AMENDMENT OF SOLICITATION	ON/MODIFICATI	ON OF CONTRACT	1. Contract		Page 1 Of 11
2. Amendment/Modification No.	3. Effective Date	4. Requisition/Purchase Req		5. Project No. (If	f applicable)
P00005	2021SEP14	SEE SCHEDULE			
6. Issued By	Code W58P05	7. Administered By (If other	than Item 6)		Code
U.S. ACC, APG , NCD					
(b) (6)					
10 GENERAL GREEN AVE, BLDG 1 NATICK, MA 01760-5011					
EMAIL: (b) (6)					
8. Name And Address Of Contractor (No., Street	t, City, County, State and	Zip Code)	9A. Amendme	ent Of Solicitation N	lo.
REGENERON PHARMACEUTICALS, INC.					
777 OLD SAW MILL RIVER RD			9B. Dated (See	e Item 11)	
TARRYTOWN, NY 10591-6717			JDi Duica (occ	- Accid 11/	
		Х	10A. Modifica	ation Of Contract/O	rder No.
		_	W15QKN-21-C-	-0014	
			10B. Dated (Se	ee Item 13)	
Code 544P9 Facility Code	A		2021JAN12		
11. T	HIS ITEM ONLY APPLI	ES TO AMENDMENTS OF S	OLICITATION	IS	
The above numbered solicitation is amende	d as set forth in item 14. 7	The hour and date specified for	receipt of Offer	rs	
is extended, is not extended.					
Offers must acknowledge receipt of this amen					-
(a) By completing items 8 and 15, and returning offer submitted; or (c) By separate letter or te		f the amendments: (b) By ackn eference to the solicitation and			
ACKNOWLEDGMENT TO BE RECEIVED					
SPECIFIED MAY RESULT IN REJECTION			-	•	
may be made by telegram or letter, provided of	each telegram or letter ma	kes reference to the solicitation	n and this amend	dment, and is receiv	ed prior to the opening
hour and date specified. 12. Accounting And Appropriation Data (If requ	ired)				
SEE SECTION G (IF APPLICABLE)					
13. THIS		TO MODIFICATIONS OF CO act/Order No. As Described In		DERS	
A. This Change Order is Issued Pursuant			The Cl	hanges Set Forth In	ı Item 14 Are Made In
The Contract/Order No. In Item 10A B. The Above Numbered Contract/Order		ha Administrativa Changas (cu	ah as ahangas in	novina office onne	ronniation data ata \ Cat
Forth In Item 14, Pursuant To The A			en as changes in	i paying office, appr	ropriation data, etc.) Set
C. This Supplemental Agreement Is Ente	red Into Pursuant To Autl	hority Of:			
D. Other (Specify type of modification an	d authority)				
E. IMPORTANT: Contractor is not,		this document and return		opies to the Issuing	
14. Description Of Amendment/Modification (O	rganized by UCF section in	leadings, including solicitation/	contract subject	t matter where feasi	ible.)
SEE SECOND PAGE FOR DESCRIPTION					
Except as provided herein, all terms and condition	ons of the document refere	enced in item 9A or 10A, as her	etofore changed	l, remains unchange	ed and in full force and
15A. Name And Title Of Signer (Type or print)		16A. Name And Title	Of Contracting	Officer (Type or pr	rint)
		(b) (6)			
15B. Contractor/Offeror	15C. Date Signed	16B. United States Of	America		16C. Date Signed
		Ву	/SIGNED/		2021SEP14
(Signature of person authorized to sign)			of Contracting (Officer)	FIRECISVS
31031 = 10 04 4 = 00 = 0		20 40 = 02		COM 4 N. P. 4 N. P	

Reference No. of Document Being Continued

PIIN/SIIN W15QKN-21-C-0014

MOD/AMD P00005

Page 2 of 11

Name of Offeror or Contractor: REGENERON PHARMACEUTICALS, INC.

SECTION A - SUPPLEMENTAL INFORMATION

Buyer Name: (b) (6)

Buyer Office Symbol/Telephone Number: CCAP-CR/

Type of Contract 1: Firm Fixed Price

Kind of Contract: Other Kind of Modification: G

Type of Business: Large Business Performing in U.S.

Surveillance Criticality Designator: A

Weapon System: No Identified Army Weapons Systems

Contract Expiration Date: 2022JUL31

Paying Office: HQ0490

DFAS-INDY VP GFEBS 8899 E, 56TH STREET

INDIANAPOLIS IN 46249-3800

*** End of Narrative A0000 ***

The purpose of this modification is to:

- 1) Procure an additional 1,400,000 doses of antibody therapeutic (REGEN-COV) to treat COVID-19 in the general population.
- 2) Vendor Managed Inventory (VMI) and distribtion activities shall continue for with a completion date of (b) (4) . See Section B.

(b) (4)

- 3) Update the contract expiration date from 11 January 2022 to 31 July 2022.
- 4) Update the Statement of Work to reflect new total contract deliverable quantities, delivery requirements, period of performance, and administrative language.
- 5) Add Attachment 0003, Contingencies and Operational Requirements.
- 6) See Section B and Section C for quantities and delivery schedule.
- 7) Increases obligation by \$2,940,000,000 from \$2,625,000,000 to \$5,565,000,000.00.

*** END OF NARRATIVE A0006 ***

Reference No. of Document Being Continued W15QKN-21-C-0014 PIIN/SIIN

MOD/AMD P00005

Page

3 **of** 11

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
	SECTION B - SUPPLIES OR SERVICES AND PRICES/COSTS				
				F 1	
0003	subCLIN 0003AA NSN: 9999-99-9999				
	'A _				
0003AA	REGEN-COV DOSES	476190	EA	\$2,100.00000	\$999,999,000.0
	COMMODITY NAME: subCLIN 0003AA				
	CLIN CONTRACT TYPE:				
	Firm Fixed Price PRON: X21ZD484W1 PRON AMD: 01 ACRN: AD				
	PSC: 6505				
	Modification P00005 establishes CLIN 0003AA for a				
	quantity of 476,190 doses for \$999,999,000.				
	Binding Delivery Schedule is located below. The Goal Delivery Schedule can be found in Section				
	C.2.				
	(End of narrative B001)				
	1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1				
	Packaging and Marking				
	Inspection and Acceptance INSPECTION: Destination				
	Deliveries or Performance				
	DOC SUPPL				
	REL CD MILSTRIP ADDR SIG CD MARK FOR TP CD 001 W15BW91256ZD21 W90ZQ2 J 3	14			
	DEL REL CD QUANTITY DEL DATE				
	001 100,000 30-SEP-2021				
	002 100,000 31-OCT-2021				
	003 100,000 30-NOV-2021				
	004 100,000 31-DEC-2021				
	005 76,190 31-JAN-2022				
	FOB POINT: Destination				
	SHIP TO:				
	(W90ZQ2) XR JOINT PROGRAM EX OFC FOR CHEM, B				
	HQ JPEO				
	5101 HOADLEY ROAD ABERDEEN PROVING GROUND,MD,21010-54				
	ADDITIONAL TROVING GROUND, PD, 21010-04				
	The parties will coordinate ordering through				
	centralized distribution via the established				l A
				Y &	

Reference No. of Document Being Continued W15QKN-21-C-0014 PIIN/SIIN

MOD/AMD P00005

Page

4 **of** 11

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
	Memorandum of Understanding between Regeneron, ASPR, and AmerisourceBergen. Exact ship-to locations for product will be identified through this coordinated process.				
	(End of narrative F001)				
	e va ve e voud v				
0003AB	REGEN-COV DOSES	476190	EA	\$ 2,100.00000	\$ 999,999,000.0
	COMMODITY NAME: SUBCLIN 0003AB CLIN CONTRACT TYPE: Firm Fixed Price PRON: X21ZD485W1 PRON AMD: 01 ACRN: AE				
	PSC: 6505 Modification P00005 establishes CLIN 0003AB for a quantity of 476,190 doses for \$999,999,000. Binding Delivery Schedule is located below. The Goal Delivery Schedule can be found in Section C.2.				
	(End of narrative B001)				
	Packaging and Marking				
	Inspection and Acceptance INSPECTION: Destination				
	Deliveries or Performance DOC SUPPL REL CD MILSTRIP ADDR SIG CD MARK FOR TP CD 001 W15BW91256ZD22 W90ZQ2 J 3 DEL REL CD QUANTITY DEL DATE 001 476,190 31-JAN-2022				
	FOB POINT: Destination				
	SHIP TO: (W90ZQ2) XR JOINT PROGRAM EX OFC FOR CHEM, B HQ JPEO 5101 HOADLEY ROAD ABERDEEN PROVING GROUND, MD, 21010-54				
	The parties will coordinate ordering through centralized distribution via the established Memorandum of Understanding between Regeneron, ASPR, and AmerisourceBergen. Exact ship-to locations for product will be identified through this coordinated process.				
	(End of narrative F001)				

Reference No. of Document Being Continued W15QKN-21-C-0014 MOD/AMD

MOD/AMD P00005

Page

5 **of** 11

COMMONITY NAME: subclin 0003AC CLIN COMPANY TYPE: PROM: Y212B46W1 PRON AMD: 01 ACBN: AF PSC: 6395 Modification P00005 establishes CLIN 0003AC for a quantity of 447,520 doses for \$940,002,000. Rinding Delivery Schedule is located below. The Goal Delivery Schedule is located below. The Goal Delivery Schedule and Descade Delow. The Goal Delivery Schedule and Acceptance: (End of narrative B001) Packaging and Marking Inspection Addressance DOC SUPPL REL CO SUPPL REL CO GUANTITY DEL DATE OO1 MISSW055202 W8020 J 3 DEL REL CO GUANTITY DEL DATE OO1 447,620 31-JAN-2022 FOR POINT Destination SHIP TO: INSD0203 NR JOINT FROGRAM EX OFC FOR CHEM, B NG JFCO SIGN MAGNETY ROAD AREROEM PROVING GROUND, ND, 21010-34 The parties will coordinate ordering through contralized distribution via the established Memorandum of Understanding between Respensor, ASPR, and AmerisacureBeyen. Exact high-to locations for product will be identified through this coordinated process. (End of narrative F001)	M NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
COMMODITY NAME: subcLIN 0003AC CLIN CONTRACT TYPE: Firm Fixed Price PROM: X2120486W1 PROW AMD: 01 ACRN: AP PEC: 6505 Modification P00005 establishee CLIN 0003AC for a quantity of 447,620 deser for 9940,002,000. Sinding Delivery Schedule is located below. The Gosl Delivery Schedule can be found in Section C.2. (End of narrative B001) Fackaging and Marking Inspection and Anceptance INSPECTION: Destination ACCEPTANCE: Destination Dolton Supplement Supplem						
CLIN CONTRACT TYPE: Firm Fixed Price PRONN AZIZD486W1 PRON AMD: 01 ACRN: AF PEC: 6505 Modification PO005 establishes CLIN 0003AC for a quantity of 447,620 doses for 8940,902,000. Binding Delivery Schedule is located below. The Goal Delivery Schedule can be found in Section C.2. (End of narrative 8001) Packaging and Marking Inspection and Acceptance INSPECTION: Destination ACCEPTANCE: Destination Deliveries or Performance DOC SUPPL REL CD MILSTRIP ADDR BIG CD MARK FOR TP CD 001 WISSW1256023 W90202 J 3 DEL REL CD GUARTITY DEL DATE 001 447,620 31-JAN-2022 FOR FOINT: Destination SHIF TO: (W90202) XR JOINT FROGRAM EX OFC FOR CHEM, B HO JPEO SIND HOADLEY ROAD ARERDEEN PROVING GROUND, MD, 21010-54 The parties will coordinate ordering through centralized distribution via the established Memorandum of Understanding between Regeneron, ASPR, and Americancembergene. Exact ship-to locations for product will be identified through this coordinated process. (End of narrative F001)	AC I	REGEN-COV DOSES	447620	EA	\$ 2,100.00000	\$ 940,002,000.00
quantity of 447,620 doses for \$940,002,000. Sinding Delivery Schedule is located below. The Goal Delivery Schedule can be found in Section C.2. (End of narrative B001) Packaging and Marking Inspection and Acceptance INSPECTION: Destination ACCEPTANCE: Destination Deliveries or Performance DOC SUPPL REL CR MILSTRIP ADDR SIG CD MARK FOR IP CD OO1 W1589312562D23 W00202 J 3 DEL REL CO QUANTITY DEL DATE 001 447,620 31-JAN-2022 FOB POINT: Destination SHIP TO: (W90202) XR JOINT PROGRAM EX OFC FOR CHEM, B RU JFCO S101 HOADLEY ROAD ABERDEEN PROVING GROUND, MD, 21010-54 The parties will coordinate ordering through centralized distribution via the established Memorandum of Understanding between Repeneron, ASPR, and AmerisourceBergen. Exact ship-to locations for product will be identified through this coordinated process. (End of narrative F001)	1	CLIN CONTRACT TYPE: Firm Fixed Price PRON: X21ZD486W1 PRON AMD: 01 ACRN: AF PSC: 6505				
Packaging and Marking Inspection and Acceptance INSPECTION: Destination ACCEPTANCE: Destination Deliveries or Performance DOC SUPPL REL.CD MILSTRE ADDR SIG CD MARK FOR TP.CD 001 WISBW912562D23 W902Q2 J 3 DEL REL CD OUANTITY DEL DATE 001 447,620 31-JAN-2022 FOB POINT: Destination SHIP TO: (W902Q2) XR JOINT PROGRAM EX OFC FOR CHEM, B HQ JFEO S101 HOADLEY ROAD ABERDERN PROVING GROUND, MD, 21010-54 The parties will coordinate ordering through centralized distribution via the established Memorandum of Understanding between Regeneron, ASPR, and AmerisourceBergen. Exact ship-to locations for product will be identified through this coordinated process. (End of narrative F001)	qu Bi Th	uantity of 447,620 doses for \$940,002,000. inding Delivery Schedule is located below. ne Goal Delivery Schedule can be found in Section				
Eackaging and Marking Inspection and Acceptance INSPECTION: Destination ACCEPTANCE: Destination Deliveries or Performance DOC SUPPL REL CD MILSTHIP ADDR SIG CD MARK FOR TP CD 001 W15EW91256ZD23 W90ZQ2 J 3 DEL REL CD QUANTITY DEL DATE 001 447,620 31-JAN-2022 FOB POINT: Destination SHIP TO: (W90ZQ2) XR JOINT PROGRAM EX OFC FOR CHEM, B HO JPEO 5101 HOADLEY ROAD ABERDEEN PROVING GROUND,MD,21010-54 The parties will coordinate ordering through centralized distribution via the established Memorandum of Understanding between Regeneron, ASPR, and AmerisourceBergen. Exact ship-to locations for product will be identified through this coordinated process. (End of narrative F001)						
Inspection and Acceptance INSPECTION: Destination ACCEPTANCE: Destination Deliveries of Performance DOC SUPPL REL CD MILSTRIP ADDR SIG CD MARK FOR TP CD 001 W15EW912562D23 W90ZQ2 J 3 DEL REL CD QUANTITY DEL DATE 001 447,620 31-JAN-2022 FOB POINT: Destination SHIP TO: (W90ZQ2) XR JOINT PROGRAM EX OFC FOR CHEM, B HQ JPEO 5101 HOADLEY ROAD ABERDEEN PROVING GROUND,MD,21010-54 The parties will coordinate ordering through centralized distribution via the established Memorandum of Understanding between Regeneron, ASFR, and AmerisourceBergen. Exact ship-to locations for product will be identified through this coordinated process. (End of narrative F001)		(End of narrative B001)				
Inspection and Acceptance INSPECTION: Destination ACCEPTANCE: Destination Deliveries of Performance DOC SUPPL REL CD MILSTRIP ADDR SIG CD MARK FOR TP CD 001 W15EW91256ZD23 W90ZQ2 J 3 DEL REL CD QUANTITY DEL DATE 001 447,620 31-JAN-2022 FOB POINT: Destination SHIP TO: (W90ZQ2) XR JOINT PROGRAM EX OFC FOR CHEM, B HQ JFEO 5101 HOADLEY ROAD ABERDEEN PROVING GROUND,MD,21010-54 The parties will coordinate ordering through centralized distribution via the established Memorandum of Understanding between Regeneron, ASFR, and AmerisourceBergen. Exact ship-to locations for product will be identified through this coordinated process. (End of narrative F001)		Dankaging and Marking				
Deliveries or Performance DOC SUPPL RELCD MILSTRIP ADDR SIG CD MARK FOR TP CD 001 W15BW912562D23 W03C92 J 3 DEL REL CD OUANTITY DEL DATE 001 447,620 31-JAN-2022 FOB POINT: Destination SHIP TO: (W90Z02) XR JOINT PROGRAM EX OFC FOR CHEM, B HQ JPEO 5101 HOADLEY ROAD ABERDEEN PROVING GROUND, MD, 21010-54 The parties will coordinate ordering through centralized distribution via the established Memorandum of Understanding between Regeneron, ASPR, and AmerisourceBergen. Exact ship-to locations for product will be identified through this coordinated process. (End of narrative F001)	1	rackaging and marking				
Deliveries or Performance DOC SUPPL RELCD MILSTRIP ADDR SIG CD MARK FOR TP CD 001 W15BW912562D23 W902Q2 J 3 DEL REL CD QUANTITY DEL DATE 001 447,620 31-JAN-2022 FOB POINT: Destination SHIP TO: (W902Q2) XR JOINT PROGRAM EX OFC FOR CHEM, B HO JPEO 5101 HOADLEY ROAD ABERDEEN PROVING GROUND,MD,21010-54 The parties will coordinate ordering through centralized distribution via the established Memorandum of Understanding between Regeneron, ASPR, and AmerisourceBergen. Exact ship-to locations for product will be identified through this coordinated process. (End of narrative F001)		Inspection and Acceptance				
DOC REL CD MILSTRIP ADDR SIG CD MARK FOR TP CD 001 W15BW91256ZD23 W90ZQ2 J 3 DEL REL CD QUANTITY DEL DATE 001 447,620 31-JAN-2022 FOB POINT: Destination SHIP TO: (W90ZQ2) XR JOINT PROGRAM EX OFC FOR CHEM, B HQ JPEO 5101 HOADLEY ROAD ABERDEEN PROVING GROUND,MD,21010-54 The parties will coordinate ordering through centralized distribution via the established Memorandum of Understanding between Regeneron, ASPR, and AmerisourceBergen. Exact ship-to locations for product will be identified through this coordinated process. (End of narrative F001)		INSPECTION: Destination ACCEPTANCE: Destination				
DEL REL CD OUANTITY DEL DATE 001 447,620 31-JAN-2022 FOB POINT: Destination SHIP TO: (W90ZQ2) XR JOINT PROGRAM EX OFC FOR CHEM, B HQ JPEO 5101 HOADLEY ROAD ABERDEEN PROVING GROUND,MD,21010-54 The parties will coordinate ordering through centralized distribution via the established Memorandum of Understanding between Regeneron, ASPR, and AmerisourceBergen. Exact ship-to locations for product will be identified through this coordinated process. (End of narrative F001)						
SHIP TO: (W90ZQ2) XR JOINT PROGRAM EX OFC FOR CHEM, B HQ JPEO 5101 HOADLEY ROAD ABERDEEN PROVING GROUND, MD, 21010-54 The parties will coordinate ordering through centralized distribution via the established Memorandum of Understanding between Regeneron, ASPR, and AmerisourceBergen. Exact ship-to locations for product will be identified through this coordinated process. (End of narrative F001)		001 W15BW91256ZD23 W90ZQ2 J 3 DEL REL CD QUANTITY DEL DATE				
(W90ZQ2) XR JOINT PROGRAM EX OFC FOR CHEM, B HQ JPEO 5101 HOADLEY ROAD ABERDEEN PROVING GROUND, MD, 21010-54 The parties will coordinate ordering through centralized distribution via the established Memorandum of Understanding between Regeneron, ASPR, and AmerisourceBergen. Exact ship-to locations for product will be identified through this coordinated process. (End of narrative F001)	1	FOB POINT: Destination				
centralized distribution via the established Memorandum of Understanding between Regeneron, ASPR, and AmerisourceBergen. Exact ship-to locations for product will be identified through this coordinated process. (End of narrative F001)		(W90ZQ2) XR JOINT PROGRAM EX OFC FOR CHEM, B HQ JPEO 5101 HOADLEY ROAD				
centralized distribution via the established Memorandum of Understanding between Regeneron, ASPR, and AmerisourceBergen. Exact ship-to locations for product will be identified through this coordinated process. (End of narrative F001)	Th	nautice will grandinate ordering through				
	ce Me an pr	entralized distribution via the established emorandum of Understanding between Regeneron, ASPR, and AmerisourceBergen. Exact ship-to locations for roduct will be identified through this coordinated				
0004 VENDOR MANAGED INVENTORY (VMI) 1 EA \$		(End of narrative F001)				
	7	VENDOR MANAGED INVENTORY (VMI)	1	EA	\$(5) (4)	\$(b) (4)
COMMODITY NAME: VMI	(COMMODITY NAME: VMI				

Reference No. of Document Being Continued W15QKN-21-C-0014 PIIN/SIIN

MOD/AMD P00005

Page 6 **of** 11

TEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
	PSC: 6505 CLIN CONTRACT TYPE: Firm Fixed Price				
	This CLIN applies to Vendor Managed Inventory (VMI)				
	that shall continue for (b) (4)				
	(End of narrative B001)				
	Packaging and Marking				
	Inspection and Acceptance INSPECTION: Destination				
	Deliveries or Performance DOC SUPPL REL CD MILSTRIP ADDR SIG CD MARK FOR TP CD 001 3				
	DEL REL CD QUANTITY DEL DATE 001 1 (b) (4)				
	FOB POINT: Destination				
	SHIP TO: (W90ZQ2) XR JOINT PROGRAM EX OFC FOR CHEM, B HQ JPEO 5101 HOADLEY ROAD ABERDEEN PROVING GROUND, MD, 21010-54				

Reference No. of Document Being Continued

PIIN/SIIN W15QKN-21-C-0014

MOD/AMD P00005

Page 7 of 11

Name of Offeror or Contractor: REGENERON PHARMACEUTICALS, INC.

SECTION C - DESCRIPTION/SPECIFICATIONS/WORK STATEMENT

STATEMENT OF WORK

Production of Regeneron Therapeutic in Support of National Emergency Response to Coronavirus 2019 (COVID-19)

C.1 Scope: The Department of Defense (DoD) and Department of Health and Human Services (DHHS), in support of the national emergency response to the Coronavirus Disease 2019 (COVID-19), requires the production of Regeneron therapeutic cocktail REGN10987 and REGN10983 (casirivimab and imdevimab, REGEN-COV) on a commercial item basis, up to 2,650,000 doses, to prevent infection or treat members of the DoD and the general population against the SARS COV-2 Virus.

C.1.1 Background: The DHHS continuously monitors emerging infectious disease risk and prepares to respond to the threat of novel emerging infectious disease outbreaks in the United States. DHHS is responding to an outbreak of respiratory disease caused by a novel coronavirus that was first detected in China, and which has now spread worldwide, including in the United States. The virus has been named SARS-CoV-2 and the disease it causes has been named Coronavirus Disease 2019 (abbreviated COVID-19).

On January 30, 2020, the International Health Regulations Emergency Committee of the World Health Organization (WHO) declared the outbreak a Public Health Emergency of International Concern (PHEIC). On January 31, Health and Human Services Secretary Alex M. Azar II declared a Public Health Emergency (PHE) for the United States to aid the nations healthcare community in responding to COVID-19. On March 11, 2020, the WHO publicly characterized COVID-19 as a pandemic. On March 13, 2020, the President of the United States declared the COVID-19 outbreak a national emergency.

In July 2020, the DoD awarded an Other Transaction Agreement under the authority of 10 USC 2371b to Regeneron to manufacture and sell drug product to the Government, and to distribute such drug product for the Government in the U.S. These manufacturing production activities included manufacturing at-scale, filling and finishing, and storage and shipping of the REGEN-COV cocktail. On November 21, 2020, Regeneron announced that the antibody cocktail casirivimab and imdevimab administered together, had received Emergency Use Authorization (EUA) from the U.S. Food and Drug Administration (FDA). On July 30, 2021, the FDA revised the EUA for the Product, authorizing the Product for emergency use as post-exposure prophylaxis (prevention) for COVID-19 in adults and pediatric individuals (12 years of age and older weighing at least 40 kg) who are at high risk for progression to severe COVID-19, including hospitalization or death.

As part of DHHS preparedness and response activities, DHHS seeks to purchase 2,650,000 doses of the EUA authorized (or Biologics License Application (BLA) approved) casirivimab and imdevimab, administered together (REGEN-COV or the product), enough to prevent infection of or treat much of the targeted US population currently or projected to be infected over the coming months.

C.2 Objectives and Quantity: The contractor shall supply and the Government will purchase 2,650,000 doses of the product, as follows:

Prior Purchases: As of the date of modification P00005 to this contract, the contractor has supplied, and the Government has purchased, 1,250,000 doses of the product.

Purchase of Additional Quantities: Following the date of modification P00005 to this contract, the contractor shall supply and the Government will purchase, an additional 1,400,000 doses of the product. The Government will purchase all of such additional 1,400,000 doses that are delivered to Vendor-Managed Inventory (VMI) by January 31, 2022 (the period from the date of execution of modification P00005 to this contract through January 31, 2022, the Delivery Period).

Delivery of Additional Quantities: See Section B for binding delivery schedule. To meet the anticipated public health need, the contractor will work in good faith to accelerate deliveries to meet the Goal Delivery Schedule below. The contractor shall use commercially reasonable efforts to deliver doses early and shall keep the Government reasonably informed of its progress against such schedule in accordance with Section C.3.2. Excess deliveries in any month will count towards the minimum amount for the next months. Prior to any extension to the Delivery Period, the contractor shall coordinate with the Government to determine an appropriate path forward, aligning with Government needs. The parties shall comply with the procedures of FAR 52.212-4(f), Excusable Delays. For clarity, payments will be made for partial deliveries.



* The Goal delivery schedule above is non-binding and for illustrative purposes only and is subject to the contingencies and operational requirements located in Attachment 0003.

Doses: For purposes of contractors obligation to supply, and the Governments obligation to purchase, the product, a dose of the product means, at the time of delivery of product, the lowest volume approved or authorized dose of REGEN-COV for adult therapeutic use, as identified in the Treatment section of the EUA or subsequent corresponding section in the BLA. Accordingly, at the date of modification P00005, the lowest volume approved or authorized dose of the product for therapeutic use is 1.2 grams of the Product (600 mg of casirivimab and 600 mg of imdevimab). If in the future a lower dose of REGEN-COV were to be approved or authorized for therapeutic use

Reference No. of Document Being Continued

W15QKN-21-C-0014

PIIN/SIIN

MOD/AMD P00005

Page 8 of 11

Name of Offeror or Contractor: REGENERON PHARMACEUTICALS, INC.

exclusive of a pediatric dose authorization, then for purposes of all deliveries and purchases of product under this contract following such approval or authorization, a dose would be such lower dose. The Product may be delivered in a co-formulated presentation or in a presentation consisting of each antibody in separate vials, provided the formulation is consistent with the FDA approval or authorization. For clarity, any product delivered in a presentation (including any dose pack) containing greater than the then-current dose of the product, shall be purchased based on the number of doses contained in such presentation, provided the FDA has authorized or approved multiple doses to be prepared from the presentation. For example, if, at the time of delivery of product, the lowest volume approved or authorized dose of the product for therapeutic use is 1.2 grams of the product (600 mg of casirivimab and 600 mg of imdevimab) and the product is delivered in a presentation consisting of 2.4 grams (1.2 grams of casirivimab and 1.2 grams of imdevimab) and the FDA has authorized or approved the preparation of multiple doses from such presentation, then such delivery shall be counted as 2 doses delivered for purposes of this contract.

EUA Wind-Down. If a BLA is issued during the term of this Contract for REGEN-COV, contractor shall ensure that any doses subsequently provided to the Government under this Contract are appropriately labeled under the terms of the EUA (before expiration) or the BLA and are otherwise suitable for use in the United States under the terms of the EUA (before expiration) or the BLA.

C.3 Requirements:

C.3.1 Distribution: The contractor shall distribute the product to Government designated sites as directed by the Government, EUA authorized or BLA approved finished drug product in vials in accordance with the products storage and handling requirements in the EUA (and, if granted, the BLA as applicable), including temperature controls. This shall include storage and distribution activities. Regeneron will engage one or more third party service providers (each a Distributor) to perform storage and distribution activities for drug product at the direction and on behalf of the Government. The Government will be solely responsible for all allocation determinations related to drug product sold hereunder, including allocation to end users and communication of such allocation determinations to the Distributor. Unless otherwise mutually agreed upon by the parties, drug product shall be shipped to the Government or distributed, as applicable, solely within the United States (including its territories and possessions). The contractor (614)

until the product is distributed to the end user (e.g., the hospital, infusion center or other end-user). To the extent that Regeneron is responsible for the correction, repair or replacement of Government property held in vendor-managed inventory or in distribution and in the possession of the Distributor, , the Government of such property. The parties will coordinate ordering through centralized distribution via the established Memorandum of Understanding between Regeneron, Assistant Secretary for Preparedness and Response (ASPR), and AmerisourceBergen (or any other ordering process mutually agreed by such entities). Storage and distribution activities shall be supported under this agreement through the end of the period of performance. The Government will make every effort to ensure appropriate delivery and utilization of Government purchased product based on clinical need. Prior to the anticipated time of FDA approval of a Biologics License Application (BLA) for REGEN-COV, the parties will plan and coordinate to ensure efficient and effective distribution of commercial and noncommercial product.

C.3.2 Product Development Manufacturing Reports and Projections: Regeneron will provide manufacturing reports and manufacturing dose tracking projections/actuals, in the format and having the content mutually agreed upon by the Government and Regeneron. Regeneron will update the reports [6][4] during manufacturing campaigns and upon manufacturing deliverable submission during COVID-19 response operations (where a Public Health Emergency has been declared), with the first deliverable submission within For clarity, the reports described in this section apply to Formulated Drug Substance and Drug Product prior to delivery and acceptance by the Government. Tracking reports for product following delivery and acceptance, shall be set forth in the Memorandum of Understanding between Regeneron, ASPR, and AmerisourceBergen.

C.4 Reporting: The contractor shall provide the following reports/deliverables in accordance with Exhibit A:

CDRL # Title

- A001 Post Award Teleconference Minutes
- A002 Kickoff Meeting Agenda and Minutes
- A003 Teleconference Minutes
- A004 Ouarterly Meetings
- A005 FDA Meeting Minutes
- A006 Daily Check-in with Project Staff for COVID-19 Agreement
- A007 Monthly Progress Reports
- Milestone Reports A008
- A009 Draft Technical Progress Report
- A010 Final Technical Progress Report
- Product Development Source Material and Manufacturing Report A011
- A012 Contractor Locations
- A013 Pandemic Management Plan
- A014 Supply Chain and Distribution Tracking
- A015 Distribution Plan
- A016 Manufacturing Development Plan
- A017 Quality Management Plan
- A018 Quality Agreement

Reference No. of Document Being Continued

PIIN/SIIN W15QKN-21-C-0014

MOD/AMD P00005

Page 9 of 11

Name of Offeror or Contractor: REGENERON PHARMACEUTICALS, INC.

A019 Release Documentation for Doses to be Delivered

A020 Manufacturing and Distribution Records

A021 Security Plan

A022 Supply Chain Resiliency Plan

A023 Manufacturing Data Requirements

A024 BARDA Audit

A025 FDA Inspections

A026 QA Audits

A027 FDA Submissions

A028 EUA Filing

A029 Provision of Public Law 115-92 SPONSOR Authorization Letter

A030 Press Releases

C.5 Period of Performance: The period of performance for this contract is from date of award through

(b) (4

C.6 Inspection/Acceptance:

- C.6.1 Inspection: The Technical Point of Contact (TPOC) is a duly authorized representative of the Government, and is responsible for the inspection and/or acceptance of all items/activities to be delivered and/or completed under this contract. The parties acknowledge that acceptance may depend on the compliance with FDA regulations at 21 CFR 600-680 regarding the BLA, current Good Manufacturing Practice (cGMP) regulations at 21 CFR 210, 211, and other FDA regulations.
- C.6.2 Acceptance: Title to drug product will pass to the Government upon delivery of such drug product to Vendor-Managed Inventory (VMI), and the Governments corresponding acceptance of such drug product, as described in this paragraph. The Government shall accept product that conforms to contract requirements based on a Certificate of Analysis (COA) and any other quality documentation required to be provided by Regeneron as set forth in the Quality Agreement (Required Documents), and the parties shall perform their obligations relating to product delivery set forth in the applicable Quality Agreement for the product. The Governments acceptance of drug product will be (0)(4)

Any visibly damaged product will be rejected immediately. The contractor will transfer product from VMI to the Distributor for distribution directed by the Government; provided that, product shall not be provided to the Distributor until it is accepted by the Government. The contractor shall provide a shipment temperature tracking report within (6)(4) of contractors receipt of such report from its storage vendor, or otherwise in accordance with the applicable Quality Agreement. Any product subject to a temperature excursion outside of acceptable tolerances, shall be rejected. Any rejected product shall be returned to the contractor or otherwise disposed of according to contractor instructions. The Government will not be obligated to pay for rejected vials, nor will rejected vials count toward the delivery requirement. The contractor shall establish a notification mechanism for delivery sites to contact the Government regarding rejected vials.

- C.7 Packaging and Marking: The contractor shall label product according to FDA guidance/instructions. Packaging shall be in shipping containers according to the contractors standard commercial practice.
- C.8 Authorized and Approved Uses: Product sold to the Government may be distributed for use in any indication approved or authorized by the FDA.

Public Disclosures: Notwithstanding any other provision in this contract, the contractor may publicly release any information related to this contract without prior approval to the extent necessary to satisfy or address regulatory requirements, contractual obligations to third parties, and the public interest in data about the safety or efficacy of the product.

Public Readiness and Emergency Preparedness (PREP) Act: The Government will ensure that no product purchased under this contract is used outside the United States (including its territories or possessions) or in a way that is not protected from liability by a declaration issued under the PREP Act that is active at the time of use, except as provided in Special Contract Requirements Paragraph 4., Donation of Excess Product, which remains in effect.

C.9 Government Technical Point of Contact:

(b) (6) HHS BARDA (b) (6)

CONTINUATION SHEET			Reference No. of Document Being Co PIIN/SIIN W15QKN-21-C-0014				ng C	ontinued MOD/AMD P00005	age 10 of 11		
Name	of Offeror or	Contract	Or: REGENERON P	HARMACE	UTICALS, I	NC.					
SECTION	G - CONTRACT	r ADMINI	STRATION DATA								
	PRON/ AMS CD/										
LINE	MIPR/	OBLG	JO NO/						INCREASE/		CUMULATIVE
ITEM	GFEBS ATA	STAT	ACCT ASSIGN		ACRN		PRIOR AMOUNT		DECREASE		AMOUNT
AAE000	X21ZD484W1	1	S.0074658.7.4	1.1.1	AD	\$	0.00	\$	999,999,000.00	\$	999,999,000.00
0003AB	X21ZD485W1	1	s.0074658.7.4	1.1.2	AE	\$	0.00	\$	999,999,000.00	\$	999,999,000.00
0003AC	X21ZD486W1	1	S.0074658.7.4	1.1.3	AF	\$	0.00	\$	940,002,000.00	\$	940,002,000.00
							NET CHANGE	\$	2,940,000,000.00		
											INCREASE/
ACRN	ACCOUNTING CI	LASSIFICA	ATION								DECREASE
AD	021 202120222	2040	A5XAH 643627E7	9RG04	2550 L07	4890014	S.0074658.7.4	.1.1		023	1001 \$ 999,999,000.00
AE	021 202120222	2040	A5XAH 643627E7	9RG04	2550 L07	4890022	s.0074658.7.4	.1.2		02:	1001 \$ 999,999,000.00
AF	021 202120222	2040	A5XAH 643627E7	9RG04	2550 L07	4890199	S.0074658.7.4	.1.3		02:	1001 \$ 940,002,000.00
										NET CHAN	NGE \$ 2,940,000,000.00
			PRIOR AM			IN	CREASE/DECREAS	Е		CUMULATIV	
			OF AWA			_	AMOUNT	_		OBLIG AN	73.7
JET CHA	NGE FOR AWARD): \$	2,625,000,000.	0.0	Ş	2,94	0,000,000.00		\$ 5,565,	000,000.0	00

021001

021001

021001

LINE ITEM

0003AA

0003AB

0003AC

ACRN EDI/SFIS ACCOUNTING CLASSIFICATION

AD 021 202120222040 A5XAH 643627E79RG04 2550 L074890014 S.0074658.7.4.1.1

AE 021 202120222040 A5XAH 643627E79RG04 2550 L074890022 S.0074658.7.4.1.2 AF 021 202120222040 A5XAH 643627E79RG04 2550 L074890199 S.0074658.7.4.1.3

Reference No. of Document Being Continued

PIIN/SIIN W15QKN-21-C-0014

MOD/AMD P00005

Page 11 of 11

Name of Offeror or Contractor: REGENERON PHARMACEUTICALS, INC.

SECTION J - LIST OF ATTACHMENTS

List of Number

Addenda Title Date of Pages Transmitted By
Attachment 0003 CONTINGENCIES AND OPERATIONAL REQUIREMENTS 13-SEP-2021 002 EMAIL

PIIN/SIIN W15QKN-21-C-0014

MOD/AMD P00005

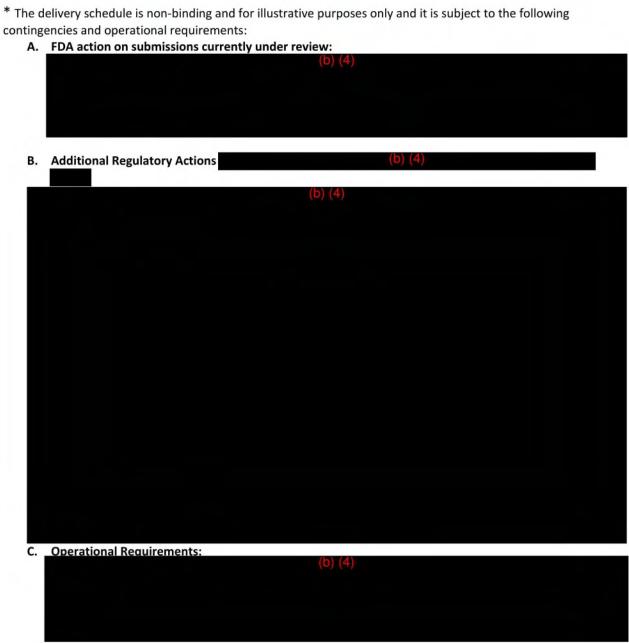
ATT/EXH ID Attachment 0003

PAGE 1

Contingencies and Operational Requirements

Goal Delivery Schedule*

•	Approximately	(b) (4)	doses delivered in	(b) (4)
•	Approximately	(b) (4)	doses delivered in	(b) (4)
•	Approximately	(b) (4)	doses delivered in	(b) (4)
•	Approximately	(b) (4)	doses delivered in	(b) (4)



W15QKN-21-C-0014 Attachment 0003 Dated 13 September 2021

