DEPARTMENT OF DEFENSE - CONGRESSIONALLY DIRECTED MEDICAL RESEARCH PROGRAMS

Contact Us (/contact) | Site Map (/sitemap)

(https://www.facebook.com/TheCDMRP) (http://twitter.com/CDMRP) (https://www.youtube.com/user/CDMRP) (/rss/funding_opportunities.xml)

CDMRP (/default)

Transforming Healthcare through Innovative and Impactful Research

Home (/default) / Search Awards

Search Awards

Back to Search Results | Modify Search | New Search

Topical Novel Nonopioid Pain Relief for Eye Injury

Principal Investigator: OLEJNIK, OREST
Institution Receiving Award: IACTA PHARMACEUTICALS, INC
Program: VRP
Proposal Number: VR200129
Award Number: W81XWH-21-1-0584
Funding Mechanism: Translational Research Award
Partnering Awards:
Award Amount: $1,098,493.00

View Technical Abstract

PUBLIC ABSTRACT

IACTA is developing IC800, a novel, non-opioid therapy for the topical treatment of ocular pain resulting from trauma, that works via the body's pain controllers, the enkephalins.

Eye injury resulting from battlefield trauma affects a large number of Service Members and Veterans, accounting for approximately 15% of all battlefield trauma. A very significant and immediate result of eye trauma is acute pain, which frequently becomes chronic pain. Non-steroidal anti-inflammatory drugs (NSAIDs) and steroids are two common treatments for ocular pain, but both have their limitations in terms of both efficacy and side-effects. There are safety concerns with long-term ocular use of NSAIDs, including corneal melting (a precursor of perforation), edema, and ulceration, accompanied by superficial ocular infections and inflammation, and delay of wound healing. While topical steroids are widely used to control ocular inflammation, their use can lead to cataracts, increased interocular pressure, glaucoma, secondary infection, and delayed healing, and, as such, are not recommended for use >1 week. Orally delivered ocular pain control options have limited efficacy and significant risks. For example, oral NSAIDs and steroids generally don't control ocular pain well, and they present many risks such as gastrointestinal bleeding, nephrotoxicity, and cardiac events. Oral opioids are perhaps the most effective for ocular pain but are only prescribed for very severe eye pain due to the risk of addiction and other side-effects. It should be noted that there are no Food and Drug Administration (FDA)-approved topical or optical formulations of opioids; they are only available via custom compounding. Currently, there are no widely available, highly effective treatments for acute or chronic ocular pain, and so following injury it is often poorly controlled. To address this unmet need, IACTA Pharmaceuticals seeks to develop a novel, stable, highly effective optical formulation for the relief of ocular pain and inflammation that is packaged in a single-use, unit dose applicator, which can be easily administered in low-resource environments such as a battlefield.

We hypothesize that IC800 will be safe and well-tolerated when administered topically to the eye in humans and will be effective with fewer side-effects in treating ocular pain than opioids and other options currently available.

The aims of the project are: (1) Develop a formulation of IC800 for topical use in the human eye; (2) conduct animal toxicology of the optical formulation of IC800; and (3) prepare and file an application for an Investigational New Drug (IND) with the FDA.

We plan to develop a human formulation in the next 12 months. Following formulation development, a 28-day animal ocular safety study will be conducted. Data from the toxicology study will be available 6 to 9 months after initiation, allowing us to submit an IND to the FDA 15 to 18 months following initiation of the study. After successful completion of this study, we will seek additional funding to be able to transition from preclinical studies to phase 1 human safety trials that will be conducted in healthy subjects, followed by one placebo-controlled phase 2 efficacy and safety study in patients (60 to 100) with eye injury. Following a successful phase 2 study, two phase 3 human efficacy and safety studies will be conducted. Following the demonstration that the product is efficacious and safe a New Drug Application will be prepared and submitted to the FDA for review and approval.

In the long term IC800 could significantly change ocular pain management and, potentially, replace opioids and other analgesics that have both safety and efficacy issues. Such outcomes will allow Service Members to receive stabilizing treatment to acute eye injuries in austere environments while being transported to medical facilities.

Back to Search Results

Note: Documents in Portable Document Format (PDF) require Adobe Acrobat Reader to view, download Adobe Acrobat Reader (http://get.adobe.com/reader/).

CDMRP

Privacy Notice (/privacynotice) · External Links/Product Disclaimers (/disclaimer) · Research Programs (/researchprograms) · Funding Opportunities (/funding/default) · Consumer Involvement (/cwg/default) · Search Awards (/search.aspx) · About Us (/aboutus)

1077 Patchel Street
Fort Detrick, MD 21702-5024

(301) 619-7071

CDMRP Webmaster (mailto:webmaster@cdmrpweb.org)

About Us

The CDMRP originated in 1992 via a Congressional appropriation to foster novel approaches to biomedical research in response to the expressed needs of its stakeholders-the American public, the military, and Congress.

(https://www.facebook.com/TheCDMRP) (http://twitter.com/CDMRP) (https://www.youtube.com/user/CDMRP) (/rss/funding_opportunities.xml)

- MRDC Family -

CDMRP (https://cdmrp.army.mil/) | TATRC (https://www.tatrc.org/) | USAARL (https://www.usaarl.army.mil/) | USAISR (https://usaisr.amedd.army.mil/) | USAMMDA (https://www.usammda.army.mil/) | USAMRAA (https://www.usamraa.army.mil/Pages/Main01.aspx) | USAMRICD (https://usamricd.amedd.army.mil/Pages/default.aspx) | USAMRIID (https://www.usamriid.army.mil/) | USARIEM (https://www.usariem.army.mil/) | WRAIR (https://www.wrair.army.mil/)