CCRP Product Development Support Services - Preclinical Efficacy Evaluation Resources: Sulfur Mustard Ocular Toxicity Model

Background

The goal of NIH Chemical Countermeasures Research Program (CCRP) centralized Product Development Support Services (PDSS) - Preclinical Efficacy Evaluation Resources (PEER) is to assist applicants with acquisition of pilot proof-of-principle efficacy data of candidate MCM(s) against the lethal and/or non-lethal effects of chemical threat agents in established or new models of chemical intoxication. PDSS resources are limited and not intended to sustain the entire spectrum of chemical MCM discovery, research, and development and should not be the sole source of support.

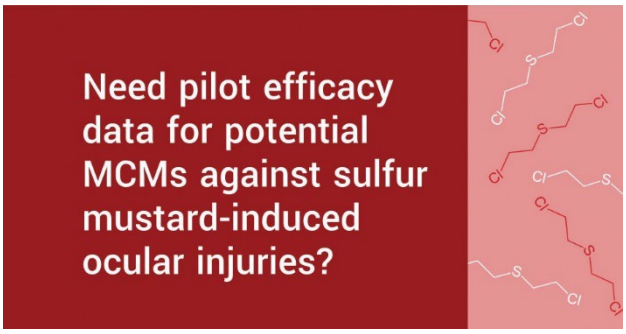
All information provided will be treated as confidential. Participants will retain custody of and have primary rights to the data developed, subject to Government rights of access consistent with current HHS, PHS, and NIH policies.

If approved, studies are performed at **no cost** to the applicant. Investigators seeking these services receive no funding from NIAID, but instead receive products or information generated by NIH-funded contractors on their behalf. NIH will deliver a final study report to the investigator at the end of the study.

PDSS Sulfur Mustard (SM) Ocular Toxicity

Vesicants such as the chemical warfare agent SM can cause moderate to debilitating injuries and pain to the eyes, skins, and mucous membranes. The eyes are usually the first and most frequent route of toxic exposure thus making them especially vulnerable to chemically induced injuries, e.g., exposure keratopathy, corneal neovascularization and fibrosis, limbal stem cell deficiency. While chemical toxicity to the eyes is generally non-fatal, injury to one of the most biologically complex and important sensory organs can result in immediate and chronic long-term incapacitation due to vision loss and overall changes in the quality of life; very serious morbidities. Attenuation of the acute pathologic effects of SM-induced ocular lesions may decrease the long term chronic ocular morbidity that often manifests long after the initial exposure.

With little to no effective therapeutic options currently available, discovery of potential therapeutics that could



prevent and/or treat the acute and/or chronic ocular injuries resulting from SM exposure is of particular interest to the CCRP.

What We Offer -

The SM ocular toxicity model employs an *in vivo* approach where toxicity progression and MCM efficacy are monitored through non-invasive clinical assessment of the eyes and histopathological analysis at scheduled termination.

The proposed pilot study will be limited in scope and aim to facilitate initial characterization of candidate MCM(s) efficacy. Preliminary evidence of therapeutic efficacy, i.e., biological response (preferably *in vivo*) against the actual threat agent OR an acceptable surrogate injury model is required. Applicants seeking label-expansion indications of already FDA-approved medications and /or those further along in the exploratory or validation stage for a conventional indication are highly encouraged to apply.

Applicant Eligibility Criteria

Utilization of PDSS resources is available to any domestic U.S.-based applicant with promising MCM candidates (and appropriate supporting preliminary data) responsive to the CCRP mission

Who to Contact

To learn more or request preparation instructions for a study pre-proposal, please contact **Houmam Araj, Ph.D.** (NEI/NIH); arajh@nei.nih.gov or **Dave Yeung, Ph.D.** (Deputy Director, CCRP); dy70v@nih.gov