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Phase 2 Enabling Evaluations of USB005 for Treatment of Corneal Injuries

Principal Investigator: DIZEREGA, GERE
Institution Receiving Award: U.S. BIOTEST, INC.
Program: VRP
Proposal Number: VR190054
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View Technical Abstract

PUBLIC ABSTRACT

Rationale: A corneal injury can be either superficial, partial-thickness, or full-thickness. A superficial injury (abrasion) affects the epithelium only, a partial-thickness injury causes stromal scarring but does not violate the globe, while a full-thickness injury penetrates completely through the cornea, causing a ruptured globe [Aaronson 2011]. 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 [Cho and Savitsky, 2012; Ewald and Hammersmith, 2009].

Objectives: This proposal will evaluate antimicrobial properties of USB005 as well as the administration of USB005 in combination with standard-of-care topical steroids. Combined, these tasks will provide the regulatory basis for further clinical testing across trauma- and laser-induced ocular injuries. Successful completion of this program would position USB005 to allow progression into Phase 2 clinical evaluation.

Hypothesis: We expect that USB005 will show no antimicrobial properties, but when packaged in FDA-approved, sterile, multi-use, preservative-free Aptar Ophthalmic Squeeze Dispenser units, will show no microbial growth, and thus gain FDA allowance for use in Phase 2 clinical trials. We also expect that the co-administration of topical steroid and USB005 will show no safety issues, thus allowing human use of the two treatments together.

Specific Aims: Aims of this program include antimicrobial effectiveness evaluation of USB005, GLP toxicology evaluations of extended dosing (13-weeks), as well as co-administration effects of USB005 and topical ocular steroid as required for Phase 2 evaluation of effectiveness of USB005 following corneal injury and Phase 2 clinical protocol development.

Civilian Impact: According to the American Academy of Ophthalmology, 2.5 million eye injuries occur in the United States every year, many of which lead to permanent vision loss. 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 [Vora 2013]. Currently, there is no FDA-approved drug to facilitate tissue regeneration in the cornea. USB005 provides a unique opportunity to treat corneal injuries through clear corneal healing. By accelerating the wound healing process and the restoration of visual acuity, USB005 will maximize function for return to normal life activities, as well as reduce the initial and long-term costs associated with restorative and rehabilitative or acute care of ocular injuries.

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 [Roth 2015]. 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 [Hilber, 2005]. 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 [Frick 2012]. An easily transported therapeutic eye drop to preserve vision, decrease optical discomfort, and induce accelerated healing would optimize the ocular health,

performance, and return to duty of military personnel across the full spectrum of operations while reducing total healthcare costs attributed to ocular injury.

Outcomes: Upon completion of the proposed project, clinical trials can be initiated to evaluate the effectiveness of USB005 in facilitating corneal repair in humans. Successful demonstration of effectiveness as a treatment that facilitates complete, clear healing of corneal injuries while reducing post-injury complications, such as blurred vision, would position USB005 as a useful treatment of a variety of corneal injuries, including post-surgery applications, such as cataract, photorefractive keratectomy, LASIK, and corneal transplant. If USB005 is shown to positively impact the healing of surgical and trauma-related corneal injuries, there is a genuine opportunity for this drug to make a significant contribution to common ocular treatment regimens in the coming years.

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