REQUEST FOR PROPOSAL (RFP):

Advanced Development of Pharmacotherapeutics for the Treatment of Combat Related Post Traumatic Stress Disorder (PTSD)

The Department of Defense (DoD) and the US Army Medical Research and Materiel Command (USAMRMC) have a requirement for a US Food and Drug Administration (FDA) approved pharmacotherapeutic(s) for the treatment of Combat Related Post Traumatic Stress Disorder (PTSD). PTSD may result from exposure to a variety of stressors/events. However, this solicitation specifically addresses PTSD associated with combat related to service in support of Operation Enduring Freedom/Operation Iraqi Freedom (OEF/OIF). The objective is a safe and efficacious FDA approved product(s) with minimal side effects that can be used to treat PTSD in two populations of Service members and veterans with PTSD diagnosed using the criteria in the fourth edition of the American Psychiatric Association Diagnostic and Statistical Manual of Mental Disorders, Text Revision (DSM-IV-TR). The first population is Service members and veterans with combat related PTSD of less than one year duration, while the second population is Service members and veterans with PTSD of greater than or equal to one year duration.

For the purpose of this RFP, these two populations include any Service member with a diagnosis of PTSD incurred while on active duty status and deployed in support of OEF/OIF. OEF/OIF veterans diagnosed with PTSD who are not presently on active duty (e.g., retired, discharged, reserve status, etc.) are included in the populations identified above. PTSD is a serious issue in combat troops and veterans, and a new pharmacotherapeutic agent(s) to address PTSD is urgently needed. Therefore, the starting Technology Readiness Level (TRL) is extremely important.

Preference will be given to promising mature products such as those already FDA approved for another indication in order to reduce the developmental timeline. Selected efforts will specifically address development of a pharmacotherapeutic(s) from a TRL of at least 6 through completion of all requirements in TRL 8, as described in Attachment 1: Pharmacotherapeutic Technical Readiness Level (TRL) Achievement Form, or online in Appendix E of the Technology Readiness Assessment (TRA) Deskbook at: http://www.dod.mil/ddre/doc/DoD_TRA_July_2009_Read_Version.pdf.

DELIVERABLES should be identified by the Offeror in the proposal and at minimum should include:
1) Letters to the Government giving full rights of access to the data and information in Contractors IND and any applicable drug master file prepared using the data collected during the contract period;
2) Project Management Plan that defines project scope, activities and schedule and which includes: (a)Integrated Master Schedule; (b)Risk Management Plan; (c)FDA Regulatory Plan;
3) Quality Assurance Plan;
4) Participate in Monthly Teleconferences;
5) Quarterly Reports;
6) Annual Report;
7) Clinical Study and Statistical Analysis Plans;
8) Collection and Analysis Data Base;
9) Copies of all Documents submitted to the FDA to include the IND, NDA/sNDA, all correspondence between the FDA and Offeror related to the funded development of the pharmacotherapeutic; and
10) Annual Meeting.

The Government reserves the right to award one or multiple contracts as a result of this solicitation. Any resulting contract(s) will be issued based on best value to the U. S. Army. It is anticipated that a cost contract(s) will be awarded.

To submit a proposal, please follow this link:

https://www.fbo.gov/index?s=opportunity&mode=form&id=2603c1b84783d9d5d5bd673204f0e370&tab=core&_cview=1