Statement of Work

Proposal Number: MTEC-20-09-COVID19-006
Organization: FUJIFILM Pharmaceuticals U.S.A., Inc.
Title: (b) (4) for the treatment of COVID-19
ACURO and/or HRPO approval needed: HRPO
EGS #: MT20009.006
FUJIFILM Pharmaceuticals U.S.A., Inc. shall provide all FDA communication or documentation related to this award per SOTR, HRPO and ORA request.

Introduction/Background

The pandemic COVID-19, a disease caused by SARS-CoV-2, continues to spread worldwide. There are currently no FDA approved vaccines or treatments for COVID-19. The goal of this program is to deliver a therapeutic that can treat COVID-19 while administered in a hospital environment as well as an option for non-hospitalized PCR-positive patients who are asymptomatic or have only mild disease.

(b) (4)

Scope/Project Objectives

The goal of this project is to (b) (4). The scope of the project includes conduct of an open label randomized Phase 2 clinical trial in hospitalized patients (b) (4) to demonstrate the anti-SARS-CoV-2 activity of (b) (4). A total of 50 subjects will be randomized within each site based on age group and disease severity to receive either (b) (4) (SOC) or SOC alone. IND 148286 has been assigned by the FDA and Safe to Proceed is expected in early April. Major milestones include HRPO approval, Last Patient Enrolled, Topline Results, and Clinical Study Report.

Potential follow-on tasks include planned Phase 3 clinical studies including (b) (4) A double-blind randomized placebo controlled pivotal study in subjects who have tested positive for COVID-19 and are hospitalized with moderate to severe disease, (b) (4) A double-blind randomized placebo controlled pivotal study in subjects who have tested positive for COVID-19 but are asymptomatic or have mild disease.

Based on results of the proposed study and the additional studies outlined above, FPHU anticipates filing an NDA for the treatment of COVID-19. *If successful, the U.S. Army Medical Research and Development Command (USAMRDC) and the Department of Defense will have a therapy for warfighters and first responders to protect, treat and optimize the health and performance of U.S. military personnel that may shorten the time of quarantine and/or reduce transmission of the disease, reduce the demands on the health care system, reduce the number of subjects who will get worse, and save lives.*

Requirements

The goal of this project is to (b) (4) for the treatment of COVID-19. The scope of the project

includes conduct of an open label randomized Phase 2 clinical trial in hospitalized patients (b) (4) (b) to demonstrate the anti-SARS-CoV-2 activity (b) (4), with potential follow-on activities.

4.1 Program Management

4.1.1 Schedule Management

FPHU shall develop an Integrated Master Schedule (IMS) will be submitted for review/approval within 20 business days of contract award and shall be maintained on a monthly basis.

4.1.2 Cost Management

FPHU shall prepare monthly invoices and financial reports comparing actual costs to budgeted costs.

4.1.3 Technical Management

FPHU shall prepare and submit a Decision Gate Report that contains (i) sufficient detail, documentation, and analysis to support successful completion of the stage according to the predetermined qualitative and quantitative criteria that were established for Go/No-Go decision making; and (ii) a description of the next stage of product development to be initiated and a request for approval to proceed to the next stage of product development.

4.1.4 Risk Management

FPHU shall develop a Risk management Plan within 20 business days of contract award highlighting potential problems and/or issues that may arise during the life of the contract; their impact on cost, schedule, and performance; and appropriate remediation plans.

4.1.5 Quarterly Reports

FPHU shall prepare a Quarterly Report which will include a Technical Status Report and a Business Status Report in accordance with the terms and conditions of the Base Agreement. (Required)

4.1.6 Annual Technical Report

FPHU shall prepare an Annual Technical Report for projects whose periods of performances are greater than one year in accordance with the terms and conditions of the Base Agreement.

4.1.7 Final Technical Report

At the completion of the Research Project Award, FPHU shall submit a Final Technical Report, which will provide a comprehensive, cumulative, and substantive summary of the progress and significant accomplishments achieved during the total period of the Project effort in accordance with the terms and conditions of the Base Agreement.

4.1.8 Final Business Status Report

At the completion of the Research Project Award, FPHU shall submit a Final Business Status Report, which will provide summarized details of the resource status of the Research Project Award, in accordance with the terms and conditions of the Base Agreement.

4.2 Clinical Study Management and Conduct

4.2.1 FPHU shall conduct an open label randomized Phase 2 clinical trial in hospitalized patients (b) (4) (b) (4) to demonstrate the anti-SARS-CoV-2 activity (b) (4).

4.2.1.1 FPHU shall provide clinical trial oversight for the proposed study.

4.2.1.2 FPHU shall provide clinical operations and statistical support for the proposed study. (b) (4) will serve as FPHU's Clinical Research Organization (CRO).

4.2.1.3 FPHU shall provide bioanalytical support for the proposed study. PPD will conduct this study in their (b) (4) laboratory.

4.2.1.4 FPHU shall provide virology and serology assays for the proposed study. All work will be performed at (b) (4) laboratories in (b) (4).

4.3 Regulatory Management

4.3.1 Regulatory Oversight

FPHU shall provide Regulatory Oversight and strategic guidance to all program activities.

4.3.2 IND Maintenance

FPHU shall generate all necessary data and preparation of all documentation for IND submissions to regulatory agencies.

Deliverables

1. A Final Study Protocol will be delivered at contract signing.
2. Topline Results will be delivered on which the Go/No-Go Decision to proceed with Phase 3 Clinical Studies will be based.
3. A DRAFT Clinical Study Report will be delivered.

Milestone Payment Schedule (*To be provided initially by the Offeror at the time of proposal submission. Submitted information is subject to change through negotiation if the Government selects the proposal for funding. The milestone schedule included should be in editable format (i.e., not a picture)*)
The Milestone Payment Schedule should include all milestone deliverables that are intended to be delivered as part of the project, a planned submission date, the monetary value for that deliverable and any cost share, if applicable. For fixed price agreements, when each milestone is submitted, the MTEC member will submit an invoice for the exact amount listed on the milestone payment schedule. For cost reimbursable agreements, the MTEC member is required to assign a monetary value to each milestone. In this case, however, invoice totals are based on cost incurred and will not have to match exactly to the amounts listed on the milestone payment schedule.
The milestones and associated deliverables proposed should, in general:

- be commensurate in number to the size and duration of the project (i.e., a $5M multiyear project may have 20, while a $700K shorter term project may have only 6);
- not be structured such that multiple deliverables that might be submitted separately are included under a single milestone;
- be of sufficient monetary value to warrant generation of a deliverable and any associated invoices;
- include at a minimum Quarterly Reports which include both Technical Status and Business Status Reports (due the 25th of Apr, Jul, Oct, Jan), Annual Technical Report, Final Technical Report, and Final Business Status Report. Reports shall have no funding associated with them.

MTEC Milestone Payment Schedule Estimate

MTEC Milestone Number	IMS Task ID	Significant Event/ Accomplishments	Due Date	Government Funds	Cost Share	Total Funding
1	42	Submission for HRPO Approval	6/1/20			
2	4	Project Kickoff	6/29/20			
3	7, 18	Draft IMS and RMP	7/1/20			
4	22	Quarterly Report 1 (May - June, Technical and Business Reports)	7/25/20			
5	45	50% Enrollment Achieved	TBD	$575,000	(b) (4)	(b) (4)
6	45	Enrollment Complete	8/10/20	$575,000	(b) (4)	(b) (4)
7	54	Topline Results	8/24/20	$150,000	(b) (4)	(b) (4)
8	22	Quarterly Reports 2 (July - Sept, Technical and Business Reports)	10/25/20	,		
9	63	Clinical Study Report	8/24/20	$81,172	(b) (4)	(b) (4)
10	22	Quarterly Report 3 (Oct - Dec, Technical and Business Reports)	12/18/20			
11	23	Final Report	12/18/20			
		TOTAL PROPOSED COST ESTIMATE		**$1,381,172**	(b) (4)	$(b) (4)

Data Rights Assertions

Data Rights

The Offeror shall comply with the terms and conditions defined in the Base Agreement regarding Data Rights. It is anticipated that anything delivered under this proposed effort would be delivered to the Government with **Government purpose data rights** or **unlimited data rights**. If this is not the intent, then the proposal should discuss data rights associated with each item, and possible approaches for the Government to gain Government purpose data rights or unlimited data rights as referenced in the Base Agreement. Rights in technical data in each Research Project Award shall be determined in accordance with the provisions of MTEC Base Agreement.
If applicable, complete the below table for any items to be furnished to the Government with restrictions. An example is provided.

Please indicate your assertion:

☐ Unlimited Data Rights.
✓ Government Purpose Data Rights.
✓ Restricted Government Rights as described below

Technical Data and Computer Software

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. (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)
3. (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)
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)	(b) (4)	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)	Fujifilm Pharmaceuticals U.S.A., Inc. on its own behalf and on behalf of FUJIFILM Toyama Chemical Co., Ltd. (Japan) and Fujifilm Corporation (Japan)

Patents

(b) (4)