AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT

1. CONTRACT ID CODE	PAGE OF PAGES
S	1 | 10

2. AMENDMENT/MODIFICATION NO.	3. EFFECTIVE DATE	4. REQUISITION/PURCHASE REQ. NO.	5. PROJECT NO. (If applicable)
P00008	7 April 2021	SEE SCHEDULE	

6. ISSUED BY	CODE	7. ADMINISTERED BY (If other than item 6)	CODE
W6QK ACC-APG NATICK DIVISION BLDG 1 GENERAL GREENE AVENUE NATICK MA 01760-5011	W911QY	See Item 6	

8. NAME AND ADDRESS OF CONTRACTOR (No., Street, County, State and Zip Code)
ELI LILLY AND COMPANY
(b)(6)
1 LILLY CORPORATE CTR
INDIANAPOLIS IN 46285

CODE 75602 FACILITY CODE

	9A. AMENDMENT OF SOLICITATION NO.
	9B. DATED (SEE ITEM 11)
X	10A. MOD. OF CONTRACT/ORDER NO. W911QY21C0016
X	10B. DATED (SEE ITEM 13) 27-Oct-2020

11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

☐ The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offer ☐ is extended, ☐ 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)
See Schedule

13. THIS ITEM APPLIES ONLY TO MODIFICATIONS OF CONTRACTS/ORDERS.
IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.

X	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. IAW FAR Part 43
	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).
	C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:
	D. OTHER (Specify type of modification and authority)

E. IMPORTANT: Contractor ☐ is not, ☒ is required to sign this document and return 1 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)
See Block 14 continuation page.

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)	16A. NAME AND TITLE OF CONTRACTING OFFICER (Type or print)
(b) (6)	TEL: (b) (6)

15B. CONTRACTOR/OFFEROR	15C. DATE SIGNED	16B. UNITED STATES OF AMERICA	16C. DATE SIGNED
(b) (6) (Signature of person authorized to sign)	4|6|2021	BY (b) (6) (Signature of Contracting Officer)	7 April 2021

SECTION SF 30 BLOCK 14 CONTINUATION PAGE

SUMMARY OF CHANGES

SECTION SF 30 - BLOCK 14 CONTINUATION PAGE

The following have been added by full text:

OBLIGATION AMOUNT: -$438,570,000.00

1. The purpose of this modification (P00008) is to descope the dose allocation quantity by 350,856 doses for SubCLIN 0001 05; deobligate excess funds of $438,570,000 from SubCLIN 0001 05 / ACRN AD; change the Period of Performance of the contract; add clause H.14 Donation of Excess Product; and to decrease the total cost of the contract.

2. This change was requested by the requiring activity in order to meet mission goals.

3. As a result of this modification, the dose allocation quantity for CLIN 0001 05 has decreased by 350,856 doses from 500,000 doses to 149,144 doses; ACRN AD has decreased by $438,570,000.00 from $625,000,000.00 to $186,430,000.00; the Period of Performance has changed from 27 Oct 20 – 30 Jun 21 to 27 Oct 20 – 07 Apr 21; the total cost of this contract decreased by $2,376,070,000.00 from $3,750,000,000.00 to $1,373,930,000.00; and the total funded amount for this document was decreased by $438,570,000.00 from $1,812,500,000.00 to $1,373,930,000.00.

4. Pursuant to FAR 52.212-4(C) and IAW FAR Part 43, this modification changes the terms and conditions of this contract as described above, and as they appear below in the Summary of Changes. The Contractor hereby acknowledges acceptance of these changes as a change order, and unconditionally waives any further entitlement to equitable adjustment. The Government agrees that all of the Contractor's obligations under the contract are concluded, including without limitation under Section H.12.

SECTION A - SOLICITATION/CONTRACT FORM

The total cost of this contract was decreased by $2,376,070,000.00 from $3,750,000,000.00 to $1,373,930,000.00.

SECTION B - SUPPLIES OR SERVICES AND PRICES

CLIN 0001

The estimated/max cost has decreased by $2,376,070,000.00 from $3,750,000,000.00 to $1,373,930,000.00.

The total cost of this line item has decreased by $2,376,070,000.00 from $3,750,000,000.00 to $1,373,930,000.00.

SUBCLIN 000105

The CLIN extended description has changed from:

PR #0011599250 for 500,000 doses to be delivered NLT 31 March 2021 per bilateral agreement by KO & contractor on 15 Jan 2021.

To:

PR #0011599250 for 500,000 doses to be delivered NLT 31 March 2021 per bilateral agreement by KO & contractor on 15 Jan 2021.Per modification P00008, the Government has descoped the dose allocation quantity by 350,856 doses from 500,000 doses to 149,144 doses. As a result of this descope in quantity, the total funded amount for ACRN AD has decreased by $438,570,000 from $625,000,000.00 to $186,430,000.00.
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SECTION F - DELIVERIES OR PERFORMANCE

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

DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
POP 27-OCT-2020 TO 30-JUN-2021	N/A	N/A FOB: Origin (Shipping Point)	

To:

DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
POP 27-OCT-2020 TO 07-APR-2021	N/A	N/A FOB: Origin (Shipping Point)	

The following Delivery Schedule item for CLIN 0002 has been changed from:

DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
POP 27-OCT-2020 TO 30-JUN-2021	N/A	BARDA (b) (6) BIOMEDICAL ADVANCED RESEARCH DEVELOPMENT AUTH 200 C STREET, SW WASHINGTON DC 20024 (b) (6) FOB: Destination	W56XNH

To:

DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE

POP 27-OCT-2020 TO 07-APR-2021	N/A	BARDA [redacted] BIOMEDICAL ADVANCED RESEARCH DEVELOPMENT AUTH 200 C STREET, SW WASHINGTON DC 20024 [redacted] FOB: Destination	W56XNH

SECTION G - CONTRACT ADMINISTRATION DATA

Accounting and Appropriation

Summary for the Payment Office

As a result of this modification, the total funded amount for this document was decreased by $438,570,000.00 from $1,812,500,000.00 to $1,373,930,000.00.

SUBCLIN 000105:

AD: 021202120222040000066565425 5 S.0074658.5.41 6100.9000021001 A5XAH (CIN GFEBS001159925000010) was decreased by $438,570,000.00 from $625,000,000.00 to $186,430,000.00

SECTION H - SPECIAL CONTRACT REQUIREMENTS

The following have been modified:

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 CO 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 Contracting Officer 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 Contracting Officer 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 Contracting Officer prior to any release, disclosure, dissemination, or publication.

6. Contracting Officer 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 monoclonal antibodies designated as LY-CoV555. 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 LY-CoV555 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 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 material communications and summaries thereof, both formal and informal, to or from FDA during the period of performance of this contract regarding LY-CoV555 as soon as possible but not later than within 48 hours. 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 June 2021 sell any COVID-19 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 June 2021, Lilly enters into any agreement with a Covered Nation to sell the COVID-19 therapeutic supplied to the Government under this Agreement at a price lower than the price currently paid by the U.S. Government for the same COVID-19 therapeutic doses under this contract, Lilly shall provide notice within 30 days to the U.S. Government and the U.S. Government may elect, at its discretion, to receive the benefit of this provision and receive such COVID-19 therapeutic doses at that lower price.

(iii) Upon any such election by the U.S. Government, 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 U.S. Government will receive that lower price for all orders of COVID-19 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 U.S. Government 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 Government 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 U.S. Government:

(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 U.S. Government 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 LY-CoV555 and the combination therapy LY-CoV555 and LY-CoV016 therapeutic; 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 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)
Asserted October 19, 2020

1. Patent Family Titled: "Anti-Coronavirus Antibodies and Methods of Use"

- (b) (4) [redacted]

- (b) (4)

2. Patent Family Titled: "Methods for Reducing Host Cell Protein Content in Protein Purification Processes"

- (b) (4)

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

H.11 Combination Therapy Negotiation

It is the intention of the parties that Lilly and the government enter into this contract for the monoclonal antibody therapeutic, while awaiting EUA on the combination therapy LY-CoV016. In the event that the combination therapy receives EUA, the parties agree to negotiate in good faith a separate contract for the combination therapy.

H.12 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 EUA has been revoked. In the event that the EUA for the monoclonal antibody therapeutic is revoked, Lilly agrees to buy back from the Government all treatments (as defined in the CLIN) accepted by the Government. 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.13 Modification to Contract

This contract contemplates acquisition of the monoclonal antibody therapeutic LY-CoV555 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.14 Donation of Excess Product

A. In the event the Government determines that doses of LY-CoV555 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 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 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.

(End of Summary of Changes)