

<b>AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT</b>			1. CONTRACT ID CODE J	PAGE OF PAGES 1   15
2. AMENDMENT/MODIFICATION NO. P00002	3. EFFECTIVE DATE 7 April 2021	4. REQUISITION/PURCHASE REQ. NO.		5. PROJECT NO. (If applicable)
6. ISSUED BY W6QK ACC-APG NATICK DIVISION BLDG 1 GENERAL GREENE AVENUE NATICK MA 01760-5011	CODE W911QY	7. ADMINISTERED BY (If other than item 6) <b>See Item 6</b>		
8. NAME AND ADDRESS OF CONTRACTOR (No., Street, County, State and Zip Code) EJ LILLY AND COMPANY (b) (6) 1 LILLY CORPORATE CTR INDIANAPOLIS IN 46285		9A. AMENDMENT OF SOLICITATION NO.		
		9B. DATED (SEE ITEM 11)		
		X 10A. MOD. OF CONTRACT/ORDER NO. W911QY21D0012		
		X 10B. DATED (SEE ITEM 13) 25-Feb-2021		
CODE 75602	FACILITY CODE 75602			
11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS				
<input type="checkbox"/> The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of offer <input type="checkbox"/> is extended, <input type="checkbox"/> is not extended. Offer must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended by one of the following methods: (a) By completing Items 8 and 15, and returning _____ copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment you desire to change an offer already submitted, such change may be made by telegram or letter, provided each telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.				
12. ACCOUNTING AND APPROPRIATION DATA (If required)				
13. THIS ITEM APPLIES ONLY TO MODIFICATIONS OF CONTRACT ORDERS. IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.				
A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: (Specify authority) THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.				
B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES (such as changes in paying office, appropriation date, etc.) SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(B).				
X C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF: IAW 52.243-1 Changes, Fixed Price				
D. OTHER (Specify type of modification and authority)				
E. IMPORTANT: Contractor <input type="checkbox"/> is not, <input checked="" type="checkbox"/> is required to sign this document and return <u>1</u> copies to the issuing office.				
14. DESCRIPTION OF AMENDMENT/MODIFICATION (Organized by UCF section headings, including solicitation/contract subject matter where feasible.) Modification Control Number: (b) (6) 211830 OBLIGATION AMOUNT: \$0  1. The purpose of this modification (P00002) is to decrease the quantity of CLIN 0001 by 350,000 doses from 1,200,000 doses to 850,000 doses; revise CLIN 0001 extended description detail; add CLIN 0003 for 350,000 doses of Monoclonal Antibody LY-CoV016; update C.1 in the Statement of Work (SOW); update clause H.11 Buy Back; and add clause H.16 Donation of Excess Product.  2. This change was requested by the requiring activity in order to meet mission goals.  3. As a result of this modification, the total cost of this contract was decreased by \$437,500,000.00 from \$2,520,000,000.00 to \$2,082,500,000.00.  Please see below for details. Except as provided herein, all terms and conditions of the document referenced in Item 9A or 10A, as heretofore changed, remains unchanged and in full force and effect.				
15A. NAME AND TITLE OF SIGNER (Type or print) (b) (6)		16A. NAME AND TITLE OF CONTRACTING OFFICER (Type or print) (b) (6)		
		TEL: (b) (6)		
15B. SIGNATURE OF PERSON AUTHORIZED TO SIGN (b) (6)		15C. DATE SIGNED 4/6/2021		16B. UNITED STATES OF AMERICA (b) (6)
		BY: (b) (6)		16C. DATE SIGNED 7 April 2021
(Signature of person authorized to sign)		(Signature of Contracting Officer)		

SECTION SF 30 BLOCK 14 CONTINUATION PAGE

**SUMMARY OF CHANGES**

SECTION SF 1449 - CONTINUATION SHEET

SOLICITATION/CONTRACT FORM

The total cost of this contract was decreased by \$437,500,000.00 from \$2,520,000,000.00 to \$2,082,500,000.00.

The number of award copies required has increased by 1 from 1 to 2.

SUPPLIES OR SERVICES AND PRICES

CLIN 0001

The CLIN extended description has changed from:

The contractor shall produce and deliver a minimum of 100,000 doses of the combination monoclonal antibody (mAb) therapeutic, consisting of LY-CoV555 and LY-CoV016, IAW dosage as specified by FDA Emergency Use Authorization (EUA) for the product. The contractor may deliver up to an additional 1,100,000 doses of the combination therapeutic by bilateral order agreement between the parties. The maximum number of doses to potentially be ordered under this agreement is 1,200,000. This CLIN shall be executed IAW the Statement of Work (SOW) and Technical Deliverables on this contract.

To:

The contractor shall produce and deliver a minimum of 100,000 doses of the combination monoclonal antibody (mAb) therapeutic, consisting of LY-CoV555 and LY-CoV016, IAW dosage as specified by FDA Emergency Use Authorization (EUA) for the product. The contractor may deliver up to an additional 750,000 doses of the combination therapeutic by bilateral order agreement between the parties. The maximum number of doses to potentially be ordered under this agreement is 1,200,000, inclusive of all product CLINs. This CLIN shall be executed IAW the Statement of Work (SOW) and Technical Deliverables on this contract.

The pricing detail quantity has decreased by 350,000.00 from 1,200,000.00 to 850,000.00.

The total cost of this line item has decreased by \$735,000,000.00 from \$2,520,000,000.00 to \$1,785,000,000.00.

CLIN 0003 is added as follows:

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0003		350,000	Each	\$850.00	\$297,500,000.00

Monoclonal Antibody LY-CoV016  
FFP

IAW negotiated modification no. P00002, the contractor shall produce and deliver a minimum of 98,000 doses of the Combination Monoclonal Antibody Therapy Component LY-CoV016, IAW dosage as specified by FDA Emergency Use Authorization (EUA) for the product. This CLIN shall be executed IAW the Statement of Work (SOW) and Technical Deliverables on this contract.

The contractor may deliver up to an additional 252,000 doses of LY-CoV016, by bilateral order agreement between the parties.

The intent is that these standalone doses of LY-CoV016 will be paired with doses of combination mAb therapy component LY-CoV555, procured via contract no. W911QY21C0016, in order to comprise a full dose of the combination treatment.  
FOB: Origin (Shipping Point)  
MFR PART NR: N/A  
PROJECT: Operation Warp Speed  
PSC CD: 6505

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NET AMT	\$297,500,000.00
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#### DELIVERIES AND PERFORMANCE

The following Delivery Schedule item for CLIN 0001 has been changed from:

DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
POP 25-FEB-2021 TO 24-NOV-2021	N/A	N/A FOB: Origin (Shipping Point)	

To:

DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
POP 25-FEB-2021 TO 24-NOV-2021	N/A	N/A FOB: Origin (Shipping Point)	

The following Delivery Schedule for CLIN 0003 has been added:

DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
POP 07-APR-2021 TO 24-NOV-2021	N/A	N/A FOB: Origin (Shipping Point)	

## INSPECTION AND ACCEPTANCE

The following Acceptance/Inspection Schedule was added for CLIN 0003:

INSPECT AT Origin	INSPECT BY Government	ACCEPT AT Origin	ACCEPT BY Government
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The following have been modified:

### SPECIAL CONTRACT REQUIREMENTS

#### **H.1 Disclosure of Information:**

Performance under this contract may require the Contractor to access non-public data and information proprietary to another Government Contractor or of such nature that its dissemination or use other than as specified in the work statement would be adverse to the interests of the Government or others. Neither the Contractor, nor Contractor personnel, shall divulge nor release data nor information that is both developed or obtained under performance of this contract, and identified by the Government in writing as confidential except authorized by Government personnel or upon written approval of the Contracting Officer (KO) which the KO will provide in accordance with OWS or other Government policies and/or guidance. The Contractor shall not use, disclose, or reproduce proprietary data that bears a restrictive legend, other than as specified in this contract, or any information at all regarding this agency. The Contractor shall comply with all applicable Government requirements for protection of non-public information. Unauthorized disclosure of nonpublic information is prohibited by the Government's rules. Unauthorized disclosure may result in termination of the contract, replacement of a Contractor employee, or other appropriate redress. Neither the Contractor nor the Contractor's employees shall disclose or cause to be disseminated, any information concerning the operations of the activity, which could result in, or increase the likelihood of, the possibility of a breach of the activity's security or interrupt the continuity of its operations. No information related to data obtained under this contract shall be released or publicized without the prior written consent of the COR, whose approval shall not be unreasonably withheld, conditioned, or delayed, provided that no such consent is required to comply with any law, rule, regulation, court ruling or similar order; for submission to any government entity' for submission to any securities exchange on which the Contractor's (or its parent corporation's) securities may be listed for trading; or to third parties relating to securing, seeking, establishing or maintaining regulatory or other legal approvals or compliance, financing and capital raising activities, or mergers, acquisitions, or other business transactions. The exceptions identified in this paragraph apply to all disclosures under this Section H.3 except to the extent that a disclosure is otherwise prohibited by law.

#### **H.2 Publication and Publicity**

The Contractor shall not release any reports, manuscripts, press releases, or abstracts about the work being performed under this contract without written notice in advance to the Government.

- (a) Unless otherwise specified in this contract, the Contractor may publish the results of its work under this contract. The Contractor shall promptly send a copy of each submission to the COR for security review prior to submission. The Contractor shall also inform the COR when the abstract article or other publication is published, and furnish a copy of it as finally published.
- (b) Unless authorized in writing by the CO, the Contractor shall not display the DoD logo including Operating Division or Staff Division logos on any publications.
- (c) The Contractor shall not reference the products(s) or services(s) awarded under this contract in commercial advertising, as defined in FAR 31.205-1, in any manner which states or implies DoD approval or endorsement of the product(s) or service(s) provided.

### **H.3 Confidentiality of Information**

1. Confidential information, as used in this article, means non-public information or data of a personal nature about an individual, or proprietary information or data submitted by or pertaining to an institution or organization.
2. The KO and the Contractor may, by mutual consent, identify elsewhere in this contract specific information and/or categories of information which the Government will furnish to the Contractor or that the Contractor is expected to generate which is confidential. Similarly, the KO and the Contractor may, by mutual consent, identify such confidential information from time to time during the performance of the contract. Failure to agree will be settled pursuant to the "Disputes" clause.
3. If it is established elsewhere in this contract that information to be utilized under this contract, or a portion thereof, is subject to the Privacy Act, the Contractor will follow the rules and procedures of disclosure set forth in the Privacy Act of 1974, 5 U.S.C. 552a, and implementing regulations and policies, with respect to systems of records determined to be subject to the Privacy Act.
4. Confidential information, as defined in paragraph (a) of this article, shall not be disclosed without the prior written consent of the individual, institution, or organization.
5. Whenever the Contractor is uncertain with regard to the proper handling of material under the contract, or if the material in question is subject to the Privacy Act or is confidential information subject to the provisions of this article, the Contractor shall obtain a written determination from the KO prior to any release, disclosure, dissemination, or publication.
6. KO Determinations will reflect the result of internal coordination with appropriate program and legal officials.
7. The provisions of paragraph (d) of this article shall not apply to conflicting or overlapping provisions in other Federal, State or local laws.

### **H.4 Regulatory Rights**

This contract involves supply of a product that requires FDA pre-market approval or clearance before commercial authorization. Contractor is seeking FDA authorization or clearance for the commercialization of SARS-CoV2- MCM neutralizing combination therapy consisting of monoclonal antibodies designated as LY-CoV555 and LY- CoV016. The Contractor will be the Sponsor of a Regulatory Application and as such, the Contractor has certain standing before the FDA that entitles it to exclusive communications related to the Regulatory Application.

Accordingly, the Contractor and the Government agree to the following:

- (a) DoD Medical Product Priority. PL 115-92 allows the DoD to request, and FDA to provide, assistance to expedite development of products to diagnose, treat, or prevent serious or life-threatening diseases or conditions facing American military personnel. The Contractor recognizes that only the DoD can utilize PL 115-92. As such, the Contractor will work proactively with the Government to leverage this law under this contract. The Contractor shall submit Public Law 115-92 Sponsor Authorization Letter to permit DoD to have Government-only access to regulatory filings that the Contractor submits to the FDA for the combination therapy consisting of LY-CoV555 and LY-CoV016 during the period of performance of this contract. This Letter will be delivered to the designated OWS POC(s) within 30 days of award.
- (b) FDA Communications and Engagement. The Contractor will provide to the Government top-line summaries and key conclusions from all studies supporting the FDA regulatory filing and commercial approval to the extent that such data, summaries, and conclusions are submitted, generated, or made during the period of performance of this contract. In addition, unless the timeline for submission is insufficient to allow for Government review, the Contractor will offer the Government the opportunity to review and provide comments on a final draft of manufacturing and quality regulatory submissions made during the period of performance of this contract. The Government will review any such submissions promptly upon receipt. The Contractor 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 Contractor will keep the Government apprised of planned FDA meetings and post-meeting outcomes relating to activities that take place during the period of performance of this Agreement. The Contractor shall provide the Government with all formal communications and summaries thereof, to or from FDA during the period of performance of this contract regarding combination therapy LY-CoV555 and LY-CoV016 as soon as possible but not later than within 5 business days. The Contractor shall notify the FDA that the Government has the right to discuss with FDA any development efforts regarding this product consistent with the terms of this contract.

## **H.5 Regulatory Compliance**

1. The manufacturing described in the Statement of Work will comply with Current Good Manufacturing Practices (cGMP) regulations at 21 CFR 210 and 211 subject to any guidance, exemptions, or waivers issued by the FDA. Production shall occur using cGMP validated manufacturing process, fully compliant with 21 CFR 210 and 211, for bulk drug substance and fill and finished drug product subject to any guidance, exemptions, or waivers issued by the FDA.
2. 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.

## **H.6 Public Readiness and Emergency Preparedness (PREP) Act:**

In accordance with the Public Readiness and Emergency Preparedness Act ("PREP Act"), Pub. L. No. 109-148, Division C, Section 2, as amended (codified at 42 U.S.C. § 247d-6d and 42 U.S.C. § 247d-6e), as well as the Secretary of HHS's Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, 85 Fed. Reg. 15198 (Mar. 17, 2020, effective Feb. 4, 2020), and amended on April 15, 2020, 85 Fed. Reg. 21012 (together, the "Prep Act Declaration"):

(i) This Agreement is being entered into for purposes of facilitating the manufacture, testing, development, distribution, administration, and use of "Covered Countermeasures" for responding to the COVID-19 public health emergency, in accordance with Section VI of the PREP Act Declaration;

(ii) Contractor's performance of this Agreement falls within the scope of the "Recommended Activities" for responding to the COVID-19 public health emergency, to the extent it is in accordance with Section III of the PREP Act Declaration; and (iii) Contractor is a "Covered Person" to the extent it is a person defined in Section V of the PREP Act Declaration.

Therefore, in accordance with Sections IV and VII of the PREP Act Declaration as well as the PREP Act (42 U.S.C. § 247d-6d), the Department of Defense contracting via assisted acquisition on behalf of the HHS, expressly acknowledges and agrees that the HHS Declaration cited above, specifically its language providing immunity from suit and liability is applicable to this acquisition as long as Contractors activities fall within the terms and conditions of the PREP Act and the PREP Act Declaration.

The Government may not use, or authorize the use of, any products or materials provided under this contract, unless such use occurs in the United States (or a U.S. territory where U.S. law applies such as embassies, military and NATO installations) and protected from liability under a declaration issued under the PREP Act, or a successor COVID-19 PREP Act Declaration of equal or greater scope. Any use where the application of the PREP Act is in question will be discussed with Lilly prior to use and, if the parties disagree on such use, the dispute will be resolved according to the "Disputes Clause" (52.233-1).

The items and technology covered by this Contract are being developed for both civil and military applications.

## **H.7 Sales to Covered Nations**

(i) Due to the exceptional and unprecedented nature of the COVID-19 threat to global public health, as well as the investments made towards the development of a safe and effective therapeutic against COVID-19, Lilly agrees that it will not at any time prior to 30 September 2021 sell any COVID-19 bamlanivimab/etesevimab combination therapeutic supplied directly to the Government under this Agreement to any centralized federal authority (i.e., federal government or equivalent) of a nation that is a member of the Group of Seven plus Switzerland ("Covered Nation") at a lower price than the prices set forth in this contract.

(ii) If, at any time prior to 30 September 2021, Lilly enters into any agreement with a Covered Nation to sell the COVID-19 bamlanivimab/etesevimab combination therapeutic supplied to the Government under this Agreement at a price lower than the price currently paid by the U.S. Government (USG) for the same COVID-19 therapeutic doses under this contract, Lilly shall

provide notice within 30 days to the USG and the U.S. Government may elect, at its discretion, to receive the benefit of this provision and receive such COVID-19 bamlanivimab/etesevimab combination therapeutic doses at that lower price.

(iii) Upon any such election by the USG, this contract shall be deemed to have been amended and modified such that, from the date on which the more favorable pricing was first provided to any Covered Nation (the “Amended Pricing Effective Date”), the USG will receive that lower price for all orders of COVID-19 bamlanivimab/etesevimab combination therapeutic doses following that Amended Pricing Effective Date.

(iv) Any price reductions provided hereunder are not intended as an inducement or reward for any procurement or purchasing decisions by the USG of any Lilly product.

## **H.8 Ensuring Sufficient Supply of the Product**

1. In recognition of the Government’s need to provide sufficient quantities of a COVID-19 therapeutic to protect the United States population, the Government shall have the remedy described in this section to ensure sufficient supply of the product to meet the needs of the public health or national security. This remedy is not available to the Government unless and until both of the following conditions ((a) and (b)) are met:

(a) Lilly gives written notice, required to be submitted to the Government no later than 15 business days, of:

i. any formal management decision to terminate manufacturing of this product therapeutic prior to delivery of the minimum required doses to USG under this contract, well as all additional orders accepted by Contractor, other than as a result of clinical failure, or serious technical or safety reasons or;

ii. any formal management decision to discontinue sale of this product therapeutic to the USG prior to delivery of the minimum required doses to USG under this contract, as well as all additional orders accepted by Contractor, other than as a result of clinical failure, or serious technical or safety reasons; or any filing that anticipates Federal bankruptcy protection; and

(b) Lilly has submitted an Emergency Use Authorization application under §564 of the FD&C Act or a biologics license application provisions of §351(a) of the Public Health Service Act (PHSA).

2. If both conditions listed in section 1 occur, Lilly, upon the request of the Government, shall provide the following items necessary for the Government to pursue manufacturing of this product therapeutic with a third party for exclusive sale to the USG:

(a) a writing evidencing a non-exclusive, nontransferable, irrevocable (except for cause), royalty-free paid- up license to practice or have practiced for or on behalf of the USG any Lilly Background Patent, Copyright, other Lilly Intellectual Property, Lilly Know-How, Lilly Technical Data rights necessary to manufacture doses of the SARS-CoV2-MCM neutralizing monoclonal antibodies designated as combination therapy LY-CoV555 and LY-CoV016 b. necessary FDA regulatory filings or authorizations owned or controlled by Lilly related to this product therapeutic and any confirmatory instrument pertaining thereto; and

(b) any outstanding Deliverables contemplated or materials purchased under this contract.

3. This remedy will remain available until the end of the contract and the license rights and items may only be used by the Government and its Contractors to the extent needed to manufacture the number of doses that are not received under this contract, including with respect to any additional orders that are accepted by Contractor.

## **H.9 Transportation to Final Destination**

During the course of performance under this contract, the Government may require storage of the drug product before delivery to the final government location. In these circumstances, the Government will accept the drug



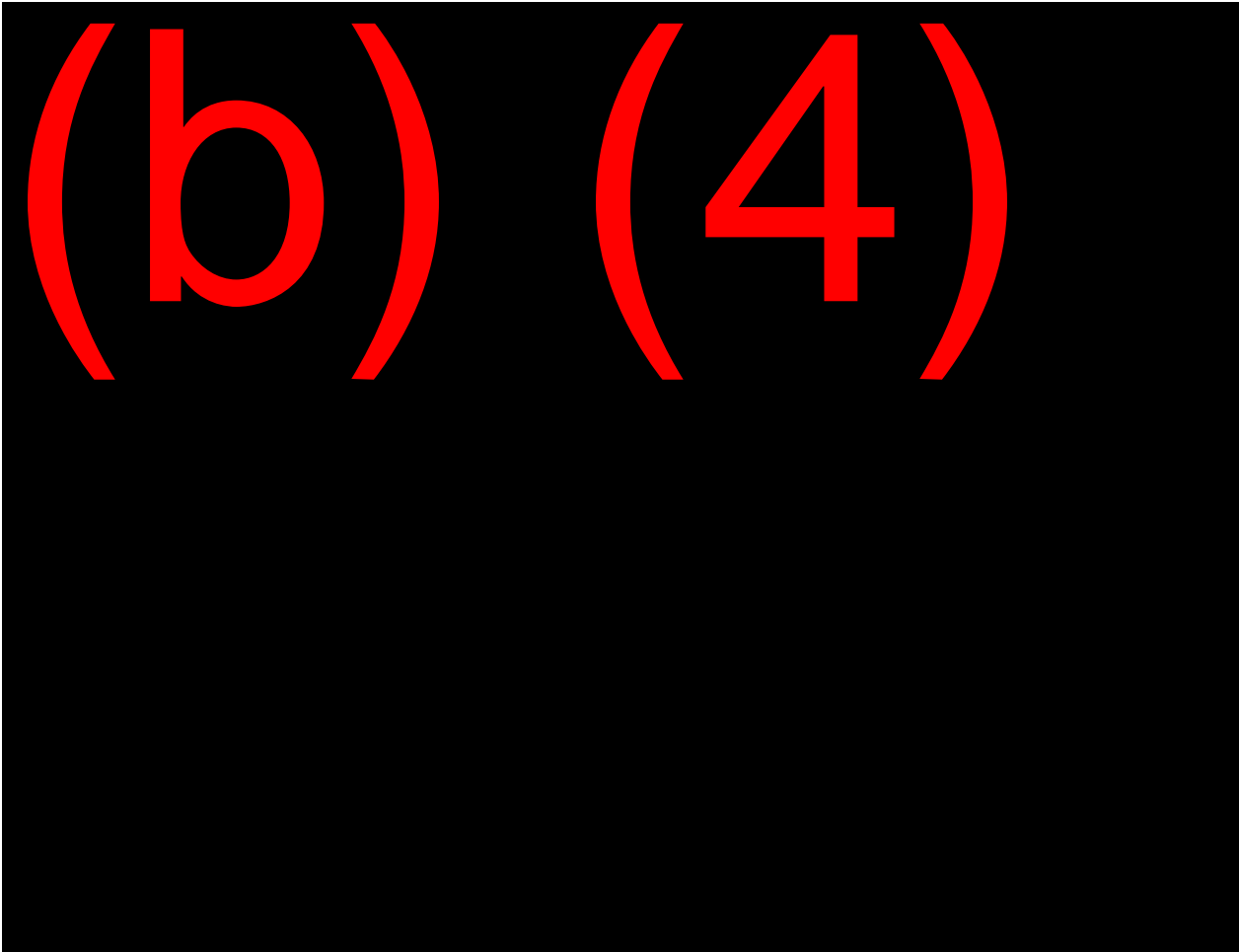
product at the Contractor facility (Origin). The Contractor; however, shall continue to be responsible for secure delivery of the therapeutic to its final destination as identified on this contract for up to sixty (60) calendar days after acceptance. Regardless of where acceptance occurs, risk of loss of or damage to supplies shall remain with the Contractor until delivery of final product to a government facility or a third-party delivery location identified by the Government.

#### H.10 Validation of IP/Data

The Contractor represents that, to its knowledge, the intellectual property license(s) and other rights held by or granted to Contractor, including but not limited to the list of patents and patent applications listed below, are sufficient to enable Contractor to perform its obligations under this Agreement.

The Parties acknowledge that the following background intellectual property and technical data assertions have been made:

List of Lilly Patent Applications Related to LY-CoV555 (bamlinvimab) and LY-CoV016 (Etesevimab)



The parties agree that, should additional information relevant to these assertions become available, the parties will reevaluate said assertions as necessary in the future.

The Contractor represents that no Government funds were used to fund any research underlying the development of the SARS-CoV2-MCM neutralizing combination therapy consisting of monoclonal antibodies designated as LY-CoV555 and LY-CoV016.

### H.11 Buy Back

It is the intention of the parties that Lilly does not want to sell, nor does the Government want to purchase, therapeutics that are not FDA-authorized or approved or for which an Emergency Use Authorization (EUA) has been revoked. In the event that the EUA for the bamlanivimab/etesevimab combination monoclonal antibody therapeutic is revoked due to safety and efficacy concerns, except for EUA revocation attributed to (1) the end of the pandemic, (2) a Biologics License Agreement approval, or (3) voluntary revocation, Lilly agrees to buy back from the Government all treatments (as defined in the CLIN) that have been accepted, but not distributed to providers, by the Government within the sixty (60) days prior to EUA revocation. This Section H.11 applies only to full combination doses and any partial doses (e.g. vials of etesevimab purchased separately) purchased under this Contract. This Section H.11 does not apply to any "not separately priced" vials of etesevimab provided by Lilly nor will it apply to subsequently combined doses (i.e., doses of bamlanivimab purchased under contract no. W911QY-21-C-0016 combined with vials of etesevimab purchased under this agreement). Lilly shall notify the contracting officer immediately upon notification of revocation. Lilly shall repurchase the treatments within (30) days of the EUA revocation at the same price as purchased by the Government unless otherwise agreed.

### H.12 Modification to Contract

This contract contemplates acquisition of the combination monoclonal antibody therapeutic LY-CoV555 and LY-CoV016 as long as there is approval and utility of this product. In the event of unforeseen circumstances including, but not limited to, delays in manufacturing, unforeseen U.S. regulatory actions, or revocation of EUA, the parties agree to negotiate in good faith, a modification to the contract to revise the minimum and/or maximum quantities and/or the period of performance.

### H.13 Ordering

Ordering placed above the agreed upon minimum contract quantity shall be done so by bilateral agreement between the USG and Lilly. The minimum quantity to be ordered by the USG is 100,000 doses. The maximum quantity ceiling available for order under this agreement is 1,200,000 doses.

### H.14 Dose Definition and Value Apportionment

For the purpose of this contract, a dose will constitute the dose authorized or approved by the FDA for the treatment of high-risk adult and pediatric patients aged 12 years and older with recently diagnosed mild-to-moderate coronavirus disease (COVID-19) prior to or on the date of delivery. (b) (4)

(b) (4)

### H.15. Contractor Assertions for U.S. Security

This contract contemplates acquisition of a therapeutic product that was at least partially developed outside the United States, and that contains at least one component owned by a non-U.S. entity and licensed by the Contractor. In recognition of the Government's need to protect and control supply of the product and related technical data, and in addition to the provisions of Sections H.1, H.2, and H.3, the Contractor agrees to the following:

- (a) The Contractor affirms it has no obligations under the license with any non- U.S. entity, or any other agreement, that precludes or interferes with Contractor's performance under this contract.
- (b) The Parties agree that all non-public technical data that (1) were generated as a result of this Agreement with the U.S. Government and (2) are related to LYCoV555 and LY-CoV016 monoclonal antibodies, is confidential information as defined in Section H.3 paragraph 1, and is subject to all provisions under Section H.3. For clarity, "non-public technical data" do not include information developed independently from this Agreement. Except for disclosures to foreign regulatory authorities for emergency use or licensure in that jurisdiction, and except for non-public technical data shared in the ordinary course of business and necessary to commercialize the therapeutic

product, the Contractor shall use reasonable measures to prevent non-public technical data related to LYCoV555 and LY-CoV016 monoclonal antibodies from becoming accessible to any country not a “designated country” as defined by the Trade Agreements Act (TAA) in accordance with FAR 52.225-5.

- (c) Any disclosure that would require the Contractor to obtain a license for export to the recipient of the disclosure, must be approved in advance by the Government.
- (d) In the event of any disclosure that violates paragraphs (b) or (c) in this Section, the Contractor will alert the Government within twenty-four (24) hours of first becoming aware of the disclosure.
- (e) The Contractor shall manufacture the therapeutic product within the United States or its territories or a “designated country” as defined by the Trade Agreements Act (TAA) in accordance with FAR 52.225-5, and shall ensure that sufficient supply of the therapeutic product within the United States and its territories, as per the terms of the contract, is not subject to interference by a non-U.S. entity.
- (f) The Contractor shall use reasonable efforts to mitigate any national security risks in connection with performance under this contract, and shall promptly seek Government guidance as needed.
- (g) The Parties agree that violation of any term in this section is material breach and may be grounds for the Government to terminate for cause.

#### **H.16 Donation of Excess Product**

- A. In the event the Government determines that doses of LY-CoV555/LY-CoV016 funded under the contract are no longer needed by the Government, the Government may donate remaining doses to any foreign nation that has an active regulatory authorization in place for use of LY-CoV555/LY-CoV016 at the time of donation.
- B. The Government shall notify Contractor prior to any planned donation to a foreign nation. Contractor agrees to work with the Government in good faith to ensure all applicable regulatory submissions, import/export permits, and other requirements for donation are completed in advance of shipment.
- C. The Government will be responsible for shipment of LY-CoV555/LY-CoV016 to the receiving foreign nation.
- D. The parties acknowledge that Article H.6 of the original award regarding PREP Act coverage does not apply to the provision of any doses under this paragraph to a foreign nation. The USG makes no representations as to PREP Act coverage thereto. Contractor assumes the risk of liability for use of these products in foreign jurisdictions and any immunity or indemnity arrangements in a foreign jurisdiction are the responsibility of Contractor.

#### STATEMENT OF WORK

**ADDENDUM: The following pages hereby supplements FAR 52.212-4**

#### **C.1 EXECUTIVE SUMMARY (Scope of Project)**

Manufacturing shall occur using current good manufacturing practices (cGMP) validated manufacturing processes for bulk drug substance and fill and finished drug product. The specific objective is the acquisition of a minimum order of 100,000 doses for a targeted US population by March 31, 2021 with the possibility to acquire additional doses, up to a maximum of 1.2M by November 24, 2021. Any additional quantities above the minimum are dependent upon available supply to USG as determined by Lilly and the need for additional product as determined by the US Government (USG). The Contractor shall also provide storage and distribution.

The product to be produced and delivered includes a combination monoclonal antibody (mAb) therapeutic, consisting of LY-CoV555 and LY-CoV016, subject to Emergency Use Authorization (EUA) from the Food & Drug Administration (FDA). LY-CoV555 vials can be acquired under this contract or previously purchased, USG owned LY-CoV555 can be used to pair with appropriately matched LY-CoV016, in ratios established by the EUA to compromise a full dose of the combination therapeutic. Lilly shall not be required to deliver any product, or be in breach of any resulting award, if an EUA is not in effect for the product prior to March 31, 2021. The USG will not purchase any drug product unless there is an active EUA for the product.

## C.2 TASKS

Task 1: The Contractor shall establish a quality agreement with the USG on requirements for the USG to accept packaged drug product as a completed deliverable. Quality agreement must be negotiated within the first 30 days of award and prior to USG acceptance of any drug product.

Task 2: The Contractor shall provide a Product Development Source Material and Manufacturing Plan within 30 days of award to fulfill the USG order. The Manufacturing Plan shall include all materials required for drug substance/active pharmaceutical ingredient manufacturing and finished drug product, an acquisition plan for acquiring necessary materials, all key subcontractors and manufacturing sites, and a detailed schedule for providing the final product to the USG.

Task 3: The Contractor shall manufacture the therapeutic product(s) using an established manufacturing process for bulk drug substance and fill and finished drug product, with a ramp-up capacity plan that provides enough doses to meet the desired number of treatment courses.

Task 4: Storage. The Contractor shall store the packaged drug product under cGMP conditions, until the USG has directed the allocation of the product.

Task 5: Distribution. The Contractor shall distribute the product as directed by the USG through the Contractor's commercial distribution network with the Contractor insuring against any supply loss from time of title transfer at origin through to end destination (site of administration) with replacement product transferred to the USG. Transfer of product to USG and distribution will not occur unless there is an active EUA or FDA approval/licensure for the product. Once the minimum order for doses is met, additional doses may be acquired based on orders placed by the USG and accepted by the Contractor.

Task 6: Program Management Activities: The Contractor shall establish the capacity in compliance with FDA cGMP regulations, and Biosafety Level standards, if applicable. The Contractor shall be responsible for management of all activities, including but not limited to, subcontractors to meet the goals of the contract, including holding routine meetings with USG, and completion of meeting minutes. On a monthly basis, the Contractor shall provide a monthly report that includes capacity availability and utilization, as well as any issues that affect the operational availability of the reserved capacity.

The Contractor shall provide minutes and reports in accordance with the following technical deliverables in accordance with Section J, Attachment 0002, Technical Deliverables.

**Post Award Teleconference.** The Contractor shall complete an initial teleconference after contract award in accordance with CDRL 01.1. The goal of this teleconference is to outline activities for the next 30 days and discuss agenda items for the post-award Kickoff Meeting.

**Kickoff Meeting.** The Contractor shall complete a Kickoff meeting after contract award in accordance with CDRL 01.2, to occur within 30 days of contract award, pending concurrence by the Contracting Officer.

**Biweekly Teleconference.** The Contractor shall participate in teleconferences every 2 weeks, with the Biomedical Advanced Research and Development Authority (BARDA) to discuss the performance on the contract in accordance with CDRL 01.3. Meeting frequency can be increased with agreement between

both parties as needed during the course of the period of performance of the contract.

**Quarterly Meetings.** At the discretion of the USG, the Contractor shall hold recurring teleconference or face-to-face Project Review Meetings up to four times per year either in either Washington D.C or at work sites of the Contractor or subcontractors in accordance with CDRL 01.4.

**FDA Meeting Minutes and other communications with FDA.** All formal communications with the FDA regarding the product should be provided to BARDA in accordance with CDRL 01.5. Contractor shall notify BARDA of upcoming FDA meeting within 24 hours of scheduling Type A, B or C meetings OR within 24 hours of meeting occurrence for ad hoc meetings.

**Daily check in with project staff for COVID-19 Contract.** Contractor shall participate in a daily checkin update, if necessary, with the Project Managers and additional project staff as needed (via teleconference or email) in accordance with CDRL 01.6. Potential triggers for the check-in include but are not limited to regulatory status changes, manufacturing and or/distribution problems that will affect delivery.

**Monthly Progress Reports.** A consolidated submission of all slides and data presented at the biweekly teleconference will serve as the monthly report in accordance with CDRL 02.1. The report only consists of a summary of quantity of product delivered, when and location of the delivery.

**Milestone Reports.** Milestone reports shall be cross-referenced to the Work Breakdown Structure (WBS), Statement of Work (SOW) and Integrated Master Schedule (IMS). As applicable, an Executive Summary highlighting the progress, issues and relevant manufacturing activities. The Executive Summary should highlight only critical issues for that reporting period and resolution approach; limited to 2 pages. This should be submitted in accordance with CDRL 03.5.

**Draft and Final Technical Progress Report.** A draft Final Technical Progress Report containing a summation of the work performed over the entire period of performance of the contract. This report shall be in sufficient detail to fully describe the progress achieved under all milestones. Report should contain a timeline of originally planned and baselined activities and milestones overlaid with actual progress attained during contract performance. Descriptions and rationale for activities and milestones that were not completed as planned should be provided. The draft report shall be duly marked as 'Draft' in accordance with CDRL 02.3. The final report should be submitted in accordance with CDRL 02.4. This report should be a comprehensive summary of the quantity of product delivered, when it was delivered and where.

**Product Development Source Material and Manufacturing Reports.** The Contractor shall submit a detailed spreadsheet regarding critical project materials that are sourced from a location other than the United States, sources, and manufacturing sites, including but not limited to: physical locations of sources of raw and processed material by type of material; location and nature of work performed at manufacturing sites in accordance with CDRL 02.6. The contract will provide manufacturing reports and manufacturing dose tracking projections/actuals utilizing the "COVID-19 Dose Tracking Templates" or similar.

**Contractor Locations.** The Contractor shall submit detailed data regarding locations where work will be performed under this contract, including addresses, points of contact, and work performed per location, to include subcontractors in accordance with CDRL 02.7.

**Pandemic Management Plan.** The Contractor will prepare an operational plan to continue operations in the current declared pandemic emergency in accordance with CDRL 02.8.

**Supply Chain and Distribution Tracking. Distribution Concept of Operations.** BARDA, and Medical Counter Measures (MCM) Manufacturers play an important role in the distribution of therapeutics to the American people under a nationwide response. BARDA will work with the manufacturer to monitor what is in the manufacturing pipeline using a dose tracking templates. The Contractor will relay final drug product information as it is being released to the BARDA/Assistant Secretary for Preparedness and Response (ASPR) for allocation and ordering by state public health departments. This information will be

returned to BARDA, the Contractor, and the distributor. Distributors will use the information to ship therapeutics in bulk to sites of administration/end users. This will be done in accordance with CDRL 02.11.

**Distribution Plan.** This plan shall describe the Contractor's process to allocate (the global allocation model) and distribute EUA-or Biologics License Application (BLA)-approved product to point of care facilities, necessary to meet the USG's need for administration. The plan 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. This will be done in accordance with CDRL 02.11.

**Manufacturing Development Plan.** This plan shall describe("describe the manufacturing process for the drug/biologic product to ensure conformity with §501(a)(2)(B) of the Food, Drug, and Cosmetics Act (FD&C Act, Title 21 United States Code (USC) §351 (a)(2)(B)), regarding good manufacturing practices (GMP)), but is not limited to planned or completed drug substance studies; list of excipients and information to support the safety of excipients that, when appropriate, shall be cross-referenced; drug product and formulation development summary from initial concept through final design; physicochemical and biological properties; manufacturing process development and validation program documents; container closure system documents [description, choice, rationale]; microbiological attributes documents and plans; compatibility documents (e.g., precipitation); assay development and validation, stability plan; and any associated risks.") This will be done in accordance with CDRL 02.12.

**Quality Management Plan.** 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. This will done in accordance with CDRL 02.13.

**Quality Agreement.** Agreement will determine the conditions of acceptance by the USG of the purchased product. No product will be accepted by the USG until a quality agreement is in place in accordance with CDRL 02.14.

**Release documentation for doses to be delivered.** Contractor will deliver Certificate of Analysis and Certificate of Compliance at least 14 days prior to all product deliveries.

**Manufacturing and Distribution Records.** In accordance with CDRL 02.6 Contractor will timely deliver the following records for drug substance and drug product for USG review and comment: (1) Certificate of Analysis; (2) Certificate of Conformance/Compliance; and (3) a sample label and carton from production run.

**Security Plan.** In accordance with Attachment 0001 the Contractor will deliver a security plan within 30 days of award.

**Supply Chain Resiliency Plan.** In accordance with CDRL 02.11 the Contractor will deliver a supply chain resiliency plan within 30 days of award.

**Manufacturing Data Requirements.** In accordance with CDRL 02.6 the Contractor will deliver manufacturing data requirements within 30 days of award.

**BARDA Audit.** The Contractor shall accommodate periodic or ad hoc site visits by BARDA. If BARDA, the Contractor, or other parties identify any issues during an audit, the Contractor shall capture the issues, identify potential solutions, and provide a report to BARDA in accordance with CDRL 03.1

**FDA Inspections.** In the event of an FDA inspection that occurs in relation to this contract and for the product, or for any other FDA inspection that has the reasonable potential to impact the performance of this contract, the Contractor shall provide the USG with an exact copy (non-redacted) of the FDA Form 483 and the Establishment Inspection Report (EIR). The Contractor shall provide the Contracting Officer's Representative (COR) and Contracting Officer (KO) with copies of the plan for addressing areas of nonconformance to FDA regulations for GLP, GMP, or GCP guidelines as identified in the audit report, status updates during the plans execution and a copy of all final responses to the FDA. The Contractor shall also provide copies of any FDA audits received from subcontractors that occur as a result of this contract or for this product. The Contractor shall make arrangements for BARDA representative(s) to be present during the final debrief by the regulatory inspector in accordance with CDRL 03.2.

**QA Audits.** BARDA reserves the right to participate in QA audits performed by the Contractor. Upon completion of the audit/site visit the Contractor shall provide a report capturing the findings, results and next steps in proceeding with the subcontractor. If action is requested of the subcontractor, detailed concerns for addressing areas of nonconformance to FDA regulations for GLP, GMP, or GCP guidelines, as identified in the audit report, must be provided to BARDA. The Contractor shall provide responses from the subcontractors to address these concerns and plans for corrective action in accordance with CDRL 03.3.

**FDA Submissions.** The Contractor shall provide BARDA the opportunity to review and comment upon all draft manufacturing and quality submissions for the product before submission to the FDA. Contractor shall provide BARDA with an electronic copy of the final FDA submission. All documents shall be duly marked as either "Draft" or "Final." This will be done in accordance with CDRL 10.2.

**EUA Filing.** The Contractor shall provide a copy of any request for EUA submitted to the FDA in accordance with CDRL 10.2.

**Provision of Public Law 115-92 Sponsor Authorization Letter.** The Contractor shall submit its proposed version of a Public Law 115-92 Sponsor Authorization Letter that will be delivered to the designated OWS POC(s).

**Press Releases.** Contractor agrees to accurately and factually represent the work conducted under this contract in all press releases in accordance with CDRL 11.

### **C.3 SECURITY**

The Contractor shall comply with all Operation Warp Speed Security requirements in Section J Attachment 0001, OWS Security Requirements.

(End of Summary of Changes)