

DEPARTMENT OF THE ARMY

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

14 December 2020

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

Dear (b) (6) :

SUBJECT: Revised Project Approval Letter (PAL) for 20-09-COVID19-006 for "(b) (4) for the treatment of COVID-19"

Version 2

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

stated evaluation criteria; (b) (4)

The purpose of this revised Project Approval Letter is to extend the period of performance at no additional cost to the Government. See below for additional detail.

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

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 ends 18 March 2021.

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 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)	(FUJIFILM Toyama)	Government Use Rights provided in DFARS 252.227- 7013,7014,7015	Fujifilm Pharmaceuticals U.S.A., Inc. onits own behalf and on behalf of FUJIFILM Toyama Chemical Co., Ltd. (Japan) and Fujifilm Corporation (Japan)
2.(b) (4)	(b) (4) (FUJIFILM Toyama)	Government Use Rights provided in DFARS 252.227- 7013,7014,7015	Fujifilm Pharmaceuticals U.S.A., Inc. onits own behalf and on behalf of FUJIFILM Toyama Chemical Co., Ltd. (Japan) and Fujifilm Corporation (Japan)
3. (b) (4)	(FUJIFILM Toyama)	Government Use Rights provided in DFARS 252.227- 7013,7014,7015	Fujifilm Pharmaceuticals U.S.A., Inc. onits own behalf and on behalf of FUJIFILM Toyama Chemical Co., Ltd. (Japan) and Fujifilm Corporation (Japan)

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

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,

BARTLETT.CH Digitally signed by BARTLETT.CHARLES.J.1 042185180 Date: 2020.12.14 14:09:46 -05'00'

Charles J. Bartlett Agreements Officer

Enclosed:

Statement of Work with Milestones