



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

9 July 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-COVID19-006 for (b) (4) for the treatment of COVID-19”

REF: Request for Project Approval from ATI dated 12 June 2020 for 20-09-COVID19-006 under OTA W81XWH-15-9-0001

EGS#: MT20009.006

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)

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

Based upon the evaluation of FUJIFILM Pharmaceuticals U.S.A., Inc. proposal (20-09-COVID19-006) entitled, “(b) (4) for the treatment of 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 FUJIFILM 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).

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 FUJIFILM 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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SPECIAL CONSIDERATIONS

External reviews and special considerations apply to this Research Project Award including use of human subjects. USAMRDC’s Office of Research Protections, Human Research Protections Office (HRPO) approval must be obtained prior to commencement of any work involving use of human subjects.

DATA RIGHTS

Technical Data or Computer Software to be Furnished with Restrictions	Basis for Assertion	Asserted Rights Category	Name of Person Asserting Restrictions
1. (b) (4)	(b) (4) (FUJIFILM Toyama)	Government Use Rights provided in DFARS 252.227-7013,7014,7015	Fujifilm Pharmaceuticals U.S.A., Inc. on its own behalf and on behalf of FUJIFILM Toyama Chemical Co., Ltd. (Japan) and Fujifilm Corporation (Japan)
2. Pre-existing and/or parallel with the program but separately funded clinical study data, protocols, brochures, and any and all documents related thereto.	(b) (4) (FUJIFILM Toyama)	Government Use Rights provided in DFARS 252.227-7013,7014,7015	Fujifilm Pharmaceuticals U.S.A., Inc. on its own behalf and on behalf of FUJIFILM Toyama Chemical Co., Ltd. (Japan) and Fujifilm Corporation (Japan)
3. Pre-existing and/or parallel with the program but separately funded information and data relating to the manufacturing, including manufacturing facility information, development and (b) (4) and know-how, packaging, labeling, storage, stockpiling and (b) (4)	(b) (4) (FUJIFILM Toyama)	Government Use Rights provided in DFARS 252.227-7013,7014,7015	Fujifilm Pharmaceuticals U.S.A., Inc. on its own behalf and on behalf of FUJIFILM Toyama Chemical Co., Ltd. (Japan) and Fujifilm Corporation (Japan)

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<p>4. Government funded information and data if combined with pre- existing and/or parallel with the program but privately funded data or software (including the items, components, and processes described in lines 1-3 of column 1, above)</p>	<p>(b) (4)</p>	<p>Specifically Negotiated License Rights under DFARS 252.227-7013(b)(4) as defined in (a) (13), or - 7014(b)(4) as Defined in (a)(14), as applicable (i.e., Limited and Restricted Rights)</p>	<p>Fujifilm Pharmaceuticals U.S.A., Inc. on its own behalf and on behalf of FUJIFILM Toyama Chemical Co., Ltd. (Japan) and Fujifilm Corporation (Japan)</p>
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PRE-AWARD COST AUTHORIZATION

The Government has authorized pre-award costs for Research Project Award for FUJIFILM Pharmaceuticals U.S.A., Inc.’s proposal 20-09-COVID-19-006 starting 26 May 2020 in an amount not to exceed \$138,117.00. The Government agrees to pay allowable costs accrued in the performance of this Research Project Award starting 26 May 2020 through the end of the period of performance.

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) \$1,381,172.00 as follows:

Government Project Funding	ATI Fixed Fee (Gov’t Funding)	Total Cost to the Government	Anticipated Non-Federal Contribution	Total Project Cost
\$1,381,172.00	\$0.00	\$1,381,172.00	(b) (4)	(b) (4)

Sincerely,

GONZALEZ.JONATHAN.FORD.13
 92612641

Digitally signed by GONZALEZ.JONATHAN.FORD.1392612641
 Date: 2020.07.09 08:48:30 -04'00'

Dr. Jonathan F. Gonzalez
 Agreements Officer

Enclosed:
 Statement of Work with Milestones