awards, including being named by TIME magazine as ‘America's Best’ in the field of spinal cord injury research in 2001.

Dr. Bruce Babbitt, PhD. is a VP at Parexel Consulting and a regulatory expert specializing in biologic drugs.

Dr. Don Berry, PhD. is a professor of Biostatistics at Univ. Texas, CEO of Berry Consulting LLC, and an expert in adaptive clinical trial design.

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CETHRIN CLINICAL STUDIES:
Forty eight patients were treated with Cethrin in a Phase IIa clinical study. The recruited patients had complete sensory and motor loss (ASIA A) below the level of spinal cord injury. The clinical trial was a multicenter study carried out in 9 sites in United States and Canada. The open-label safety study achieved its goal of demonstrating safety and a very promising indication of efficacy. Cervical patients in the most effective dose cohort (3 mg) showed a 27 point improvement in ASIA motor score compared to 10 points expected. Thirty one percent of cervical patients regained some motor function and converted to ASIA C or better, compared to 8% expected. Cethrin was safe and well tolerated, with no serious adverse events associated with administration of the drug. Cethrin is now poised to enter a pivotal Phase II/III study.

TECHNOLOGY OF CETHRIN:
Rho family GTPases act as molecular switches which are turned on or off in response to growth inhibitory signals in the CNS. In the case of spinal cord injury, Rho becomes activated, blocking neuronal attempts to regenerate their broken axons. Cethrin blocks growth inhibitory signaling, which also reduces apoptosis and tissue loss after injury. Cethrin also reduces infiltration of damaging inflammatory cells. Cethrin™ is a designer drug created specifically to treat SCI. Cethrin has been engineered to penetrate cells to inactivate Rho, and was designed for high-yield manufacturing.

Unexpected and surprising motor recovery of patients with cervical injury in the most effective dose groups

Expected motor score change from historical studies.

From Fawcett et al. 2007. Spinal cord 45:190-205

3 mg dose