Announcement for Request for Project Proposals (RPP)

“Drug Treatment for Traumatic Brain Injury (DTTBI)”

The Medical Technology Enterprise Consortium (MTEC) is excited to announce a Request for Project Proposals (RPP) focused on Drug Treatment for Traumatic Brain Injury (DTTBI) – to rapidly advance the development of TBI drug candidate prototypes, through focused Phase 2 clinical trial testing, to produce a TBI drug that has been fully characterized and ready for Phase 3 trial. The end goal of DTTBI is a commercial TBI drug product that is approved by the U.S. Food and Drug Administration (FDA) to treat moderate – severe TBI.

Technical Background:
Treating traumatic brain injury (TBI) remains one of the top priorities for the Department of Defense (DoD). The DoD and the military services require solutions to fill the capability gap to treat TBI as close to point of injury as possible. The current standard of care for TBI remains supportive in nature, based on management of symptoms, with no drug therapies that address the brain damage. Despite numerous clinical trials on potential therapies, there is no U.S. Food and Drug Administration (FDA) approved drug therapy for the treatment of TBI. TBI has been shown to increase long-term mortality and reduce life expectancy. Estimated economic costs of care for TBI are >$75B per year according to the Centers for Disease Control (CDC). Therefore, it is important to develop a therapy that will decrease lost duty time and mitigate the life-long disability and rehabilitation costs associated with these post-injury conditions.

Overall Program Objective:
The overall objective of the Drug Treatment for TBI (DTTBI) program is to rapidly advance the development of TBI drug candidate prototypes, through focused Phase 2 clinical trial testing, to produce a TBI drug(s) that has been fully characterized and has the best chance for success in a Phase 3 trial.

The Department of Defense (DoD) is seeking proposals for utilization of an already established and experienced TBI Clinical Consortium (TBI CC) that will enable the rapid development and clinical testing of TBI drug candidates currently in FDA-regulated clinical development. Through this RPP, the DoD will establish a contractual relationship with an existing TBI CC, and fund the evaluation of several drug candidates (potentially in collaboration with non-DoD sources of funding) in Phase 2 clinical trials.

Drug candidates for consideration must have already successfully completed Phase 1 clinical studies and will be jointly selected by the TBI CC management, associated subject matter experts, and the DoD Government Steering Committee. It is the DoD’s expectation that the TBI CC shall design and execute focused Phase 2 clinical trials on multiple TBI drug candidate prototypes, to enhance the Phase 2 data set and reduce the overall risk of future investment into a Phase 3 clinical trial.
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The deliverable at the end of the award’s period of performance is to demonstrate efficacy in Phase 2 clinical trials with at least one TBI candidate drug and recommend its continued development toward FDA regulatory clearance. The overall end goal of the DTTBI program is a commercial drug product that is approved by the FDA to treat TBI.

Financial Framework:
The DTTBI MTEC award has a Milestone and Deliverable dependent incremental funding structure, with a total of approximately $25M over a five year period of performance.

MTEC:
The MTEC mission is to assist the U.S. Army Medical Research and Materiel Command (USAMRMC) by providing cutting-edge technologies and 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, “non-traditional” government contractors, academic research institutions and not-for-profit organizations.

Administrative Information:
Full proposals are due no later than May 21, 2018 at noon ET. This RPP is posted to the MTEC website (www.mtec-sc.org) and a notice was posted to FedBizOpps (www.fbo.gov) to notify interested parties. MTEC membership is required for the submission of a proposal in response to this MTEC RPP. To join MTEC, please visit http://mtec-sc.org/how-to-join/

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

- Technical questions
  Dr. Lauren Palestrini, MTEC Director of Research, Lauren.Palestrini@officer.mtec-sc.org
- Contracting questions:
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- Administrative questions
  Ms. Kathy Zolman, MTEC Program Manager, Kathy.Zolman@ati.org
- Membership questions
  Ms. Stacey Lindbergh, MTEC Executive Director, execdirect@mtec-sc.org

To view this solicitation, click here.