Request for Project Information

Solicitation Number: MTEC-20-18-Burns
“PLANAR DELIVERY PLATFORM FOR CERIUM AND SILVER INTO BURN WOUNDS”

Issued by:
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for the
Medical Technology Enterprise Consortium (MTEC)

Request Issue Date: August 4, 2020
Amendment No. 01 Issue Date: August 28, 2020

Proposal Due Date: September 2, 2020
Noon Eastern Time

Amendment No. 02 extends the proposed due date from September 1, 2020 at 11:59pm ET to September 2, 2020 at 12:00pm ET.

All other terms and conditions remain unchanged.
The Medical Technology Enterprise Consortium (MTEC) is excited to post this announcement for a Request for Project Information (RPI) focused on the development and fabrication of a medical-grade planar delivery system for effective delivery of cerium and silver into burn wounds for improved burn outcome. This Request for Project Information (RPI) contains background information and guidance for MTEC members and non-members to prepare Project Information Papers for submission to MTEC. Project Information Papers will be used by the Sponsor (the U.S. Army Institute of Surgical Research, USAISR) to shape a potential future MTEC Request for Project Proposals (RPP) for the development of the product.

BACKGROUND

Without timely treatment, burn wounds deteriorate, become infected, causing unwanted short- and long-term outcomes, and at worst, increased mortality. Under large scale multi-domain operations, delayed evacuation of the combat wounded is anticipated. Therefore, under prolonged field care environments, the treatment of burn injuries to stabilize the wounds, lessen progression, and limit complications is paramount to improve wound outcomes and decrease mortality.

Severely burn-injured skin forms an eschar (dead skin) that includes denatured macromolecules and other metabolites that contribute to local and systemic inflammation, immunosuppression, hypermetabolism, and ultimately multi-organ dysfunction. Early excision of the eschar and autologous skin grafting within a few days of injury reduces these detrimental effects and lowers infection risk, reducing morbidity and mortality. But eschar excision and grafting under prolonged field care during combat is not possible. Therefore, to mitigate the detrimental effects of the burn eschar when it cannot be excised, treatments are needed to temporize burn wounds. One such treatment with demonstrated effectiveness is cerium nitrate (CN).

Topical treatment of burn wounds with CN has been established to stabilize the eschar to: 1) reduce burn-injured patient care burden, 2) decrease inflammatory mediators in burn tissue and circulation, and 3) provide a leathery covering resistant to eschar detachment and infection that permits delayed excision and grafting.

Flammacerium, a cream formulation that contains both silver sulfadiazine and CN, is a topical antimicrobial that has been in widespread use in European burn units, particularly in Belgium, Netherlands, Switzerland, France, and the UK since the mid-1980s. It has also been compounded in hospital pharmacies and used in the U.S., including in New York after the 9/11 terrorist attacks.
under an emergency Investigational New Drug (IND) filing with the U.S. Food and Drug Administration (FDA).

At the USAISR (Sponsor), researchers have demonstrated that CN solution (40 mM) treatment of rat full-thickness scald burns (Walker-Mason model) can reduce pro-inflammatory damage-associated molecular patterns (DAMPs), including high-mobility group box protein 1 (HMGB1), hyaluronan, and xanthine oxidase (XDH) in circulation on post-burn day 1. On post-burn day 7, both the DAMPs in circulation and the pro-inflammatory mediators, IL-1β, IL-10, GRO-KC, and MIP-1α in wound tissue were on average halved by CN treatment (Qian L. et al. J Burn Care & Res. 2020. 41(3):576-584. PMID: 31808807).

Moreover, researchers at the USAISR have investigated the use of fabric-based silver dressings to deliver CN to burn wounds. Compared to the silver dressings alone, the combination of silver dressings and CN reduced burn wound inflammation and restricted microbial growth in the burned tissue (rat model; manuscript in revision).

**TECHNOLOGY FOCUS AREA**

The USAISR is seeking technology input(s) for the development and fabrication of a planar system for the delivery of cerium and silver to burn wounds. The delivery system must be stable, lightweight, small footprint, and easy to deploy by medical and non-medical personnel for treating burn wounds at or near the point of injury under prolonged field care.

**KEY FEATURES OF THE PLANAR DELIVERY PLATFORM**

- Planar delivery platform (e.g., textile). SEMI-SOLID FORMULATIONS WILL NOT BE CONSIDERED.
- Conformable to various body and wound surface contours and anatomical structures and suited for the treatment of severe burn wounds.
- Controlled and continuous release of CN and silver to burned human or animal skin for a minimum of 72 hours.
- Scalable and cost-effective manufacturing process.
- Stable during storage and operation (based on ICH Guidelines).

**REQUIREMENTS OF THE PROJECT INFORMATION PAPER**

- Format
  - 4-page limit, inclusive of contact information
  - 12 point Arial font, smaller font may be used in figures and tables, but must be clearly legible
  - Single-spaced, single-sided, 8.5 inches x 11 inches.
  - Margins on all sides (top, bottom, left, and right) should be at least 0.5 inch
  - Project Information Paper should be in *.pdf format
  - These project information submissions will be shared with the Sponsor; therefore, all information must be nonproprietary.
The Project Information Paper must include the following information:

- Date: [Insert Date of Submission]
- PI Organization: [Insert submitter’s name, organization, email address, phone number]
- Approach: [Describe your approach to solving the problem. Include relevant background/preliminary data about your approach. Describe the existing technology. Include strategies for incorporating silver and cerium into the Planar Delivery Platform with details of risks and mitigations. Note: References are included within the page limit. There is no required format for the inclusion of references.]
- Manufacturing: [Describe your ability to produce under good manufacturing practices (GMP) conditions and distribution capabilities and partnerships.]
- Intellectual Property: [Describe relevant intellectual property and patent right assertions in U.S. and abroad.]
- Experience: [Have submitters and/or their partners obtained FDA approval and marketed other solutions?]
- Estimated Funding Required to Advance Project: [Please estimate the required funding needed for each major task that advances the project into its next stage of development/milestone dependent upon its current maturity. Do not provide budget detail – only provide a total estimated budget for each major milestone. This information will be used to provide the Sponsor with a reasonable representation of the amount of funding required to advance the project. Examples of tasks include, but are not limited to:
  - late animal testing and regulatory filing;
  - conduct Phase 1 clinical trials]

**MTEC**

The MTEC mission is to assist the USAMRDC by providing cutting-edge technologies and supporting effective materiel life cycle management to transition medical solutions to industry that protect, treat, and optimize Warfighters’ health and performance across the full spectrum of military operations. MTEC is a biomedical technology consortium collaborating with multiple government agencies under a 10-year renewable Other Transaction Agreement (OTA), Agreement No. W81XWH-15-9-0001, with the U.S. Army Medical Research Acquisition Activity (USAMRAA). MTEC is currently recruiting a broad and diverse membership that includes representatives from large businesses, small businesses, “nontraditional” government contractors, academic research institutions, and not-for-profit organizations.

**ADMINISTRATIVE INFORMATION**

Project Information Papers must be submitted by **12:00 pm ET on September 2, 2020** via [BIDS](https://ati2.acqcenter.com/ATI2/Portal.nsf/Start?ReadForm). Include the MTEC Solicitation Number (MTEC-20-18-Burns) on each Project Information Paper submitted. Project Information
Papers may be submitted by both MTEC members and non-members. Please note that MTEC membership is required for the submission of a proposal in response to a future MTEC Request for Project Proposals for Planar Delivery Platform for Cerium and Silver. To join MTEC, please visit [http://mtec-sc.org/how-to-join/](http://mtec-sc.org/how-to-join/)

For inquiries, please direct your correspondence to the following contacts:

- Technical questions - Dr. Lauren Palestrini, PhD, MTEC Director of Research, Lauren.Palestrini@officer.mtec-sc.org
- Other questions – Ms. Kathy Zolman, MTEC Director of Program Operations, Kathy.Zolman@ati.org

Sincerely,

MTEC Project Team
MTEC BIDS REGISTRATION

MTEC BIDS URL:
HTTPS://ATI2.ACQCENTER.COM
Navigate to the MTEC BIDS website and select “New Registration” from the home screen.
Select “Submitter”
Complete the registration form. Be sure to select how you want to receive the dual factor verification code (SMS text message is recommended).

Select “Submit Registration” to complete BIDS registration.
BIDS registration is instantaneous. It does not require any verification by the MTEC team. After successfully registering, you can submit proposals to any open MTEC RPP.

- MTEC Membership will be verified once a proposal is received and after the proposal deadline.
- Updates to submitted documents can be made anytime prior to the due date and time.
- MTEC RPP links will be opened, within BIDS, at least two weeks prior to the submission deadline.

Please note: For RPPs that are two stages (i.e. White Paper to Full Proposal) only the account that submitted the stage 1 proposal (the White Paper) will be allowed to submit for stage 2 (the Full Proposal), if selected.

ALL PROPOSALS MUST BE SUBMITTED BEFORE THE SUBMISSION DUE DATE AND TIME. LATE PROPOSALS CAN NOT BE ACCEPTED.
MTEC BIDS REQUEST FOR PROJECT INFORMATION (RPI) SUBMISSION

MTEC BIDS URL:
HTTPS://ATI2.ACQCENTER.COM
Proposition Submission BIDS

Navigate to the MTEC BIDS site and login. After login select the “MTEC BIDS Home” link.

Then select the “MTEC BIDS Home” link

Login to your BIDS Account.

SECURITY NOTICE: Unauthorized attempts to deny service, upload information, change information, or attempt to access a non-public site from this service are strictly prohibited and may be punishable under Title 18 of the U.S. Code to include the Computer Fraud and Abuse Act of 1986 and the National Information Infrastructure Protection Act.
Select the “Respond to RPI” link under the submitter tools. After login, your username will appear here.

Click the “Respond to RPI” link.

RPP and RPI information is provided in this section.
Select which RPI you will be responding to.

Select which RPI to respond to. If multiple RPIs are open, they will be listed here.
Complete the submission form.

Select the Focus Area or Technical Area your submitting to as identified in the RPI.
Proposal Submission BIDS

Complete the submission form by uploading the required documents and click submit.

Upload documents in this section.

Once the submission form is completed select submit.
Once you have successfully submitted a proposal, you will receive a notification with your submission number (ex. MTEC-23-24-Everest-045).

ALL PROPOSALS MUST BE SUBMITTED BEFORE THE SUBMISSION DUE DATE AND TIME. LATE PROPOSALS CAN NOT BE ACCEPTED.