



DEPARTMENT OF THE ARMY
US ARMY MEDICAL RESEARCH ACQUISITION ACTIVITY
820 CHANDLER STREET
FORT DETRICK MD 21702-5014

11 September 2020

Advanced Technology International (ATI)
ATTN: (b) (6) Contracts Administrator
315 Sigma Drive
Summerville, SC 29486

Dear (b) (6)

SUBJECT: Project Approval Letter (PAL) for 20-09-COVID19-079 for "Production and Phase 1/2A trial (b) (4) for COVID-19"

REF: Request for Project Approval from ATI dated 17 August 2020 for 20-09-COVID19-079 under OTA W81XWH-15-9-0001

EGS#: MT20009.79

In support of the U.S. Army Medical Research and Development Command (USAMRDC), ATI, on behalf of the Medical Technology Enterprise Consortium (MTEC) issued RPP 20-09-COVID19 on 25 March 2020. Members of the MTEC submitted Enhanced White Papers in response to this RPP, in accordance with the terms of the RPP and the Proposal Preparation Guide (PPG). (b) (4)

(b) (4) Subsequently, the Government evaluated technical proposals in accordance with the stated evaluation criteria; (b) (4)

Based upon the evaluation of Inhalon Biopharma, Inc.'s proposal (20-09-COVID19-079) entitled, "Production and Phase 1/2A trial (b) (4) for COVID-19," and ATI's request for PAL (which includes the Statement of Work (SOW), inclusive of an acceptable milestone schedule), ATI is hereby authorized to issue a Research Project Award (RPA) to Inhalon Biopharma, Inc. for the subject initiative. This approval is contingent upon the provision of funding via a separate modification to the Other Transaction Agreement Task Order, W81XWH-20-9-0008. At no time shall the Government's obligation exceed the funding provided for this RPA. The Sponsor Office Technical Representative (SOTR) for this RPA is (b) (6) (b) (6)

The period of performance of the Research Project Award is 8 months. Note, however, that the period of performance within the Other Transaction Agreement Task Order, W81XWH-20-9-0008, includes additional time to account for the final negotiations between ATI and Inhalon Biopharma, Inc. to finalize negotiations for the RPA. This additional time is intended to align the end dates for the Task Order and RPA.

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(b) (4) for COVID-19”

SPECIAL CONSIDERATIONS

External reviews and special considerations apply to this Research Project Award including use of animal subjects and use of human subjects. U.S. Army Medical Research and Development Command’s (USAMRDC) Office of Research Protections, Human Research Protections Office (HRPO) approval must be obtained prior to commencement of any work involving human subjects. Approval from the MRDC Animal Care and Use Review Office (ACURO) must be obtained prior to commencement of the tasks involving animal use.

PRE-AWARD COST AUTHORIZATION

The Agreements Officer approved via email the use of pre-award costs on 15 June 2020 for a not-to-exceed amount of \$496,473.10 (see the sub-folder B06 in PCF of the initial task order award), which Inhalon Biopharma acknowledged on 18 June 2020. The task order will be modified to incorporate approval to bill for costs starting on 18 June 2020.

PERFORMER CONTRIBUTION (NON-INCURRED COSTS)

Inhalon Biopharma shall provide additional resources in the form of labor, indirect costs, consultant costs, and other direct costs, for which it has not proposed costs and for which the Government will not be providing funding. These unique non-incurred costs are hereby considered as Inhalon’s contribution to the development of the project prototype.

TERMINATION

Due to the unique non-incurred cost arrangement approved by the Government, the following language shall be added to the Research Project Award section addressing Termination (also addressed in the base agreement):

In the event of termination of this Research Project Award pursuant to this section, or expiration of this Agreement at the end of the period of performance, this Agreement shall forthwith become null and void and have no effect, without any liability on the part of any Party; provided, that the termination or expiration of this Agreement shall not release any Party hereto of any liability, including any outstanding payments of the Government, which at the time of termination or expiration had already accrued to the other party in respect to any act or omission prior thereto.

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The total authorized value has been determined fair and reasonable and this proposal has been selected IAW the RPP evaluation criteria. The Agreements Officer documented the appropriate use of Section 815 prototype OTA authority. The total approved cost to the Government for this effort is Not-to-Exceed (NTE) \$4,956,163.00 as follows:

Government Project Funding	ATI Fixed Fee (Gov't Funding)	Total Cost to the Government	Anticipated Non-Federal Contribution	Total Project Cost
\$4,956,163.00	\$0.00	\$4,956,163.00	\$0.00	\$4,956,163.00

Sincerely,

BARTLETT.CHA Digitally signed by
RLES.J.1042185 BARTLETT.CHARLES.J.104
2185180
Date: 2020.09.11 08:35:12
180 -04'00'
Charles J. Bartlett
Agreements Officer

Enclosed:
Statement of Work with Milestones