DEPARTMENT OF THE ARMY
U.S. ARMY CONTRACTING COMMAND – NEW JERSEY
PICATINNY ARSENAL, NEW JERSEY 07806-5000

REPLY TO
ATTENTION OF

13 August 2020

Army Contracting Command – New Jersey
ACC-NJ, Building 9
Picatinny Arsenal, NJ 07806

SUBJECT: Technical Direction Letter for Medical CRBN Defense Consortium (MCDC), Request for Prototype Proposals (RPP) 20-06, Objective Area TRE-PRE-20-06, Definitization of "Advanced Development and Emergency Use of Leukine® for COVID-19 Acute Hypoxic Respiratory Failure" (Partner Therapeutics, Inc. - PTx)

REF: Request for Updated Proposal Submitted in Response to RPP 20-06 under OTA W15QKN-16-9-1002 for Objective TRE-PRE-20-06, dated 02 July 2020

Advanced Technology International
ATTN: (b) (6), Sr. Contracts Manager
315 Sigma Drive
Summerville, SC 29486

Dear (b) (6),

The Army Contracting Command – New Jersey (ACC-NJ), in supporting the Joint Project Manager – Medical Countermeasure Systems (JPM-MCS), issued MCDC RPP 20-06 on 04 May 2020. Members of the MCDC submitted proposals in accordance with this RPP. The Government received and evaluated all proposal(s) submitted and a Basis of Selection has been executed, selecting Partner Therapeutics, Inc. (PTx) as the awardee. The Government requests that a Firm-Fixed-Price Agreement be issued to PTx to award this proposal under Other Transaction Agreement W15QKN-16-9-1002, to be performed in accordance with the attached Government Statement of Work (SOW).

The Government received the undefinitized Rough Order of Magnitude (ROM) proposal update on 08 July 2020, and reviewed the costs and documentation accordingly. Based on the acceptable ROM proposal update, the Government issued an Undefinitized Project Action (UPA) on 13 July 2020. In order to definitize the UPA, the Government finalized an analysis of the cost proposal on 07 August 2020, which focused on evaluation of the cost components and documentation. Based upon the acceptable update of PTx's proposal for "Advanced Development and Emergency Use of Leukine® for COVID-19 Acute Hypoxemic Respiratory Failure" and 1) The Project Agreement Recipient's concurrence with the requirements included in the Government SOW; 2) An acceptable milestone schedule that meets SOW requirements, and; 3) The Cost Proposal that has been analyzed and negotiated final by the Government, you are hereby directed to issue a Definitized Project Agreement to PTx for the subject project. The total project value has been determined fair and reasonable and PTx's proposal has been selected IAW the above referenced Basis of Selection.

The total approved cost to the Government for this effort is not to exceed (b) (4) The break-out of the costs is as follows: $34,977,402.00 to perform project efforts included in the SOW and (b) (4) for the Consortium Management Firm (CMF) Administrative Cost. The effort is fully funded.

The prime contractor is considered a small business, nontraditional defense contractor, or nonprofit research institution and determined to be providing a significant contribution. The affirmation of business status certifications submitted as part of the proposal are hereby incorporated into the agreement. The contractor shall notify the MCDC CMF of any deviation from the final proposed affirmation of business status certifications that would affect the contributions of the small business, nontraditional defense contractor, or nonprofit research institution as proposed.

In accordance with 10.U.S.C. 2371b(f), and upon a determination that the prototype project for this transaction has been successfully completed, this competitively awarded prototype OTA may result in the award of a follow-on production contract or transaction without the use of competitive procedures.

Points of Contact:

Agreements Specialist:
(b) (6)
E-mail: (b) (6)
Phone: (b) (6)

Agreements Officer:
(b) (6)
E-mail: (b) (6)
Phone: (b) (6)

Regards,

(b) (6)

(b) (6)
Agreements Officer
Signed by: (b) (6)

Attachments:
Attachment 1: Encl 1_2006-012 Partner SOW PTx Ver FINAL_13JUL2020

Statement of Work
for
Advanced Development and Emergency Use of Leukine® for
COVID-19 Acute Hypoxemic Respiratory Failure

RPP #: 20-06
Project Identifier: MCDC2006-012
Consortium Member: Partner Therapeutics, Inc.
Title of Proposal: Advanced Development and Emergency Use of Leukine® for COVID-19 Acute Hypoxemic Respiratory Failure
Requiring Activity: Joint Program Executive Office for Chemical, Biological, Radiological and Nuclear Defense (JPEO-CBRND) Joint Program Manager-Medical (JPM-Medical)

1.0 INTRODUCTION, SCOPE, AND OBJECTIVES

1.1 Introduction

The Department of Defense (DoD) desires the development of Medical Countermeasures (MCM) for civilians, first responders, and military personnel to treat the symptoms and reduce the transmission of Coronavirus Disease 2019 (COVID-19). COVID-19 infection is a worldwide epidemic with a significant infection and death rate in the United States (U.S.). Forecasters have suggested that there could be between 2.3 million – 23 million people infected with the virus in the U.S. by March 2021, with potential deaths reaching 350,000. The COVID-19 infection results in approximately 20% of patients needing hospitalization and about 5-7% needing Intensive Care Unit (ICU) care. Mortality rates among patients entering the ICU have reached levels as high as 88%.[(2)] Given the ongoing epidemic, there is a need for interventions that can not only prevent the infection (such as vaccines), but also reduce the course of the illness (such as anti-virals). Additionally, there is need for a therapeutic treatment for patients hospitalized for respiratory distress that can decrease or prevent them from progressing to intubation, being admitted to the ICU, and, ultimately, experiencing morbidity or mortality. Sargramostim (Leukine®) is a recombinant human granulocyte-macrophage colony stimulating factor (rhu-GM-CSF) that, based on its critical role in maintaining lung health and ability to increase viral clearance, is anticipated to aid COVID-19 patients in recovery from respiratory distress and decrease the need for ICU care and intubation. Partner Therapeutics (PTx) is proposing to develop Leukine as a prototype medical intervention for COVID-19 treatment.

1.2 Scope

PTx will conduct two randomized controlled Phase II clinical studies to obtain additional efficacy and safety data for Leukine® inhalation delivery in patients with COVID-19 associated respiratory hypoxemia. These trials will further expand the efficacy and safety data collected from the ongoing randomized controlled Phase II study (SARPAC) in Belgium, which is nearing completion. PTx will utilize the efficacy and safety data from SARPAC, and data from the studies proposed herein, to fully brief the Food and Drug Administration (FDA) and prepare and file for Emergency Use Authorization (EUA) within three months of contract initiation. Based on preliminary safety and efficacy data available from the SARPAC study, PTx is confident that

Leukine represents a probable complete solution to the U.S. Government's requirement. Data from the proposed studies will provide a definitive dataset for evaluation and conclusions.

1.3 Objective

The program is designed to provide the following end products:

- Application for and potential achievement of EUA of Leukine® to treat respiratory hypoxemia in COVID-19 patients – the primary cause of mortality in civilians, military personnel and first responders infected with the Novel Coronavirus (SARS-CoV-2).
- Final Clinical Study Reports (CSR) for two Phase II studies of up to 520 patients, conducted under Good Clinical Practice (GCP) on the benefit and safety of inhaled Leukine in COVID-19 patients, delivered to the FDA and JPEO-CBRND, JPM-Medical under eCTD standards.

The PTx development plan provides a complete solution to the US Government's requirement, with an estimated period of performance of twelve months.

This is a prototype project because the contractor will develop Leukine® Inhalation by conducting randomized controlled clinical studies and filing for EUA, in order evaluate the technical feasibility of product use in patients with acute hypoxic respiratory failure due to COVID-19, an indication not with the current FDA approved label for Luekine.

In accordance with 10 U.S.C. 2371b(f), and upon a determination that the prototype project for this transaction has been successfully completed, this competitively awarded prototype OTA may result in the award of a follow-on production contract or transaction without the use of competitive procedures. Any follow-on production effort is expected to be between 100,000 and 500,000 units or total dosing regimens, but could be larger or smaller, depending on requirements to be determined upon demonstration of utility and DoD requirements. This prototype project will be successfully completed if the contractor meets the key technical goals of the project, as listed within this document, meets the success metrics established by this agreement or, at the accomplishment of particularly favorable or unexpected results that justifies transition to production.

If there is a conflict between the Project Agreement and the Base Agreement, the Project Agreement language will supersede and control the relationship of the parties.

2.0 APPLICABLE REFERENCES

N/A

3.0 REQUIREMENTS

Overall Scope & Objectives of the Prototype Project

While it is envisioned that Leukine® - currently FDA approved for use in multiple indications - will ultimately be FDA approved for use in COVID-19 acute hypoxic respiratory failure, PTx intends to complete the necessary steps as proposed herein, required to apply for and obtain EUA for Leukine® inhalation for acute respiratory failure, and prepare for manufacture and delivery of Good Manufacturing Practice (GMP) final drug product to the Government for use in humans. These steps include conducting a randomized controlled clinical trial of Leukine in COVID-19 patients with acute hypoxic respiratory failure, increasing final drug product fill capacity, and supporting DoD efforts to obtain EUA of Leukine for treatment of acute hypoxic respiratory failure in patients with COVID-19.

Base Contract Period (12 Months)

1.1 Human Clinical Studies

1.1.1 Human Clinical Efficacy Studies (WBS 1.1.1)

1.1.1.1 Phase II Efficacy Study – iLeukPulm (WBS 1.1.1.1)

PTx will conduct a Phase II, randomized, controlled multicenter study of the safety and efficacy of Leukine®, plus standard of care therapy versus standard of care therapy alone. Standard of care therapy plus/minus Leukine inhalation will be administered to up to 120 COVID-19 patients experiencing acute hypoxemic respiratory failure. The study will assess the effects of Leukine inhalation on measures of benefit, including oxygenation, requirement for mechanical ventilation and rate of nosocomial infection, as well as observations of clinical benefit. The design and execution of this study will utilize a clinical protocol reviewed and accepted by the DoD in consultation with the FDA. PTx will obtain Institutional Review Board (IRB) and US Army Medical Research and Development Command (USAMRDC) approval for planned clinical trials. Any human research shall be reviewed and approved in accordance with Department of Defense Instruction (DoDI) 3216.02, The Protection of Human Subjects and Adherence to Ethical Standards in DoD Conducted and Supported Research. PTx shall furnish evidence of such registration and approval to the Agreements Officer (AO) before beginning work under this contract.

PTx will notify the DoD in writing upon treatment of the first patient within this study. The Data Safety Monitoring Board (DSMB) will oversee safety and conduct interim analysis of the data as deemed necessary to assure safety of patients. Minutes of the DSMB meetings shall be provided to the DoD AO, Agreements Officer's Representative (AOR), and the Senior Director Medical Regulatory (SDMR). Additionally, PTx will submit a final report upon completion of the study, which compiles the full study results and details Leukine's safety profile and efficacy, as measured by the primary and secondary endpoints agreed upon with DoD.

1.1.1.2 Phase II Efficacy and Safety Study – Efficacy Optimization (WBS 1.1.1.2)

PTx will conduct a Phase II, multicenter study of the safety and efficacy of Leukine® inhalation administered to up to 400 patients experiencing acute hypoxemic respiratory failure. This study will focus on optimizing Leukine as an inhalation therapy. The study will include the evaluation of dose-response, quality of life, assessment as to whether a particular patient population is more likely to benefit from treatment or is at higher risk of adverse events (e.g., effects by gender, race, age), and explore predictive biomarkers. PTx will obtain IRB and USAMRDC approval for

planned clinical trials. Any human research shall be reviewed and approved in accordance with DoDI 3216.02, The Protection of Human Subjects and Adherence to Ethical Standards in DoD Conducted and Supported Research. The Contractor shall furnish evidence of such registration and approval to the AO before beginning work under this contract.

PTx will notify DoD in writing upon treatment of the first patient within this study. The DSMB will oversee the safety of patients and conduct interim analysis of the data as deemed necessary. Minutes of the DSMB meetings shall be provided to the DoD AO, AOR, and the SDMR. Additionally, PTx will submit a final report upon completion of the study, which compiles the full study results and details Leukine's safety profile and efficacy as measured by the primary and secondary endpoints agreed upon with DoD.

1.2 Drug Manufacturing and Supply

1.2.1 GMP Drug Product for Clinical Trial (WBS 1.2.1)

1.2.1.1 Phase II – Part A GMP Drug Product (WBS 1.2.1.1)

PTx will provide up to 1,360 5-Packs (6800 vials) of Leukine product for the conduct of the Phase II clinical trials part A and B, detailed in SOW # 1.1.1.1 and 1.1.1.2. A copy of the batch release record for the product lots from which these vials are provided, will be submitted to the DoD AO and AOR.

1.2.2 Manufacturing Capacity Enhancements (WBS 1.2.2)

1.2.2.1 Addition of Second Line for Drug Product Fills (WBS 1.2.2.1)

(b) (4)

PTx has also been working with (b) (4) to qualify its plant in (b) (4) as a second fill finish provider. In order to increase fill capacity to meet potential demand as described by DoD, PTx will either: a) qualify a second fill line at the (b) (4) plant on an accelerated basis, or b) qualify a fill line at (b) (4) plant on an accelerated basis. PTx will submit its recommendation on which option to follow to the DoD for approval, and will provide monthly updates on progress in achieving qualification of the new line. A final report including batch release records will be provided to the DoD.

1.3 Regulatory Activities

1.3.1 FDA Filings and Correspondence (WBS 1.3.1)

Clinical trials defined in SOW # 1.1.1.1 and 1.1.1.2 will be conducted under Investigational New Drug (IND) #149323, which was opened for the development of inhaled Leukine® in COVID-19 patients with acute hypoxic respiratory failure. Approval to proceed with the Phase II clinical study outlined in SOW # 1.1.1.1 was received from the FDA on May 20, 2020.

1.3.1.1 Provide DoD with EUA Package (WBS 1.3.1.1)

PTx will utilize the efficacy and safety data from SARPAC, and data from the studies proposed herein, to prepare and file for EUA for Leukine as a treatment for acute hypoxemic respiratory failure in COVID-19. As the Sponsor, PTx shall submit a letter to the FDA indicating the SDMR as a co-contact, and that the FDA is authorized to contact SDMR for DoD regulatory/policy input as needed for the Leukine development effort. To the maximum extent practicable, the Government will include PTx in any and all meetings and correspondence with the FDA. If it is

not practicable to include PTx in any interaction with the FDA, the Government will provide a summary of the interaction to PTx within ten (10) business days.

If requested by DoD, PTx shall coordinate with One Network of Excellence for Regulatory Affairs and Quality Assurance (ONE-RAQA) SDMR, a Priority Review Request under PL-115-92 (if not garnered under another mechanism, e.g., Fast Track Designation/Breakthrough Therapy Drug).

Management Approach

Integrated Product Development Plan

Work Breakdown Structure (WBS)

PTx will utilize the following WBS in the execution and tracking of tasks under this contract. If alterations to the WBS are required, PTx will submit draft revisions to the DoD for approval prior to changes being implemented.

Work Breakdown Structure		SOW	Cost ($)
1	**Leukine® Advanced Development for Acute Respiratory Failure**		
1.1	**Human Clinical Studies**		
1.1.1	Human Clinical Efficacy Studies		
1.1.1.1	*Phase II – iLeukPulm Study (120 Patients)*	1.1.1.1	(b) (4)
1.1.1.2	*Phase II – Treatment Optimization Study (400 Patients)*	1.1.1.2	(b) (4)
1.2	**Drug Manufacturing and Supply**		
1.2.1	GMP Drug Product for Clinical Trials		
1.2.1.1	*Phase II Studies Drug Supply (1360 5-Packs)*	1.2.1.1	(b) (4)
1.2.2	Manufacturing Capacity Enhancements		
1.2.2.1	*Increase FDP Fill Capacity by Adding Second Line*	1.2.2.1	(b) (4)
1.3	**Regulatory Activities**		
1.3.1	FDA Filings and Correspondence		
1.3.1.1	*Submit Emergency Use Authorization Package*	1.3.1.1	(b) (4)
1.4	**Contract Administration & Project Management**		
1.4.1	Project Management and Contract Administration		
1.4.1.1	Base Period (CLIN 0001) Management		(b) (4)

4.0 DELIVERABLES

(Assumes Contract Start Date of July 13, 2020)

Del. #	Deliverable Description	Due Date	Milestone Reference	SOW Reference	Government Role	Data Rights
4.1	Project Kick-Off	07/31/20	5.1	1.4.1.1	Attend	Unlimited

4.2	Deliver GMP FDP for Clinical Studies	07/31/20	5.2	1.2.1.1	None	Unlimited
4.3	IRB and USAMRDC Approval for iLeukPulm Study	07/31/20	5.3	1.1.1.1	None	Unlimited
4.4	Monthly Business and Technical Report	07/31/20	5.4	1.4.1.1	Review/ Approve	Unlimited
4.5	Monthly Business and Technical Report	08/31/20	5.5	1.4.1.1	Review/ Approve	Unlimited
4.6	First DSMB Review of iLeukPulm Study	09/15/20	5.6	1.1.1.1	Review/ Advise	Unlimited
4.7	Submit EUA to FDA with PL 115-92 Sponsor Authorization Letter	09/30/20	5.7	1.3.1.1	Review/ Advise	Unlimited
4.8	Qualify 2nd Line for FDP Fill	09/30/20	5.8	1.2.2.1	Review/ Approve	Unlimited
4.9	IRB and USAMRDC Approval for Treatment Optimization Study	09/30/20	5.9	1.1.1.2	Review/ Approve	Unlimited
4.10	Annual Business and Technical Report	09/30/20	5.10	1.4.1.1	Review/ Approve	Unlimited
4.11	Second DSMB Review iLeukPulm Study	10/31/20	5.11	1.1.1.1	Review/ Advise	Unlimited
4.12	Monthly Business and Technical Report	10/31/20	5.12	1.4.1.1	Review/ Approve	Unlimited
4.13	Submit EUA to FDA (if not already granted)	11/30/20	5.13	1.3.1.1	Review/ Advise	Unlimited
4.14	End of iLeukPulm Study In-Life	11/30/20	5.14	1.1.1.1	None	Unlimited
4.15	Monthly Business and Technical Report	11/30/20	5.15	1.4.1.1	Review/ Approve	Unlimited
4.16	100th Patient Dosed in Treatment Optimization Study	10/31/20	5.16	1.1.1.2	None	Unlimited
4.17	Quarterly Business and Technical Report	12/31/20	5.17	1.4.1.1	Review/ Approve	Unlimited
4.18	200th Patient Dosed in Treatment Optimization Study	01/31/21	5.18	1.1.1.2	None	Unlimited

4.19	Monthly Business and Technical Report	01/31/21	5.19	1.4.1.1	Review/ Approve	Unlimited
4.20	300th Patient Dosed in Treatement Optimization Study	02/28/21	5.20	1.1.1.2	None	Unlimited
4.21	Monthly Business and Technical Report	02/28/21	5.21	1.4.1.1	Review/ Approve	Unlimited
4.22	End of Treatment Optim-ization Study In-Life	03/31/21	5.22	1.1.1.2	None	Unlimited
4.23	Quarterly Business and Technical Report	03/31/21	5.23	1.4.1.1	Review/ Approve	Unlimited
4.24	Monthly Business and Technical Report	04/30/21	5.24	1.4.1.1	Review/ Approve	Unlimited
4.25	Final iLeukPulm Study Report	04/30/21	5.25	1.1.1.1	Review/ Approve	Limited
4.26	Final Treatment Optim-ization Study Report	05/31/21	5.26	1.1.1.2	Review/ Approve	Limited
4.27	Monthly Business and Technical Report	05/31/21	5.27	1.4.1.1	Review/ Approve	Unlimited
4.28	Final Business, Patent and Technical Report	06/30/21	5.28	1.4.1.1	Review/ Approve	Unlimited

5.0 MILESTONE PAYMENT SCHEDULE

Milestone #	Milestone Description (Deliverable Reference)	Due Date	Total Program Funds
5.1	Project Kick-Off; Deliverable 4.1	07/31/2020	(b) (4)
5.2	Clinical Drug Supply; Deliverable 4.2	07/31/2020	(b) (4)
5.3	IRB and USAMRDC Approval for iLeukPulm Study; Deliverable 4.3	07/31/2020	(b) (4)
5.4	July 2020 Monthly Technical and Business Status Report; Deliverable 4.4	07/31/2020	(b) (4)
5.5	August Monthly Technical and Business Status Report; Deliverable 4.5	08/31/2020	(b) (4)
5.6	First DSMB Review of iLeukPulm Study; Deliverable 4.6	09/15/2020	(b) (4)
5.7	Submit EUA to FDA; Deliverable 4.7	09/30/2020	(b) (4)
5.8	Qualify 2nd Line for FDP Fill; Deliverable 4.8	09/30/2020	(b) (4)

Milestone #	Milestone Description (Deliverable Reference)	Due Date	Total Program Funds
5.9	IRB and USAMRDC Approval for Treatment Optimization Study; Deliverable 4.9	09/30/2020	(b) (4)
5.10	Annual Technical and Business Status Report, see above for submission schedule; Deliverable 4.10	09/30/2020	(b) (4)
5.11	Second DSMB Review of iLeukPulm Study; Deliverable 4.11	10/31/2020	(b) (4)
5.12	October Monthly Business and Technical Report; Deliverable 4.12	10/31/2020	(b) (4)
5.13	Submit EUA to FDA; Deliverable 4.13	11/30/2020	(b) (4)
5.14	End of iLeukPulm Study In-Life; Deliverable 4.14	11/30/2020	(b) (4)
5.15	November Monthly Business and Technical Report; Deliverable 4.15	11/30/2020	(b) (4)
5.16	100th Patient Dosed in Treatment Optimization Study; Deliverable 4.16	12/31/2020	(b) (4)
5.17	Quarterly Business and Technical Report; Deliverable 4.17	12/31/2020	(b) (4)
5.18	200th Patient Dosed in Treatment Optimization Study; Deliverable 4.18	01/31/2020	(b) (4)
5.19	January Monthly Business and Technical Report; Deliverable 4.19	01/31/2021	(b) (4)
5.20	300th Patient Dosed in Treatment Optimization Study: Deliverable 4.20	02/28/2021	(b) (4)
5.21	February Monthly Business and Technical Report; Deliverable 4.21	02/28/2021	(b) (4)
5.22	End of Treatment Optimization Study In-Life; Deliverable 4.22	03/31/2021	(b) (4)
5.23	Quarterly Business and Technical Report; Deliverable 4.23	03/31/2021	(b) (4)
5.24	April Monthly Business and Technical Report; Deliverable 4.24	04/30/2021	(b) (4)
5.25	Final iLeukPulm Study Report; Deliverable 4.25	04/30/2021	(b) (4)
5.26	Final Treatment Optimization Study Report; Deliverable 4.26	05/31/2021	(b) (4)
5.27	May Monthly Business and Technical Report: Deliverable 4.27	05/31/2021	(b) (4)

Milestone #	Milestone Description (Deliverable Reference)	Due Date	Total Program Funds
5.28	Final Business, Patent and Technical Report; Deliverable 4.28	06/30/2021	(b) (4)
		Total (FFP):	**$34,977,402**
		Period of Performance:	**12 Months**

6.0 SHIPPING PROVISIONS

All Quarterly, Annual and Final Reports will be sent to: deliverables.mcdc@ati.org

All deliverables intended for the AOR will be sent to: (b) (6)

A copy of all data deliverables will be sent to:

usarmy.detrick.dod-jpeo-cbrnd.mbx.otadeliverable@mail.mil

7.0 INTELLECTUAL PROPERTY, DATA RIGHTS, AND COPYRIGHTS

Unless specified otherwise in this agreement, no party relinquishes rights to any background patents to any other party under this agreement. Additionally, no party to the awarded agreement shall enter into an agreement with any contract manufacturer or other third party whereby the third party will obtain rights in Subject Invention or Subject Data, as those terms are defined in Other Transaction Agreement number W15QKN-16-9-1002, absent the mutual consent of the parties to the awarded agreement.

Patent Rights

Article X, §B ("Allocation of Principal Rights") and §E ("Minimum Rights to the MCDC PAH and Protection of the MCDC PAH's Right to File") of Other Transaction Agreement number W15QKN-16-9-1002, is hereby amended for the purpose of this Project Agreement as follows:

a) Subject Inventions. Grants of Non-Exclusive License to Subject Inventions. Any Subject Invention[1] that is Made by a party under this agreement will be owned by the party having Made the invention. For each Subject Invention Made solely by the Contractor, the Government will receive a non-exclusive, worldwide, transferable, paid-up, royalty-free, irrevocable license to practice the invention and the right to sublicense same to third parties to practice the invention for any purpose, including but not limited to continuing research and development related to the Subject Invention, and eventual regulatory approval and commercialization thereof. For any Subject Invention Made solely by the Government, the Contractor will receive a non-exclusive, worldwide, transferable, paid-up, royalty-free, irrevocable license to practice the invention or allow a third party to practice the invention for any purpose.

[1] "Subject Invention" is hereby redefined as "any invention of the Government, PAH, or developed jointly by the parties, that was conceived or first actually reduced to practice in the performance of work under this Agreement."

b) Grant of Rights of First Refusal to Exclusive License of Subject Invention. For each Subject Invention Made solely by the Contractor, the Contractor shall provide the Government a right of first refusal for an exclusive license to the Subject Invention, within a commercially reasonable time prior to the offer of license to any third party, and subject to no less than a fifty percent (50%) share of royalty based on gross royalty revenue received by the Government. For each Subject Invention Made solely by the Government, the Government shall provide a right of first refusal for an exclusive license to the Subject Invention, within a commercially reasonable time prior to the offer of license to any third party, and subject to a reasonable share of royalty income and subject to a retention of Government use for research purposes only, for purposes of FDA licensure of the technology described herein, limited to the field of use described in the product indication, subject to a termination terms substantially similar to the events described in "Regulatory Rights" below:

c) Joint Inventions. Any Subject Invention Made jointly by the Contractor and any Government employee shall be jointly owned by the Parties. The Contractor shall have the first option to prepare and file the patent application(s) covering the Subject Invention, at its own expense. In the event that the Contractor declines to file or complete prosecution of such patent application at its own expense in a timely manner, the Contractor waives its co-ownership interest therein, and agrees to assign its full right, title and interest to such joint Subject Invention to the Government, so as to allow the Government to prepare, file or continue prosecution of such patent application(s), in exchange for a non-exclusive, irrevocable, transferable, paid-up license to practice such Subject Invention throughout the world. In the event that the Contractor elects to file and complete prosecution of such patent applications, the Government shall receive a nonexclusive, nontransferable, irrevocable, paid-up license to practice the invention, have the invention practiced throughout the world by or on behalf of the Government, and sublicense the invention to third parties for any purpose, including but not limited to continuing research and development related to the Subject Invention, and eventual regulatory approval and commercialization thereof. The Contractor will receive a right of first refusal for an exclusive license to the subject joint invention upon terms identified in Section (b) above.

d) Filing of Patent Applications. The party having the right to retain title to, and file patent applications on, a specific Subject Invention may elect not to file patent applications, provided it so advises the other party within ninety (90) days from the date it reports the Subject Invention to the other party, or at least ninety (90) days before a statutory bar date or public disclosure, whichever occurs earlier. Thereafter, the other party may elect to file patent applications on the Subject Invention and the party initially reporting the Subject Invention agrees to assign its ownership interest in the Subject Invention to the other party.

e) Patent Expenses. The expenses attendant to the filing of patent applications shall be borne by the party filing and/or prosecuting the patent application. Each party shall provide the other party with copies of the patent applications it files on any Subject Invention, along with the power to inspect and make copies of all documents retained in the official patent application files by the applicable patent office. The Parties agree to reasonably cooperate with each other in the preparation and filing of patent applications resulting from this agreement.

f) Relationship to Base OTA Patent Terms. If there is a conflict between this Section and Article X of W15QKN-16-9-1002, the Project Agreement language will supersede and control the relationship of the parties. Where no modifications are made by this Section to the base terms in Article X of W15QKN-16-9-1002, those sections remain operative.

Data Rights

Article XI, §C of Other Transaction Agreement number W15QKN-16-9-1002, is hereby amended, consistent with the "Specifically Negotiated License Rights" capability at Article XI, §§A(12) and (C)(4), as follows:

a) Subject Data Ownership. Subject Data (defined as Technical Data under Article XI, §A(13), generated, directly or indirectly, related to the work performed under this agreement) shall be jointly owned by the Parties. Each party, upon request to the other party, shall have the right to review and to request delivery of all Subject Data, and delivery shall be made to the requesting party within two (2) weeks of the request, except to the extent that such Subject Data are subject to a claim of confidentiality or privilege by a third party. All Deliverables, as described in the Deliverable Table within the Statement of Work, or mentioned elsewhere in this document, are considered Subject Data under this agreement.

b) Confidential Information. Neither Party, as the Receiving Party, shall, directly or indirectly, divulge or reveal to any person or entity any confidential information of the other Party without the Disclosing Party's prior written consent, or use such Confidential Information except as permitted under this agreement.

c) Exclusion. Such obligation of confidentiality shall not apply to information which the Receiving Party can demonstrate through competent evidence: (i) was at the time of disclosure in the public domain; (ii) has come into the public domain after disclosure through no breach of this agreement; (iii) was known to the Receiving Party prior to disclosure thereof by the Disclosing Party; (iv) was lawfully disclosed to the Receiving Party by a Third Party which was not under an obligation of confidence to the Disclosing Party with respect thereto; or (v) was approved for public release by prior written permission of the Disclosing Party.

d) Background Technical Data Rights Assertions. Contractor asserts background technical data rights as follows:

The table below lists the Awardee's assertions regarding data rights.

Technical Data or Computer Software to be Furnished with Restrictions	Basis for Assertion	Asserted Rights	Name of Organization Asserting Restrictions	Deliverables Affected
Know-how and documentation associated with the manufacturing of Leukine Drug Substance	Developed exclusively at private expense	Limited (Category)	Partners Therapeutics	4.2

Documents and technical knowhow related to communication with FDA on non-COVID-19 related indications	Developed exclusively at private expense	Limited (Category)	Partners Therapeutics	4.22 4.23

e) Relationship to Base OTA Data Rights Terms. If there is a conflict between this Section and Article XI of W15QKN-16-9-1002, the Project Agreement language will supersede and control the relationship of the parties. Where no modifications are made by this Section to the base terms in Article XI of W15QKN-16-9-1002, those sections remain operative.

Regulatory Rights

This agreement includes research with an investigational drug, biologic or medical device that is regulated by the U.S. FDA, and requires FDA pre-market approval or clearance before commercial marketing may begin. It is expected this agreement will result in the FDA clearance and commercialization of product(s) (the "Technology"). The PAH may be the Sponsor of the Regulatory Application (an Investigational New Drug Application (IND), Investigational Device Exemption (IDE), New Drug Application (NDA), Biologics License Application (BLA), Premarket Approval Application (PMA), or 510(k) pre-market notification filing (510(k)) or another regulatory filing submitted to FDA) that controls research under this agreement. If the PAH is the Sponsor of the Regulatory Application to FDA (as the terms "sponsor" and "applicant" are defined or used in at 21 CFR §§3.2(c), 312.5, 600.3(t), 812.2(b), 812 Subpart C, or 814.20), they have certain standing before the FDA that entitles it to exclusive communications related to the Regulatory Application.

The SDMR is the JPEO-CBRND and DTRA-JSTO representative for all regulatory and quality activities. The PAH shall coordinate with the SDMR prior to communicating or meeting with the FDA, or other regulatory authorities, as appropriate for this OTA Project. The PAH shall invite the SDMR to all FDA meetings and regulatory discussions applicable to this OTA Project.

This following clause protects the return on research and development investment made by the Government, in the event of certain regulatory product development failures related to the Technology.

The PAH agrees to the following:

a. The PAH will provide to the Government all data including top-line summaries and key conclusions from all studies supporting the regulatory filing and commercial approval to the extent that such data, summaries, and conclusions are funded by this Agreement. In addition, the PAH will offer the Government the opportunity to review and provide comments on a final draft of regulatory submissions, which include data funded by this Agreement. The Government will review any such submissions promptly upon receipt. The PAH will reasonably consider any comments provided by the Government, and prior to submission will provide notification to the Government of any additional edits or revisions. The PAH will keep the Government apprised of planned FDA meetings and post-meeting outcomes relating to activities funded by this Agreement.

b. Communications. PAH will provide the Government with copies of all communications, both formal and informal, to or from FDA, regarding the Technology within 48 hours, and ensure that the Government representatives are invited to participate in any formal or informal Sponsor meetings with FDA, as appropriate for this OTA Project;

c. Non-compliance with section (a. & b.) may result in termination of the agreement.

d. Product Development Failure. Certain product development failures may trigger certain remedies in Section "e." below for the Government advanced developer funding the development of this Technology. This remedy is not available to the Government for any cause outside of the following:

(i) if this agreement is terminated for nonperformance,

(ii) if this agreement is successfully completed and the Government advanced developer funding this project agreement, offers to provide funding to continue development to FDA approval for the indication identified in this project agreement, and the PAH refuses to or is unable to continue such development.

e. If any of the product development failures listed in Section "d." occur, the PAH, upon the request of the Government:

(i) shall transfer possession, ownership and sponsorship or holdership of any Regulatory Application (including any associated expedited review designation, priority review voucher, or marketing exclusivity eligibility or award), regulatory correspondence, and supporting regulatory information related to the Technology, as related to this Project Agreement, to the Government or its designee;

(ii) shall inform FDA of the transfer of sponsorship or holdership of the Regulatory Application transferred under section (e)(i) above;

(iii) shall negotiate in good faith a non-exclusive license, at customary industry rates and under reasonable terms and conditions, to any patent, copyright or other intellectual property owned or controlled by the PAH, developed prior to or outside the scope of this agreement, or any technical data that is necessary for the Government to pursue commercialization of this technology, as related to this OTA Project with a third party for sale to the Government or otherwise.

f. This clause will survive the acquisition or merger of the PAH by or with a third party. This clause will also be included in any subcontracts/sub-agreements relating to the development of the Technology, as appropriate for this Project Agreement. This clause will survive for one year after the Government elects to discontinue funding the development or procurement of this product for the indication identified in this project agreement.

g. Public Law 115-92 Sponsor Authorization Letter

The PAH shall submit to the Government, within thirty (30) days of project award, a fully executed sponsor authorization letter enabling FDA to disclose information to JPEO-CBRND and its

Government support contractors, related to the proposed product under Public Law 115-92. A template for the sponsor authorization letter was attached to the RPP as Exhibit 4.

JPEO-CBRND shall formally submit the executed letter to the FDA under the Regulatory Application, only if the proposed product becomes a DoD medical product priority under Public Law 115-92.

If the product becomes a DoD medical product priority, to the maximum extent practicable, JPEO-CBRND will include the PAH in any and all meetings and correspondence conducted with the FDA under Public Law 115-92. If it is not practicable to include the Awardee in any Public Law 115-92 interaction with the FDA regarding the product (for example, discussions conducted at quarterly or semi-annual DoD-FDA meetings mandated by the Public Law), JPEO-CBRND will provide a summary of the interaction to the PAH within ten (10) business days.

h. Deliverable(s): Public Law 115-92 Sponsor Authorization Letter.

8.0 SECURITY

The security classification level for this effort is Unclassified.

9.0 MISCELLANEOUS REQUIREMENTS (SAFETY, ENVIRONMENTAL, ETC.)

N/A

10.0 GOVERNMENT FURNISHED PROPERTY/MATERIAL/INFORMATION

N/A

11.0 AGREEMENTS OFFICER'S REPRESENTATIVE (AOR) AND ALTERNATE AOR CONTACT INFORMATION

AOR

NAME: (b) (6)
MAILING ADDRESS: (b) (6)
EMAIL: (b) (6)
PHONE: (b) (6)
AGENCY NAME/DIVISION/SECTION: JPEO-CBRND, JPM-Medical

Alternate AOR

NAME: (b) (6)
MAILING ADDRESS: (b) (6)
EMAIL: (b) (6)
PHONE: (b) (6)
AGENCY NAME/DIVISION/SECTION: JPEO-CBRND, JPM-Medical