DEPARTMENT OF DEFENSE - CONGRESSIONALLY DIRECTED MEDICAL RESEARCH PROGRAMS

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Amnion Cell Secretome Mediated Therapy for the Restoration of Traumatic Optic Neuropathy After Brain Trauma

Principal Investigator: MOUZON, BENOIT
Institution Receiving Award: THE ROSKAMP INSTITUTE INC
Program: VRP
Proposal Number: VR190058
Award Number: W81XWH-20-1-0694
Funding Mechanism: Investigator-Initiated Research Award - Funding Level 1
Partnering Awards:
Award Amount: $421,179.00

View Technical Abstract

PUBLIC ABSTRACT

Physical or chemical injuries of the eye, and their related visual dysfunctions, are important public health issues. An eye injury can be a serious threat to vision if not treated appropriately and in a timely fashion. In recent conflicts (i.e., Operations Enduring Freedom, Iraqi Freedom, and New Dawn) and among active duty personnel, traumatic eye injury ranks fourth, behind traumatic brain injury (TBI), post traumatic stress disorder, and hearing loss, in terms of common injuries.

While Veterans may suffer vision problems as a result of age, most of the vision problems were triggered by service-related injuries. Researchers have found that upward of 75 percent of all Veterans who screened positive for TBI-related trauma experienced short- or long-term visual dysfunction, including double vision, sensitivity to light, and inability to read print. Mild TBI (mTBI) encompasses concussion, sub concussion, and most exposures to artillery and explosive blasts from improvised explosive devices. It is now recognized that the adverse effects, particularly of repetitive mTBI, continue for many years after the original event. Consequently, the Department of Defense has created military-related injury surveillance systems that provide the scientific data needed to calculate injury rates, monitor patterns of injury, and identify risk factors. Since its initiation in 2000, the Defense and Veterans Brain Injury Center has reported nearly 350,000 TBI incidents in the U.S. military. Among those deployed, the estimated rates of TBI range from 11% to 23%, and 59% of affected military personnel reported more than one mTBI. Furthermore, when we look at the recent concussion data, they show that about 85% of all concussions do not occur in the combat theater, but rather in training activities, physically demanding sports, or other causes. In the absence of treatments specific for these injuries, many Service members and Veterans will not improve their current visual condition and will experience gradual loss of vision over time.

The objective of this application is to evaluate the potential usefulness of ST266, a novel neuroreparative cell-free therapeutic produced by Noveome Biotherapeutics, Inc., to treat visual dysfunction resulting from battlefield trauma. For this project, instead of a single drug that targets a specific problem, we will use a rich, complex solution, called ST266, that comprises molecules secreted from proprietary cells that modulate inflammation, accelerate wound healing, and potentially restore visual function to improve patient outcomes. This work will be carried out in our well-characterized mouse model of repetitive mild TBI, which demonstrates TBI-dependent visual dysfunction. The four aims of the project will investigate:

1. Dose of ST266 that produces the optimal functional recovery for the visual system

2. Long-term therapeutic efficacy of an acute treatment with ST266, to determine whether an acute treatment with ST266 has long lasting benefits on the visual system

3. Therapeutic efficacy of a delayed treatment with ST266, to better model the patient population who likely seek treatment at some time after the injury has been sustained

4. Therapeutic efficacy of a prophylactic treatment in order to protect or reduce vision damages in Service members that will be deployed into an environment with high risk of TBI.

At the conclusion of this two-year project, our findings could significantly impact the health of Veterans with vision dysfunction, and their families, by offering them new therapeutic approaches to treat and potentially reverse vision problems. The aims of this study - to find both an effective treatment and an effective administration regimen - mean that the results can be useful for both active duty military, Veterans, and the civilian population; the prophylactic treatment paradigm having great translational relevance for our active duty military, and the delayed treatments of value for Veterans who have previously sustained the traumatizing injury. Visual dysfunction is an

under-investigated sequela of TBI that has significant deleterious effects on performance, return to duty, and quality of life. We anticipate that positive results from this preclinical study could rapidly translate into clinical testing and implementation of an effective treatment.

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CDMRP

1077 Patchel Street
Fort Detrick, MD 21702-5024

(301) 619-7071

CDMRP Webmaster (mailto:cdmrpwebmaster@webcdmrp.org)

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