OBJECTIVE: PLEASE NOTE - DHA topic DHA201-D001 is a Direct to Phase II topic. Offerors must provide documentation showing they have completed research and development to establish Phase I feasibility outlined in the topic description. Only Phase II proposals will be accepted for this topic.

Develop a field-expedient, antimicrobial, hydration-providing wound dressing for acute care of large burn wounds.

DESCRIPTION: In future battlespace scenarios, mission-impactful increases in the numbers of burned casualties and in burn wound severity in terms of burn depth and size may be anticipated compared to recent conflicts. The projected operational paradigm also suggests that casualty evacuation may be delayed in the future fight, creating conditions in which burn injury treatments to save lives, hasten return to combat effectiveness, and improve functional recovery must be provided out of hospital for a period of days or longer, under degraded circumstances in the absence of surgical capability (i.e., prolonged field care). This prolonged care context will preclude the current standard of care for burn injuries, defined as evacuation from Theater to the San Antonio Military Medical Center Burn Center for definitive treatment. Currently only minimal burn wound management tools are available in the prehospital environment, consisting primarily of silver-containing wound dressings to prevent/minimize infection until evacuation to surgical care. There remains in the marketplace a lack of proven, clinically effective, acute burn wound treatment technologies, for example, to not only reduce infection but also promote healing of severe burn injuries. Furthermore, the prevalence of known and emerging weapon systems capable of thermal, electrical, and novel mechanisms of burn injury underscores a need for applicability of advanced acute burn care tools to mass casualty situations, potentially in dense urban environments, where the care capability and capacity of available medical providers may be rapidly overwhelmed. These circumstances underscore a critical necessity for the development of novel, advanced, effective, easy to use therapies for acute management of severe burns under austere, prolonged prehospital care to save lives, preserve combat readiness in the operational environment, and optimize long-term recovery and functional outcomes for burned Service members.

PHASE I: Advanced, innovative, topical solutions (e.g., dressings) for acute stabilization of large-sized, deep partial-thickness and full-thickness burn wounds are sought. Prevention of fluid loss, antimicrobial activity (to include anti-biofilm activity), and acceleration of wound healing are important qualities for the product to be developed. The candidate technology will demonstrate properties suggesting ease of use of the ultimate product by lower skilled responders under austere, prehospital conditions. Severe burns are defined as deep partial thickness and full thickness burn injuries. The technology developed will eventually be required to be incorporated into a therapeutic product that is highly mobile with low logistic burden (weight, power, cube) for field use under prolonged care. The minimum end goal of Phase I is readiness of an innovative, novel, candidate technology for acute care of severe burn for proof-of-concept studies in an established, combat-relevant animal model of severe burn.

PHASE II: Using the novel burn wound healing material developed in Phase I, the Offerer must design and engineer the candidate material /dressing formulation and demonstrate feasibility of use in austere environments by unskilled individuals for acceleration of large size (>15% total body surface area), deep partial thickness or full thickness burn wound healing in the absence of grafting. Initial prototypes and proof of principle of the material’s ability to control gram-negative and/or gram-positive infections using standard microbiological tests must be demonstrated in a time frame of use relevant to prolonged field care conditions. The Offeror must conduct a proof-of-concept evaluation of the technology compared to standard of care silver-containing dressings available in the marketplace in appropriate combat-relevant, animal model(s) of large-sized, deep-partial thickness or full-thickness burn wound. Efficacy in preventing/managing infection and potentiating healing in vivo is a priority. Topical treatments which are thin, conformable, breathable, non-toxic (safe), and bio-absorbable are sought. The ultimate product should also be self-administrable in the field, functional immediately upon application, provide a barrier to fluid loss, prevent or reduce infection, and potentially reduce blood loss. In addition, the product should be easily removed (i.e., dressing changes) without causing damage to the wound bed or not require active removal (i.e., left in place as self-shed or biodegradable). Expected users of the technology are medical providers (including...
those who are not burn care specialists), non-providers (i.e., medics), and untrained personnel (i.e., “buddy care”) in austere operational environments. Field-expediency is an important characteristic of the desired technological solution. Field-expediency standards for the expected use profile of the developed technology require that the candidate solution must be readily applicable in dirty, harsh, resource limited, prehospital conditions for up to 72 hours of prolonged care prior to surgical intervention, as well as durable during storage for long periods of time and during use. Reasonable cost is also key. Other required Phase II deliverables include: biocompatibility, cytotoxicity and immunogenicity analysis, and the demonstration of acceleration of burn wound healing over standard of care in both uninfected and infected wounds. During Phase II product safety/toxicity and stability using FDA standardized models performed under appropriate Good Laboratory Practice (GLP) conditions must be demonstrated. A detailed description of any additional studies, strategy for clinical studies, and transition pathway of the novel product into clinical practice must be addressed. Development and discussion of a plan for the potential regulatory pathway for the material for ACURO and HRPO and approval is required. Additional objectives, which are desirable but not required, are that the technology demonstrates eschar-stabilizing, anti-inflammatory, and local pain analgesic properties. Efficacy in preventing/treating acute infection and accelerating healing of other traumatic soft tissue injuries in addition to severe burn wounds would be advantageous, while effectiveness specifically in acute management of large-size, severe burn injuries is paramount and required.

PHASE III DUAL-USE APPLICATIONS: Phase III efforts should include focus on technology transition, preferably commercialization of SBIR research and development. The product developed is intended to be suitable for use and potential procurement by all of the Services for primary use in the field/prehospital environment, including austere, prolonged care scenarios. Realization of a dual-use technology applicable to both the military and civilian use is preferred. Therefore, the successful transition path of the technology is expected to include close engagement with military medical acquisition program managers (USAMMDA) during product commercialization to ensure appropriate product applicability for military field deployment. The minimum goal of Phase III is to finalize all pre-clinical testing and validation of a material for treatment of large, deep-partial thickness and/or full thickness burn wounds that can receive regulatory approval. In this phase the Offeror, in consultation with the FDA, may conduct a small, pilot, large animal validation study to establish safety/toxicity in an appropriate Good Laboratory Practice (GLP) model relevant to combat burn, and demonstrate appropriate product stability. Efforts leading to FDA approval require execution of Phase II plans on regulatory pathway, including identifying relevant patient population for clinical testing to evaluate safety and efficacy and GMP manufacturing of sufficient materials for evaluation. The end state of Phase III consisting of preclinical research is completion of appropriate studies required to receive FDA approval for the conduct of human clinical trials. Alternatively, dependent on the end state of Phase II of the program, the most desirable Phase III effort would consist of human clinical trials designed to demonstrate a product with the appropriate indications for treatment of large, deep-partial thickness and/or full thickness burns under prolonged care in austere environments. Human trials must demonstrate safety and efficacy of the product with the described desirable characteristics to promote burn wound healing and provide infection control. Demonstration that the novel technology yields improved results over standard of care for the parameters described in the “OBJECTIVE” and “DESCRIPTION” sections above is the ultimate goal of this SBIR program announcement. Phase III studies designed as human comparative effectiveness trials with competitive technologies under conditions relevant to the prolonged care combat environment are also sought.

REFERENCES:

1. TRADOC Pamphlet 525-3-1, The U.S. Army in Multi-Doman Operations; 6 DEC 2018; tradoc.army.mil/Portals/14/Documents/MDO/TP525-3-1_30Nov2018.pdf

2. JTS Clinical Practice Guideline: Burn Care (CPG ID: 12); 11 MAY 2016; jts.amedd.army.mil/assets/docs/cpgs/JTS_Clinical_Practice_Guidelines_(CPGs)/Burn_Care_11_May_2016_ID12.pdf

KEYWORDS: Burn, Hydrogel, Antimicrobial, Anti-inflammatory, Healing, Topical