AMENDMENT OF OTHER TRANSACTION AGREEMENT (OTA)

OTHER TRANSACTION FOR ADVANCED RESEARCH (OTAR)

BETWEEN

JANSSEN RESEARCH & DEVELOPMENT LLC
920 ROUTE 202
RARITAN, NJ 08869, USA

AND

THE UNITED STATES OF AMERICA
DEPARTMENT OF HEALTH AND HUMAN SERVICES
BIOMEDICAL ADVANCED RESEARCH AND DEVELOPMENT AUTHORITY
O'NEILL HOUSE OFFICE BUILDING
WASHINGTON, DC 20515

CONCERNING

INFLUENZA PORTFOLIO AND OTHER EMERGING PATHOGENS DEVELOPMENT CANDIDATES

Amendment No. 0006
Effective Date of Amendment: Upon Last Signature in Section III

Other Transaction Agreement No. HHSO100201700018C
Effective Date of Agreement: August 15, 2017

Except as provided in this Amendment, all terms and conditions of the Agreement, as heretofore changed, remain unchanged and in full force and effect.

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I. AMENDMENT PURPOSE

By the Parties' mutual agreement and within the existing Agreement's general scope, this Amendment No. 0006 bilaterally:

i. adds an additional asset to develop a vaccine in response to the current novel coronavirus ("2019-nCoV") outbreak,

ii. incorporates a realigned budget structure around (b)(4) and the 2019-nCoV asset. This structure aligns with (b)(4) (b)(4)

iii. updates the Statement of Work (Exhibit-A) to reflect 2019-nCoV work packages. The 2019-nCoV asset work packages 6.1 – 6.7 (CLINs 0001- 0007) as described on the Exhibit-A, Statement of Work are considered added and funded (b)(4) (b)(4) work packages as of the date of this amendment. Work Package 6.7 is an option to be exercised at a future date based on (i) JOC recommendation, (ii) availability of funding and (iii) a signed amendment between the Parties,

iv. modifies the PMO steering committee and USG agreement team to add the respective Technical Leads for this 2019-nCoV Vaccine development, and

v. (b)(4)

II. AMENDMENTS TO AGREEMENT

A. Incorporate new budget and workplan structure to reflect the new 2019-nCoV asset and redirected (b)(4)

1) Pursuant to Agreement Article VI(C), the budget allocation summary of assets is hereby replaced to incorporate the following.

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(b)(4)

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(b)(4)

2) Exhibit B budget allocation summary provide details for the budget restructuring are incorporated and attached to this Amendment 0006. (b)(4)

(b)(4)

B. Updated the Statement of Work

1) The Statement of Work shall be replaced to reflect the new asset structure. The updated SOW for incorporation in the OTA is included in Exhibit A.

C. Update of Recipient's Key Personnel and the Government's personnel working under the Agreement

1) Article IV *Management of the Project* Section A (3) *Organizational Chart* is deleted and replaced with the following:

(b)(6)

(b)(4)

(b)(4)

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III. SIGNATURES

Acknowledged, accepted, and agreed for

JANSSEN RESEARCH & DEVELOPMENT, LLC

(b)(6)

U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES
OFFICE OF THE ASSISTANT SECRETARY FOR
PREPAREDNESS & RESPONSE

(b)(6)

DATE: 2/11/2020

ATTACHMENT 1: TASK DESCRIPTION DOCUMENT (SOW)

Overall Objectives and Scope

Seasonal and pandemic influenza remains one of the most important public health threats despite current vaccine and therapeutic options. The Consortium is developing a broad portfolio of innovative and novel countermeasures against influenza and other emerging infectious diseases comprising small molecules, biologics and vaccines. The portfolio employs (b)(4) modes of action complementary to current Standard of Care treatments to develop single or combination therapies that have the potential to increase therapeutic benefit and preclude the rapid emergence of drug resistance. The (b)(4) aims to (b)(4) the influenza vaccine field by providing broad protection for both seasonal and pandemic influenza.

Specifically, this Agreement includes: an influenza (b)(4) that is now ready for (b)(4) (b)(4) (b)(4) influenza A or B (b)(4); and (b)(4)

In addition, Recipient may propose to augment the portfolio by replacing molecules listed in this SOW with backup molecules from their ongoing research programs. With support from the JOC, the Consortium may also consider in-licensing drug or vaccine candidates to supplement the Program's portfolio of emerging infectious disease medical countermeasures in the Field. Recipient may also add Consortium Members as may be appropriate or complimentary to the performance and goals of this Agreement.

(b)(4)

(b)(4)

(b)(4)

6 Novel Coronavirus ("2019-nCoV") Vaccine

6.1 Antigen design, manufacturability testing and preMVS manufacturing

Activities

- Several designs based on the 2019-nCoV spike sequence will be made and (b)(4) at multiple CROs
- Ad26 research batches encoding the different spike variants (b)(4)
- (b)(4)
- (b)(4)
- (b)(4)
- Several critical reagents such as expression plasmids, soluble proteins, peptide pools and detection antibodies will be generated or ordered

(b)(4)

(b)(4)

6.2 pre-clinical immunology and protective efficacy

Activities

(b)(4)

(b)(4)

6.3 CMC development

Activities

- (b)(4)
- (b)(4) ethod development will occur to make insert specific assays fit for purpose.

(b)(4)

Activities

- Setup of immunological assays
  - (b)(4)
- Writing of protocol elements document (PED)
- Protocol writing
- Writing and submission of preIND document
- Writing and submission of IND documents

(b)(4)

6.5 GLP Toxicology

Activities

- A GLP Toxicity study will be performed (b)(4)
- (b)(4)
-

(b)(4)

6.6 GMP manufacturing

Activities

- Master Virus Seed manufacturing and release
- Drug substance manufacturing at appropriate scal (b)(4)
(b)(4)
- Drug product manufacturing (b)(4)
and release
- DS and DP stability analysis

(b)(4)

(b)(4)

6.7 Ph1 clinical trial – OPTION Work Package

Activities

- Randomized, placebo-controlled, double blind study in healthy adult volunteers
- Primary objective will be assessment of safety and reactogenicity. Secondary and exploratory endpoints will evaluate vaccine-induced immunogenicity.
- (b)(4)
-
- (b)(4) will be enrolled at (b)(4) to allow additional exploratory immunogenicity analysis, including potentially passive transfer studies if such model can be developed.

(b)(4)