Clinical Safety Evaluation of USB005 for Treatment of Traumatic Corneal Lacerations

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View Technical Abstract
Objectives/Rationale: Injury to the cornea can be either partial- or full-thickness. A partial-thickness injury does not violate the globe of the eye (abrasion), while a full-thickness injury penetrates completely through the cornea, causing a ruptured globe. When the corneal epithelium is breached and the sensory nerves are exposed, significant discomfort or pain can result. Defects in the barrier of the corneal epithelium are a gateway for outside organisms, leading to corneal ulcers and subsequent vision loss. Corneal-wound management typically includes pain relief and topical antibiotic administration and has historically included eye patching.

This proposal aims to demonstrate that treatment of normal, healthy volunteers with USB005, a sterile, non-preserved, multi-use, eye drop formulation of NorLeu3-A(1-7), is safe and suitable for follow-on clinical evaluation for enhancing corneal re-epithelialization and stromal healing. Tissue regeneration and anti-inflammatory activity of USB005 will reduce scar formation, preserve vision, and decrease distortion of visual acuity as well as the associated optical discomfort. In order to accomplish the objectives of this proposal, USB005 must be manufactured under current Good Manufacturing Practices (cGMP), an Investigational New Drug (IND) application must be submitted, and a Phase 1 clinical trial must be completed, demonstrating safety.

Civilian Impact: According to the American Academy of Ophthalmology, 2.5 million eye injuries occur in the United States every year, many of which can lead to permanent vision loss. Corneal lacerations represent a significant percentage of ocular trauma cases. Management of these injuries requires rapid diagnosis and depending on the size of the wound, either medical or surgical treatment. Wound closure in a timely manner with restoration of original anatomic relationships provides patients the best chance to regain optimal visual function. Currently, there is no Food and Drug Administration (FDA)-approved drug to facilitate tissue regeneration in the cornea. USB005 provides a unique opportunity to treat traumatic corneal lacerations through clear corneal healing and the reduction of associated pain. By accelerating the wound healing process and the restoration of visual acuity, USB005 will maximize function for return to duty or civilian life as well as reduce the initial and long-term costs associated with restorative and rehabilitative or acute care of ocular injuries. At the end of the proposed 15-month project, USB005 will have been investigated in human subjects, demonstrating safety after 28 days of treatment. Upon completion of the proposed and follow-on clinical trials, the product will be available as a treatment that facilitates complete, clear healing of corneal injuries while reducing post-injury complications such as blurred vision. USB005 is expected to be available for use across a variety of traumatic corneal injuries as well as in post-surgery applications such as cataract and photorefractive keratectomy.

Military Benefit: Traumatic eye injuries accounted for about 16% of all battlefield injuries in Iraq and Afghanistan, according to the National Alliance for Eye and Vision Research, and 80% of Soldiers with eye injuries were unable to return to duty, compared to 20% with other types of injuries. Such injuries significantly reduce visual function and cause severe pain due to inflammation, corneal vascularization, scar formation, and disordered stromal healing. In 2005, the Department of Defense found that 26% of ocular injuries suffered by active duty personnel were attributed to traumatic corneal abrasions and lacerations, with an incident rate of 5.89 per 1000 personnel, three times more common than the next leading ocular injury. A 2012 study estimated that combat eye injuries had cost nearly $2.3 billion a year over the previous decade, including medical costs, projected government benefits, and lost contributions to the economy. A novel, easily transported therapeutic intervention to preserve vision, decrease associated optical discomfort, and induce accelerated avascular healing would optimize the ocular health, performance, and return to duty of military personnel across the full spectrum of operations while also reducing total healthcare costs attributed to ocular injury.
CDMRP

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