

OTHER TRANSACTION AUTHORITY FOR PROTOTYPE AGREEMENT

BETWEEN

Merck Sharp & Dohme Corp (Awardee)
2000 Galloping Hill Rd.
Kenilworth, NJ 07033-1310
DUNS Number: 001317601
CAGE Code: 6B2S4

And

NATICK CONTRACTING DIVISION (Government)
15 General Greene Ave.
Natick, MA 01760

Effective Date:

2 December 2020

Agreement Number:

W911QY-21-9-0001

Total Amount of the Agreement:

\$355,562,292.00

December 2, 2020

(b) (6)

Merck Sharp & Dohme Corp.
2000 Galloping Hill Rd.
Kenilworth, NJ 07033

Re: Letter Agreement to Rapidly Develop Manufacturing and Distribution Capability of CD24Fc for the Treatment of Severe and Critical COVID-19

Dear (b) (6)

Pursuant to 10 U.S.C. § 2371b, the U.S. Government is issuing this letter agreement to Merck Sharp & Dohme Corp. (“Merck”) through Army Contracting Command on behalf of the Joint Program Executive Office for Chemical, Biological, Radiological and Nuclear Defense and the Biomedical Advanced Research and Development Authority. This letter agreement is effective upon execution by both parties and will remain in effect until delivery of the product required under this letter agreement, replacement by a definitive agreement, or earlier termination by either party as described below.

In response to the worldwide COVID-19 pandemic and Public Health Emergency caused by the novel coronavirus SARS-CoV-2, the U.S. Government has identified CD24Fc, as a first-in-class biologic for treatment of severely and critically ill COVID-19 patients. The CD24Fc product has progressed rapidly through advanced research and development activities without U.S. Government funding. Merck, upon completion of its acquisition to acquire CD24Fc, is proposing to manufacture at-scale and fill and finish the therapeutic CD24Fc for treatment of the SARS-CoV-2 threat, for provision to the U.S. Government, subject to technical, clinical and regulatory success if clinical trials are successful and the FDA grants an Emergency Use Authorization (“EUA”). This letter agreement is necessary to meet certain development and manufacturing deadlines, as described below, including the need to reserve manufacturing suite space. The parties expect to enter into a definitized agreement no later than 180 days from the date of this letter agreement that more fully sets forth the terms and conditions of this agreement.

The desired end product of this effort is: submission of an EUA request no later than March 31, 2021, with FDA approval of the EUA request no later than June 30, 2021; the development of a proven at-scale manufacturing process capable of producing 100,000 doses by June 30, 2021; and development of a distribution process capable of delivering CD24Fc to point of care facilities (hereinafter referred to as the “Prototype Project” or “Technology”). The parties understand there are manufacturing uncertainties and, therefore, Merck shall use commercially reasonable efforts to successfully perform the Prototype Project pursuant to the statement of work included as Attachment A. In return, the USG shall pay Merck \$355,562,292 for delivery of all Merck’s production of CD24Fc through June 30, 2021 not to exceed 100,000 doses, with an anticipated quantity of 60,000 to 100,000 doses; provided that Merck will not have an obligation to deliver doses, and the Government will not have an obligation to make payment under this agreement, if the FDA has not issued an emergency use authorization by June 30, 2021 for the use of CD24Fc in the United States to treat COVID-19; provided further that Merck will deliver these doses on a rolling basis within a reasonable period of time after

they are released to the extent feasible if Merck receives an emergency use authorization prior to June 30, 2021. To the extent that Merck's commercially reasonable efforts will not yield 100,000 doses by June 30, 2021, the parties agree that the price paid to Merck shall be reduced proportionately to the number of doses actually delivered by that date or another date negotiated by the USG and Merck under a no-cost extension. Merck is entering into this pricing arrangement due to exigent circumstances posed by the COVID-19 pandemic, and the price ultimately paid by the USG under this agreement reflects the price of the Prototype Project and does not necessarily reflect the full value of CD24Fc. Merck is a nontraditional defense contractor as defined in 10 U.S.C. § 2302(9).

The parties agree that issuing this letter agreement is necessary to reserve capacity and initiate manufacturing in order to meet the project goals defined above. The maximum amount for which the Government shall be liable if this letter agreement is terminated is the amount obligated by this agreement or by an amendment to the agreement. The parties agree to begin promptly negotiating the terms of a definitive prototype Other Transaction Agreement pursuant to 10 U.S.C. 2371b that will include all conditions required by law on the date of execution of the definitive agreement and any other mutually agreeable clauses, terms, and conditions. The definitive agreement resulting from this undefinitized action will include a negotiated firm fixed price. In addition, within 45 days of issuance of this letter agreement, the parties intend to establish mutually agreeable detailed requirements for reporting, such as biweekly meetings, monthly technical reporting, Integrated Master Schedule ("IMS") submissions, regulatory compliance reporting and coordination, security reporting, manufacturing reporting, and specific terms and conditions proposed by Office of the Secretary of Defense, BARDA, and OWS (including OPSEC and other security clauses) in addition to those described in the Deliverables table in Attachment A and Appendix 1. Pending definitization, any such requirements will be enforceable only pursuant to a mutually agreed to amendment to this letter agreement.

Merck agrees to submit a firm fixed price proposal no later than March 31, 2021 for the purpose of establishing a definitized final agreement. The proposal shall contain sufficient information to enable the Government to understand and evaluate the basis for the \$355,562,292 price and technical information contained in the proposal. (b) (4)

[REDACTED]

If agreement on definitive terms to supersede this undefinitized action is not reached within one hundred and eighty days (180) of the date of the letter agreement, or within any extension granted by the Agreements Officer, the Agreements Officer may determine a reasonable price or fee for any unpriced units, subject to the disputes paragraph contained herein. The agreement shall be governed by all clauses required by law as of the date of the Agreement Officer's determination; and to the extent agreed to by Merck, specific terms and conditions proposed by Office of the Secretary of Defense, BARDA, and OWS (including OPSEC and other security clauses); and any other clauses, terms, and conditions mutually agreed upon. The Government shall not obligate more than 50 percent of the maximum price (\$355,562,292) before definitization, unless a greater amount is authorized by the Agreements Officer. Until this agreement is fully funded, Merck may cease performance under this agreement if the cost of

Merck's performance exceeds the funds obligated to the agreement. Merck shall notify the Agreements Officer in writing at least 60 days in advance of Merck's intent to cease performance under the prior sentence in order to provide the Agreements Officer with sufficient opportunity to obligate additional funding to this agreement if appropriate.

Under this letter agreement, Merck will engage in commercially reasonable efforts to successfully perform the Prototype Project pursuant to the statement of work included as Attachment A. Merck shall not be in breach of this agreement for the failure of Merck to successfully complete the Prototype Project (including without limitation technical, clinical, regulatory matters) provided Merck's efforts are in good faith and are commercially reasonable and Merck complies with the other provisions of this agreement. The parties understand Bulk Drug Substance ("BDS") manufacture at 500L, 1000L, and 2000L scales may not generate sufficient volume to produce Drug Product ("DP") suitable for use under an EUA (that is, a product that meets historical yields, established critical quality attributes, stability profiles, and other characterization elements) at the rates and quantities contemplated by this agreement. As such, the parties agree to reassess the feasibility of the current delivery schedule for 100K doses and to define an expected quantity of doses to be delivered by 30 June 2021 once the parties are informed by the data generated from the BDS batches manufacture initiated in October and November 2020 at the 500L and 1000L scales, the release of which is anticipated in January and February 2021.

The Government may terminate this agreement for any or no reason by providing at least thirty (30) calendar days' prior written notice to the Awardee. The Government and Awardee will negotiate in good faith a reasonable and timely adjustment of all outstanding issues between the Parties as a result of termination by the Government for convenience, consistent with the terms of this agreement. Settlement of costs for any doses that have not been accepted under this agreement shall be determined on the basis of the FAR 52.249-6(h).

Merck will deliver product to end users in the United States constituting individual hospital sites designated by the U.S. Government. The U.S. Government will promptly accept conforming product upon receiving certificates of conformance and analysis, and risk of loss for product will transfer from Merck to the U.S. Government upon delivery to the sites designated by U.S. Government.

Neither party will have further obligations under this letter agreement and this letter agreement shall be deemed terminated in the event that Merck does not by January 31, 2021 close its pending acquisition of OncoImmune, Inc. Within fifteen (15) days of any termination under this paragraph, Merck shall provide any outstanding deliverables contemplated or materials purchased under this letter agreement in Merck's possession on the date of termination; and shall also, to the extent it has legal rights to do so on the date of termination, provide necessary technical data, licenses, and rights of reference or any other necessary regulatory rights sufficient to enable a third party to develop and manufacture CD24Fc for the sole purpose of meeting the delivery obligations contemplated by this letter agreement and solely for the purpose of treating SARS-CoV-2.

(b) (4)

(b) (4)



Merck shall indemnify the U.S. Government and its officers, employees and agents against liability, including costs, for actual or alleged direct or contributory infringement of, or inducement to infringe, any United States or foreign patent, trademark or copyright, arising out of this letter agreement, provided that Merck is reasonably notified of such claims and proceedings. In the unlikely event that an invention is conceived or first actually reduced to practice in the performance of this agreement (“Agreement Invention”), ownership of any Agreement Invention, regardless of whether it is not patentable, or is patentable under U.S. patent law that is conceived or first reduced to practice under this agreement will follow inventorship in accordance with U.S. patent law. Neither the Government nor Awardee anticipate the conception or reduction to practice of any Agreement Invention.

Any technical data, as defined in 48 C.F.R. § 252.227-7013(a)(15), generated in connection with the performance of work under this letter agreement, including clinical trials, shall be owned by the Merck. For any data generated using U.S. Government funding in connection with the performance of work under this letter agreement, including clinical trials and any manufacturing scale-up and distribution capability, the U.S. Government shall have government purpose rights for use and activities in connection with SARS-CoV-2 with an obligation to limit disclosure of such information outside the U.S. Government to contractors that have entered into an agreement with the U.S. Government that includes 48 C.F.R. § 252.227-7025 or to a recipient that has entered into the use and non-disclosure agreement set forth in 48 C.F.R. § 227.7103-7; provided that rights for specific deliverables may be modified in the Statement of Work.

In recognition of the Government’s need to provide sufficient quantities of a COVID-19 treatment to protect the United States population, the Government shall have the remedy described in this section to ensure sufficient supply of CD24Fc to meet the needs of the public health or national security. If Merck informs the U.S. Government of any formal management decision to terminate the product development effort before all milestones in this agreement are satisfied for reasons other than technical feasibility or regulatory matters, including safety or efficacy failure, Merck shall provide necessary technical data, licenses, and rights of reference or any other necessary regulatory rights sufficient to enable a third party to develop and manufacture CD24Fc for the sole purpose of meeting the delivery obligations contemplated by this letter agreement and solely for the purpose of treating SARS-CoV-2; and Merck shall provide any outstanding deliverables contemplated or materials purchased under this letter agreement in Merck’s possession on the date of Merck’s notice.

The U.S. Government shall ensure that any CD24Fc delivered under this letter agreement, or a corresponding definitive agreement, is only used in the United States (or a U.S. territory where U.S. law applies including, but not limited to, embassies, military installations

and NATO installations) in a way that would be subject to liability protection under an active declaration issued under the Public Readiness and Emergency Preparedness Act, 42 U.S.C. § 247d-6d.

The Comptroller General of the United States will have access to and the right to examine records of any entity that performs activities under this letter agreement, or a corresponding subagreement, to the extent that such records directly pertain to, and involve transactions relating to, this letter agreement. This right will survive for a period of three years after final payment under this letter agreement or its expiration or termination. Notwithstanding the foregoing, this right will not apply with respect to any entity that performs activities under this letter agreement or a subagreement to the extent that an entity has not entered into an agreement providing such a right in the year prior to performing such activities. This paragraph only applies to any record that is created or maintained in the ordinary course of business or pursuant to a provision of law.

For any disagreement, claim, or dispute arising under this agreement, the parties shall communicate with one another in good faith and in a timely and cooperative manner. Whenever disputes, disagreements, or misunderstandings arise, the parties shall attempt to resolve the issue by discussion and mutual agreement as soon as practicable. Failing resolution by mutual agreement, the aggrieved party shall request a resolution in writing from the AO. The AO will review the matter and render a decision in writing within thirty (30) calendar days. Thereafter, either party may pursue a dispute at a court of competent jurisdiction at any time. The parties intend for the U.S. Court of Federal Claims to have jurisdiction over disputes under this letter agreement pursuant to 28 U.S.C. § 1491(a)(1). As contemplated by 28 U.S.C. § 2516(a), this letter agreement provides for the payment of prejudgment interest from the date on which a claim accrues.

This letter agreement is a rated order with a DO-C9 and DO-HR rating certified for national defense and use, and Merck is required to follow all the provisions of the Defense Priorities and Allocations System regulation (15 C.F.R. Part 700) and the Health Resources Priorities and Allocations System (45 C.F.R Part 101). This rated order is placed for the purpose of emergency preparedness. Accordingly:

1. The Government has the right to purchase all materials produced utilizing this rated order, including BDS and DP, up to 100,000 doses.
2. Merck shall not sell or otherwise transfer any such materials to any third party without the Government's prior written consent or refusal to accept delivery under this agreement within thirty (30) calendar days after the date on which particular doses are ready for delivery.

This rated order must be accepted or rejected within forty-eight hours after receipt.

Sincerely,

Attachment

(b) (6)
Agreements Officer

* * *

By signing below, the representatives of each party to this letter agreement confirm that they have authority to bind the party that they represent. This letter agreement may be executed in one or more counterparts, each of which will be deemed an original and together will constitute one agreement. This letter agreement may be executed and transmitted electronically in PDF format.

MERCK SHARP & DOHME CORP.

U.S. GOVERNMENT

(b) (6)

(b) (6)

Date: December 2, 2020

Date: December 2, 2020

Attachment A – Statement of Work

BAA Number: MCS-BAA-17-01, Amendment 0006

Full Proposal Number: W911QY2190003

Development and Rapid Emergency Supply of CD24Fc for the Treatment of Severe and Critical COVID-19

Preamble

Independently, and not as an agent of the Government, the Awardee shall furnish all necessary services; qualified professional, technical and administrative personnel; and material, equipment and facilities not otherwise provided by the Government under the terms of this agreement, as needed to perform the tasks set forth below.

Overall Objectives and Scope

The overall objective of this proposal is to manufacture and deliver CD24Fc to the Government for the treatment of severely and critically ill COVID-19 patients under Emergency Use Authorization (EUA). The scope of work is to scale-up manufacturing of final drug product (“FDP”), submit an EUA request, and distribute the FDP under the EUA.

- 1) Submit EUA request for CD24Fc by 31 March 2021.
- 2) Delivery of a minimum of 60,000 doses but up to 100,000 doses of CD24Fc product by 30 June 2021.

The items outlined are based on current plans and are subject to change as the development plan progresses, regulatory input is received on the program and funding allocations are agreed upon.

Major Milestones

Milestone	Notes
Confirmed reservation of the first 15 batches	Complete by 15 December 2020
Clinical data from the completed phase 3 study	Within 10 calendar days of clinical database lock
Enrollment of CD24Fc in I-SPY clinical trial if appropriate, including if a confirmatory study is needed by FDA	TBD
EUA submitted to FDA	Completed by 31 March 2021
Delivery of a minimum of 60,000 doses but up to 100,000 doses of CD24Fc product	Completed by 30 June 2021. Delivery to occur on a rolling basis within a reasonable period of time after doses are released to the extent feasible if EUA received prior to 30 June 2021.
Distribution and, as detailed in definitization, storage of final drug product to point of care facilities	As necessary to meet the Government’s needs for administration and in line with EUA requirements

Major Deliverables¹

CDRL#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
	Public Law 115-92 Sponsor Authorization Letter	Merck will provide the U.S. Government with a letter under Public Law 115-92 authorizing the U.S. Food and Drug Administration to discuss regulatory filings for CD24Fc with the U.S. Department of Defense. The U.S. Government will ensure that any information received under a Public Law 115-92 authorization, or that Merck provides under this letter contract and identifies as proprietary and confidential, will not be used or disclosed outside the U.S. Government or for commercial purposes .	Delivery within 30 days of letter agreement award
01	Meetings		
01.1	Post Award Teleconference	<p>The Awardee shall complete an initial teleconference after letter agreement execution</p> <ol style="list-style-type: none"> 1. Outline activities for the next 30 days <ul style="list-style-type: none"> •Discuss agenda items for the post-letter agreement execution Kickoff Meeting (01.2) 	<ul style="list-style-type: none"> •Within one week of letter agreement execution •Awardee shall provide agenda and establish a teleconference number at least 3 business days in advance of the teleconference unless notified that BARDA will supply one •AOR edits/approves and instructs Awardee to distribute agenda prior to meeting by at least 2 business days •Awardee provides meeting minutes to AOR within 3 business days after the meeting •AOR reviews, comments and approves minutes within 10 business days
01.2	Weekly Teleconference	<p>The Awardee shall participate in teleconferences every week, with BARDA to discuss the performance on the contract. Meeting frequency can be decreased or increased as needed during the course of the project</p>	<ul style="list-style-type: none"> •Awardee provides agenda to AOR no later than 2 business days in advance of meeting •AOR edits/approves and instructs Awardee to distribute agenda prior to meeting •Awardee distributes agenda and presentation materials at least 24 hours in advance •Awardee provides meeting minutes to AOR within 3 business days of the meeting

¹ Within 45 days of the execution of this letter agreement, the parties intend to issue a mutually agreed-upon amendment that will include a revised deliverables table with additional agreement deliverables; further define certain deliverables, where noted in this table; and delineate the Government's rights in data for each deliverable.

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CDRL#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
			<ul style="list-style-type: none"> •AOR reviews, comments, and approves minutes within 6 business days
01.3	Daily check in with project staff for COVID-19 Contract	To be outlined in more detail within 45 days of award	
02	Technical Reporting		
02.1 (Final)	Final Clinical Study Reports	Awardee shall provide Final Clinical Study Reports to BARDA	<ul style="list-style-type: none"> •Top-Line results from clinical study NCT04317040 shall be provided to BARDA within ten calendar days of Merck's receipt of the data •Other details to be defined within 45 days of award
02.2	Manufacturing Reports	<p>At BARDA's request, Awardee shall provide Manufacturing Reports and manufacturing dose tracking projections/actuals to BARDA for review and comment</p> <p>Reports will include at a minimum DS, DP and release assay reports and data associated with yield and product quality.</p> <p>The AOR and AO reserve the right to request within the PoP a non-proprietary Manufacturing Report for distribution within the USG</p>	<ul style="list-style-type: none"> •Merck will provide BDS manufacturing reports for all of the BDS manufacturing runs, and all of the FDP fill-finishing runs. Awardee will submit Manufacturing Reports within 5 business days of final data availability •The Government will provide written comments to the manufacturing report within 10 business days after the submission •If corrective action is recommended, Awardee must address all concerns raised by BARDA in writing
03	Quality		
03.1	Quality Management Plan	The Quality Management Plan may include, but is not limited to the quality policy and objectives, management review, competencies and training, process document control, feedback, evaluation, corrective action and preventive action, process improvement, measurement, and data analysis processes. The framework is normally divided into infrastructure, senior management responsibility, resource management, lifecycle management, and quality management system evaluation.	Plan will be delivered electronically within 60 days of letter agreement award
03.2	cGMP Certification	Certificate of Analysis ("COA") and Certificate of Conformance ("COC")	Prior to shipment and/or Government acceptance
04	Audits		
05	Advanced R&D Products		
06	Regulatory Documents		
06.1	FDA Correspondence	To be outlined in more detail within 45 days of award	
06.2	FDA Submissions	To be outlined in more detail within 45 days of award	
	EUA filing	To be outlined in more detail within 45 days of award	

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CDRL#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
07	Press Releases		
07.1	Press Releases	Awardee agrees to accurately and factually represent the work conducted under this contract in all press releases	<ul style="list-style-type: none"> • Awardee shall submit to the PO, AO and BARDAclearance@hhs.gov an advanced copy of any press release to this contract not less than 5 business days prior to the issuance of the press release • The AO must approved the advanced copy prior to the issuance of the press release. • If corrective action is required, the Awardee agrees to accurately and factually represent the work conducted under this contract in all press releases • Any final press releases shall be submitted to BARDA no later than one (1) calendar day prior to its release

1.0 Technical and Program Management

Awardee shall provide for the overall management, integration and coordination of all contract activities, including a technical and administrative infrastructure to ensure the efficient planning, initiation, implementation and direction of all contract activities to support the timely delivery of all deliverables required under the contract.

2.0 Nonclinical and Clinical Activities

2.1 Nonclinical Activities

Awardee shall conduct toxicity studies as required by the FDA, as well as development of bioanalytical methods or assays to support EUA regulatory filings and comparability of drug substance and FDP during process improvement and scale up.

2.2 Clinical Activities

Awardee shall conduct, complete, and support clinical trial activities to support EUA, including completion of the ongoing Phase 3 efficacy study, and other clinical activities as required by the FDA to achieve/maintain EUA status. Topline data from the completed phase 3 clinical trial will be delivered to the USG within 10 calendar days of clinical database lock to ensure continued HRPAS rating.

3.0 Manufacturing Capability

Awardee shall perform manufacturing process and scale-up development, analytical and formulation development, and characterization activities to produce Drug Product (“DP”) suitable for use under an EUA. Multiple GMP Bulk Drug Substance (“BDS”) batches shall be manufactured at 500L, 1000L, and 2000L scales using MCB1. In order to ensure stable EUA drug supply of MCB1 BDS and FDP, comparability must be demonstrated by meeting the product

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established critical quality attributes, stability profiles, and other characterization elements, and accepted by the FDA at the 500L, 1000L, and 2000L scales. All BDS batches shall be filled, packed, and labeled at the US-based CMOs or Merck manufacturing sites. The process scale-up and scale-out strategy is based on the process design knowledge and data gathered from multiple runs performed with a 10L scale-down model and from previous GMP batches performed at 500L scale. Further commercial scale process development and engineering run will be conducted to ensure drug supply for EUA.

3.1 BDS manufacture, process development, scale up and test

- 1) BDS manufacture at Catalent Madison (WI) Site at 500L, 1000L and 2000L scales;
- 2) BDS manufacture at Catalent Bloomington (IN) Site at 1000L scale;
- 3) BDS release testing;
- 4) BDS stability testing;
- 5) Commercial scale BDS process development.
- 6) BDS Manufacturing Reports for each of the runs

3.2 DP manufacture and test

- 1) Fill and finish DP;
- 2) DP release testing;
- 3) DP stability testing;
- 4) Commercial scale fill and finish process development.
- 5) DP Manufacturing Reports for each of the fill-finishing runs.

4.0 Technology Transfer

Awardee shall transfer the manufacturing process technology from the Catalent Madison (WI) site to the Catalent Bloomington (IN) for BDS, and from LSNE Bedford to LSNE Madison site for DP; as well the analytical testing for product release to enable large-scale GMP manufacturing of CD24Fc. Transfer to other sites, including Merck manufacturing sites, may also be considered.

The detailed tech transfer process to BDS and DP manufacturing sites consists of 3 stages:

4.1 Information transfer:

The scope of this stage is to enable transfer of process and site information to the manufacturing site. This effort shall enable understanding of process definition and detailed manufacturing site capabilities and practices.

For BDS transfers at this stage, media and buffer compositions, filter types, resin types/bed heights, target bioreactor volumes and inoculation densities are determined. Additionally, the raw material vendors and raw material methods are developed.

The DP transfers for this stage involves identifying and reviewing product requirements such as vial and stopper size and type, aseptic assurance (media challenge fit), Time out of Refrigerator

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("ToR") requirements, hold time and cold chain requirements, mixing and product homogeneity assurance, filtration parameters, photostability, scale-up, facility dependent process development and shipping conditions.

4.2 Facility fit assessment:

The scope of this stage is to perform detailed assessments on process and facility and perform scale and facility specific calculations.

For BDS transfers at this stage the media, buffer and pool volumes at each intermediate step are identified. Based on this information raw material amounts and resin quantity are determined and overall list of materials is finalized. Additionally, at this stage long lead materials are identified, safety stock strategy is established and procurement planning is in place. Finally, at this stage risk assessments are performed based on identified risk to manufacturing execution and product quality.

For DP transfers at this stage fill volumes and batch sizes are established and the BOM is finalized. Additionally, similar to DS transfer, risk assessments are performed for any changes in processing and impact to presumptive critical process parameters ("pCPP") and presumptive critical quality attributes ("pCQA") are evaluated.

4.3 Manufacturing campaign preparation:

The scope of this stage is to ensure manufacturing and GMP readiness.

For BDS transfer at this stage, the change controls in secured GMP Quality Management System are finalized, batch records are drafted and approved, sampling plans are established and approved, Pre-PPQ and/or PPQ protocols are also authored and approved.

For DP transfer at this stage the scope would be similar to BDS transfer and would include finalizing the change control in quality systems, finalizing batch records etc. Other scope items involve performing development/engineering runs, performing filter validation studies, Component Compatibility Operational Qualification ("CCOQ") studies and finalizing the documents, PPQ protocols if needed and approved batch records.

5.0 Regulatory Activities

The Awardee shall work with FDA and the U.S. Government to utilize all available mechanisms for expediting access to CD24Fc, including seeking EUA. If the data from the pivotal study support a favorable benefit/risk profile, Awardee shall request an EUA of CD24Fc for the treatment of COVID-19.

The manufacturing described in the Statement of Work will comply with Current Good Manufacturing Practices ("cGMP") regulations at 21 CFR 210 and 211. Production shall occur using cGMP manufacturing process, fully compliant with 21 CFR 210 and 211, for bulk drug

substance and fill and finished drug product subject to exceptions or authorizations allowed by FDA.

Production and distribution shall comply with applicable provisions of the Drug Supply Chain Security Act (“DSCSA”), Sections 581-585 of PL 113-54 (Nov 27, 2013), taking into account FDA’s regular guidance for the COVID-19 public health response.

The clinical trial described in the Statement of Work will comply with ICH Good Clinical Practices (“GCP”) regulations at 21 CFR Part 11.

5.1 EUA considerations:

The Awardee shall prepare and submit the EUA request to the FDA based on the newly completed Phase III trial results and the scale-up and scale-out activities;

6.0 Storage and Distribution

The Awardee and the Government will work collaboratively to develop a plan to stockpile and distribute doses of CD24Fc to point of care facilities, necessary to meet the Government’s needs for administration. After the plan is developed and approved by both the Government and Awardee, the Awardee shall take necessary steps to implement stockpiling and distribution capability, ensuring that appropriate systems are fully operational by the time CD24Fc receives EUA from the FDA.

6.1 Storage considerations

To be addressed in definitization.

6.2 Shipping considerations:

Shipping qualification studies shall be performed to support the transfer of FDP to storage facility. The storage warehouse/facility will be qualified and shipping at -20⁰C frozen conduction will use Temperature monitoring devices to monitor temperature excursion. The acceptable range of temperature excursion will be established during shipping validation.

6.3 Pack and Label:

The scope of label and pack tech transfer involves identifying the components based on the packaging design. Typical components include vial label, carton/partitions, case and case label. Additionally, other steps include: securing and qualifying equipment and change parts for cartoner, qualifying vision systems and label printer, enabling packaging and serialization capabilities, and performing shipping qualification prior to manufacturing.

6.4 Distribution considerations:

The Awardee shall ship the drug product to storage facility and distribute drug products to specified end users as directed by the Government.

AWARD/CONTRACT		1. THIS CONTRACT IS A RATED ORDER UNDER DPAS (15 CFR 700)		RATING DO-C9	PAGE OF PAGES 1 10		
2. CONTRACT (Proc. Inst. Ident.) NO. W911QY2190003		3. EFFECTIVE DATE 02 Dec 2020		4. REQUISITION/PURCHASE REQUEST/PROJECT NO. 0011581080			
5. ISSUED BY W6QK ACC-APG NATICK DIVISION BLDG 1 GENERAL GREENE AVENUE NATICK MA 01760-5011		CODE W911QY	6. ADMINISTERED BY (If other than Item 5) See Item 5				
7. NAME AND ADDRESS OF CONTRACTOR (No., street, city, county, state and zip code) MERCK SHARP & DOHME CORP. MERCK (b) (6) 200 GALLOPING HILL RD KEN L WORTH NJ 07033-1310			8. DELIVERY [] FOB ORIGIN [X] OTHER (See below)		9. DISCOUNT FOR PROMPT PAYMENT Net 30 Days		
CODE 6B2S4		FACILITY CODE 6B2S4		10. SUBMIT INVOICES 1 (4 copies unless otherwise specified) TO THE ADDRESS SHOWN IN: Section G			
11. SHIP TO/MARK FOR BARDA (b) (6) BIOMEDICAL ADVANCED RESEARCH DEVELOPMENT AUTH 200 C STREET, SW WASHINGTON DC 20024		CODE W56XNH	12. PAYMENT WILL BE MADE BY DEFENSE FINANCE AND ACCOUNTING SERVICE DFAS- NDY VP GFEB5 8899 E 56TH STREET INDIANAPOLIS IN 46249-3800		CODE HQ0490		
13. AUTHORITY FOR USING OTHER THAN FULL AND OPEN COMPETITION: [] 10 U.S.C. 2304(c)() [] 41 U.S.C. 253(c)()			14. ACCOUNTING AND APPROPRIATION DATA See Schedule				
15A. ITEM NO.	15B. SUPPLIES/ SERVICES	15C. QUANTITY	15D. UNIT	15E. UNIT PRICE	15F. AMOUNT		
SEE SCHEDULE							
15G. TOTAL AMOUNT OF CONTRACT					\$355,562,292.00		
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	D	PACKAGING AND MARKING		PART IV - REPRESENTATIONS AND INSTRUCTIONS			
X	E	INSPECTION AND ACCEPTANCE	3		K	REPRESENTATIONS, CERTIFICATIONS AND OTHER STATEMENTS OF OFFERORS	
X	F	DELIVERIES OR PERFORMANCE	4		L	INSTRS., CONDS., AND NOTICES TO OFFERORS	
X	G	CONTRACT ADMINISTRATION DATA	5 - 8		M	EVALUATION FACTORS FOR AWARD	
	H	SPECIAL CONTRACT REQUIREMENTS					
CONTRACTING OFFICER WILL COMPLETE ITEM 17 (SEALED-BID OR NEGOTIATED PROCUREMENT) OR 18 (SEALED-BID PROCUREMENT) AS APPLICABLE							
17 [X] CONTRACTOR'S NEGOTIATED AGREEMENT Contractor is required to sign this document and return [] copies to issuing office. Contractor agrees to furnish and deliver all items or perform all the services set forth or otherwise identified above and on any continuation sheets for the consideration stated herein. The rights and obligations of the parties to this contract shall be subject to and governed by the following documents: (a) this award/contract, (b) the solicitation, if any, and (c) such provisions, representations, certifications, and specifications, as are attached or incorporated by reference herein. (Attachments are listed herein)				18 [] SEALED-BID AWARD (Contractor is not required to sign this document) Your bid on Solicitation Number _____ including the additions or changes made by you which additions or changes are set forth in full above, is hereby accepted as to the terms listed above and on any continuation sheets. This award consummates the contract which consists of the following documents: (a) the Government's solicitation and your bid, and (b) this award/contract. No further contractual document is necessary. (Block 18 should be checked only when awarding a sealed-bid contract)			
19A. NAME AND TITLE OF SIGNER (Type or print) Michael Nally				20A. NAME OF CONTRACTING OFFICER (b) (6) TEL: _____ EMAIL: _____			
19B. NAME OF CONTRACTOR (b) (6)		19C. DATE SIGNED 02 Dec 2020		20B. UN (b) (6)		20C. DATE SIGNED 02 Dec 2020	
BY _____ (Signature of person authorized to sign)				BY _____ (Signature of Contracting Officer)			

Section B - Supplies or Services and Prices

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0001	CD24Fc Prototype Project FFP	100,000	Each	\$3,555.62292	\$355,562,292.00
	The desired end product of this effort is: submission of an EUA request no later than March 31, 2021, with FDA approval of the EUA request no later than June 30, 2021; the development of a proven at-scale manufacturing process capable of producing 100,000 doses by June 30, 2021; and development of a distribution process capable of delivering CD24Fc to point of care facilities (hereinafter referred to as the "Prototype Project" or "Technology"). The parties understand there are manufacturing uncertainties and, therefore, Merck shall use commercially reasonable efforts to successfully perform the Prototype Project pursuant to the letter agreement and statement of work included as Attachment A.				
	FOB: Destination				
	SHIP VIA: Best Way (Shippers Option)				
	PSC CD: 6505				
				NET AMT	\$355,562,292.00

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
000101	ACRN AA @ \$177,781,146.00 FFP				\$0.00
	Funding for W911QY-21-9-0003				
	PURCHASE REQUEST NUMBER: 0011581080				
				NET AMT	\$0.00
	ACRN AA				\$177,781,146.00
	CIN: GFEB001158108000001				

Section E - Inspection and Acceptance

INSPECTION AND ACCEPTANCE TERMS

Supplies/services will be inspected/accepted at:

CLIN	INSPECT AT	INSPECT BY	ACCEPT AT	ACCEPT BY
0001	Origin	Government	Origin	Government
000101	N/A	N/A	N/A	N/A

Section F - Deliveries or Performance

DELIVERY INFORMATION

CLIN	DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
0001	POP 02-DEC-2020 TO 30-JUN-2021	N/A	BARDA (b) (6) BIOMEDICAL ADVANCED RESEARCH DEVELOPMENT AUTH 200 C STREET, SW WASHINGTON DC 20024 (202) 868-9359 FOB: Destination	W56XNH
000101	N/A	N/A	N/A	N/A

Section G - Contract Administration Data

ACCOUNTING AND APPROPRIATION DATA

AA: 0212021202220400000665654255 S.0074658.5.35 6100.9000021001
 COST CODE: A5XAH
 AMOUNT: \$177,781,146.00

ACRN	CLIN/SLIN	CIN	AMOUNT
AA	000101	GFEB001158108000001	\$177,781,146.00

CLAUSES INCORPORATED BY FULL TEXT

252.232-7006 WIDE AREA WORKFLOW PAYMENT INSTRUCTIONS (DEC 2018)

(a) Definitions. As used in this clause—

“Department of Defense Activity Address Code (DoDAAC)” is a six position code that uniquely identifies a unit, activity, or organization.

“Document type” means the type of payment request or receiving report available for creation in Wide Area WorkFlow (WAWF).

“Local processing office (LPO)” is the office responsible for payment certification when payment certification is done external to the entitlement system.

“Payment request” and “receiving report” are defined in the clause at 252.232-7003, Electronic Submission of Payment Requests and Receiving Reports.

(b) Electronic invoicing. The WAWF system provides the method to electronically process vendor payment requests and receiving reports, as authorized by Defense Federal Acquisition Regulation Supplement (DFARS) 252.232-7003, Electronic Submission of Payment Requests and Receiving Reports.

(c) WAWF access. To access WAWF, the Contractor shall—

(1) Have a designated electronic business point of contact in the System for Award Management at <https://www.sam.gov>; and

(2) Be registered to use WAWF at <https://wawf.eb.mil/> following the step-by-step procedures for self-registration available at this web site.

(d) WAWF training. The Contractor should follow the training instructions of the WAWF Web-Based Training Course and use the Practice Training Site before submitting payment requests through WAWF. Both can be accessed by selecting the “Web Based Training” link on the WAWF home page at <https://wawf.eb.mil/>.

(e) WAWF methods of document submission. Document submissions may be via web entry, Electronic Data Interchange, or File Transfer Protocol.

(f) WAWF payment instructions. The Contractor shall use the following information when submitting payment requests and receiving reports in WAWF for this contract or task or delivery order:

(1) Document type. The Contractor shall submit payment requests using the following document type(s):

(i) For cost-type line items, including labor-hour or time-and-materials, submit a cost voucher.

(ii) For fixed price line items—

(A) That require shipment of a deliverable, submit the invoice and receiving report specified by the Contracting Officer.

(B) For services that do not require shipment of a deliverable, submit either the Invoice 2in1, which meets the requirements for the invoice and receiving report, or the applicable invoice and receiving report, as specified by the Contracting Officer.

Invoice 2in1

(iii) For customary progress payments based on costs incurred, submit a progress payment request.

(iv) For performance based payments, submit a performance based payment request.

(v) For commercial item financing, submit a commercial item financing request.

(2) Fast Pay requests are only permitted when Federal Acquisition Regulation (FAR) 52.213-1 is included in the contract.

(3) Document routing. The Contractor shall use the information in the Routing Data Table below only to fill in applicable fields in WAWF when creating payment requests and receiving reports in the system.

Routing Data Table*

<i>Field Name in WAWF</i>	<i>Data to be entered in WAWF</i>
Pay Official DoDAAC	HQ0490
Issue By DoDAAC	W911QY
Admin DoDAAC**	W911QY
Inspect By DoDAAC	W56XNH
Ship To Code	W56XNH

(4) Payment request. The Contractor shall ensure a payment request includes documentation appropriate to the type of payment request in accordance with the payment clause, contract financing clause, or Federal Acquisition Regulation 52.216-7, Allowable Cost and Payment, as applicable.

(5) Receiving report. The Contractor shall ensure a receiving report meets the requirements of DFARS Appendix F.

(g) WAWF point of contact.

(1) The Contractor may obtain clarification regarding invoicing in WAWF from the following contracting activity's WAWF point of contact.

Agreement Specialist

(b) (6)



(2) Contact the WAWF helpdesk at 866-618-5988, if assistance is needed.

(End of clause)

AGREEMENT ADMINISTRATION

A. In no event shall any understanding or agreement, modification, change order, or other matter in deviation from the terms of this Agreement between the Awardee and a person other than the OTAO be effective or binding upon the Government. All such actions must be formalized by a proper contractual document executed by the OTAO.

B. The telephone number and e-mail addresss of the Agreement Officer and Agreement Specialist are:

Other Transaction Agreements Officer (OTAO)

(b) (6)

ACC-APG Natick
1 General Greene Ave.
Natick, MA 01760

(b) (6)

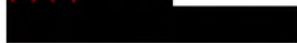


Lead Other Transaction Agreement Specialist (OTAS)

(b) (6)

ACC- APG Natick
1 General Greene Ave.
Natick, MA 01760

(b) (6)



Other Transaction Agreement Specialist (OTAS)

(b) (6)

ACC-APG Natick
1 General Greene Ave.
Natick, MA 01760

(b) (6)



C. The telephone number and e-mail addresss of the Agreement Officer Representatives are:

Agreements Officer Representative (AOR):

(b) (6)

Health Scientist
Division of CBRN Countermeasures
Biomedical Advanced Research and Development Authority (BARDA)
Office of the Assistant Secretary for Preparedness & Response (ASPR)
U.S. Department of Health & Human Services (HHS)

(b) (6)
[Redacted]

Agreements Officer Representative (AOR) Alternative:

(b) (6)
[Redacted]

JPM CBRN Medical
Assistant Product Manager
Alphavirus and Smallpox Threats

(b) (6)
[Redacted]

Section I - Contract Clauses

CLAUSES INCORPORATED BY REFERENCE

52.204-25	Prohibition on Contracting for Certain Telecommunications and Video Surveillance Services or Equipment.	AUG 2020
252.204-7012	Safeguarding Covered Defense Information and Cyber Incident Reporting	DEC 2019

CLAUSES INCORPORATED BY FULL TEXT

52.204-26 COVERED TELECOMMUNICATIONS EQUIPMENT OR SERVICES--REPRESENTATION (OCT 2020)

(a) Definitions. As used in this provision, "covered telecommunications equipment or services" and "reasonable inquiry" have the meaning provided in the clause 52.204-25, Prohibition on Contracting for Certain Telecommunications and Video Surveillance Services or Equipment.

(b) Procedures. The Offeror shall review the list of excluded parties in the System for Award Management (SAM) (<https://www.sam.gov>) for entities excluded from receiving federal awards for "covered telecommunications equipment or services".

(c) Representations.

(1) The Offeror represents that it [___] does, [___] does not provide covered telecommunications equipment or services as a part of its offered products or services to the Government in the performance of any contract, subcontract, or other contractual instrument.

(2) After conducting a reasonable inquiry for purposes of this representation, the offeror represents that it [___] does, [___] does not use covered telecommunications equipment or services, or any equipment, system, or service that uses covered telecommunications equipment or services.

(End of provision)

Section J - List of Documents, Exhibits and Other Attachments

ATTACHMENTS & EXHIBITS

Attachment(s):

Attachment 0001 - Letter Contract for CD24Fc

Attachment A – Statement of Work

Appendix:

Appendix 1 Clause for MCDC Other Transaction Authority Agreement