PROJECT DESCRIPTION/STATEMENT OF OBJECTIVES

2.1 OBJECTIVE AREA – Prevention (PRE-20-11) – COVID-19 Pandemic – Vaccine Rapid Advanced Research and Development (ARD) to Large Scale Manufacturing

2.1.1 DESCRIPTION/OBJECTIVE OF THE PROJECT: The Department of Defense (DoD) and Department of Health and Human Services (HHS), seeks Offerors to perform at-scale prototype manufacturing and fill-finish of Coronavirus Disease 2019 (COVID-19) Medical Countermeasures (MCM) currently in advanced development, in order to ensure nationwide access.

An outbreak of respiratory disease caused by a novel coronavirus, was first detected in China and has now spread worldwide, including the United States. The virus has been named Severe Acute Respiratory Disease Coronavirus-2 (SARS-CoV-2), and causes 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, the United States Department of Health and Human Services Secretary, Alex M. Azar II, declared a Public Health Emergency (PHE) for the United States to aid the nation's healthcare community in responding to COVID-19. On March 11, WHO publicly characterized COVID-19 as a pandemic. On March 13, the President of the United States declared the COVID-19 outbreak a national emergency. The United States Government (USG) has identified COVID-19 vaccine candidates (prototypes) that are progressing rapidly through advanced research and development activities. It is critical for the sponsors of these prototype MCMs to initiate at-scale prototype manufacturing to demonstrate the target population capability. As such, the USG will support at-scale manufacturing (through packaging and release testing) of selected prototype MCMs, to ensure timely availability to the US population when needed.

2.1.2 STATEMENT OF OBJECTIVES (SOO):

1) **Project Objectives:** The objective of this prototype project is to initiate an advanced development SARS-CoV-2 MCM prototype for clinical/non-clinical development and/or manufacturing scale-up to demonstrate the capability to support sustained large scale manufacturing necessary to meet surge requirements, with little advance notification. Candidate MCMs shall have a minimum capability of obtaining Emergency Use Authorization (EUA) and/or a reasonable chance of moving to Phase 3 clinical trials by January 2021, with all development plans and efforts, including manufacturing, done in support of, and with the goal of achieving Food and Drug Administration (FDA) licensure in 2021. The Offeror will need to demonstrate the capability to manufacture, stockpile, and distribute large quantities of MCM to respond when needed. Optional line items associated with full scale production quantities to vaccinate an estimated 300M people, may be included in the negotiated project agreement. These option line items may be exercised at the Government's sole discretion, in accordance with paragraph 2.1.4.3.

2) **Performance Objectives (Required Results):** The U.S. Government, in support of Operation Warp Speed, seeks Offerors to perform non-clinical and clinical advanced development and/or at-scale prototype manufacturing and fill-finish of a SARS-CoV-2

MCM. Manufacturing shall take place in a US-based facility, with assurance of sourcing of adequate material for production. Production shall occur using cGMP validated manufacturing process for bulk drug substance and fill and finished drug product, with a ramp-up capacity that provides up to 100M doses for a targeted US population within six (6) months of award, in order to vaccinate the US population indicated in the Offeror's target population. The Offeror's proposal should include a validation plan and associated timelines. The project shall be accomplished using aggressive risk management and taking advantage of any regulatory flexibilities. A description of the manufacturing facility quality assurance and regulatory acceptance, including quality systems and regulatory milestones towards facility approval, is required.

3) **Regulatory Objectives:** The proposed at-scale prototype manufacturing is expected to meet the necessary US FDA requirements for beginning a Phase 3 clinical trial, and the product be granted licensure by the FDA.

4) **Project Management Objectives:** Mandatory reporting requirements are described in the base agreement: Monthly progress reports should include both technical and financial status and expenditure forecast; final prototype project report; patents reports, work breakdown structure; integrated master schedule; regulatory documents, including communications with the FDA, all submissions, and the PL 115-92 Sponsor Authorization Letter.

   Project management oversight will be comprised of an Agreements Officer's Representative (AOR) and USG Project Coordination Team (PCT), which will perform ongoing technical reviews and approvals of milestones.

   The Offeror shall invite the Government to attend all FDA meetings, with regard to this project.

5) **Logistics Objectives:** The USG seeks at-scale prototype manufacturing and fill-finish of a SARS-CoV-2 MCM currently in advanced development. Capability and capacity to manufacture prototype doses of the vaccine, shall reside within the US. Production shall occur using an established manufacturing process for bulk drug substance and fill and finished drug product, with a ramp-up capacity plan that provides up to 100M doses for a targeted US population, within six (6) months of award.

6) **Performance Requirements:** Production of the vaccine product shall occur 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 vaccine treatment regimen. The Offeror's proposal should include a validation plan and associated timelines. The project shall be accomplished using aggressive risk management and taking advantage of any regulatory flexibilities. A description of the manufacturing facility quality assurance and regulatory acceptance, including quality systems and regulatory milestones towards facility approval, is required.

7) **Operational Constraints/Limitations/Restrictions:** Manufacturing operations shall be based in the US.

2.1.3 PERIOD AND PLACE OF PERFORMANCE: The anticipated Period of Performance for this effort is up to two (2) years from the date of award (including options). Specific dates to be negotiated. It is anticipated that the primary place of performance will be the contractors' or subcontractors' facilities, however this aspect can be negotiated as part of each Offerors' submission.

2.1.4 DELIVERABLES:

2.1.4.1 DATA DELIVERABLE(S):

Data Deliverables required include:

- MCDC Base Agreement mandatory reports.
- Meeting minutes from all scheduled and ad-hoc meetings with the AO and AOR.
- Monthly financial reports required for invoice approval.
- All FDA communications, including minutes and submissions.
- Detailed Work Breakdown Structure that enables the proposed Statement of Work.
- The Offeror shall have a comprehensive Supply Chain Resiliency Program that provides for identification and reporting of critical components associated with the secure supply of drug substance, drug product, and work-in-process through to finished goods.
- FDA Form 483 and the Establishment Inspection Report (EIR), if applicable.
- FDA correspondence (formal and informal, including minutes of teleconferences).
- Bi-Weekly performance meeting agendas, meeting minutes, and briefings.

Note: Technical data deliverables described herein shall be delivered to the Government with Government Purpose Rights

2.1.4.2 PROTOTYPE DELIVERABLE(S):

The prototype deliverables include the fill/finished vaccine drug product authorized for use by the FDA, and/or demonstrated manufacturing capability meeting the performance objectives.

2.1.4.3 Follow-on Production: In accordance with 10.U.S.C. 2371b(f), and upon a determination that the prototype project for this transaction has been successfully completed, or at the accomplishment of particularly favorable or unexpected results that would justify transitioning to production, any competitively awarded prototype OTA as a result of this RPP may result in the award of a follow-on production contract or transaction without the use of competitive procedures. The Government intends to purchase sufficient quantities to vaccinate an estimated 300M people with the selected MCM vaccine. The Offeror's proposal shall include production option(s) to purchase the fill/finished drug product, based on maximum production capability, providing quantity per month, price per dose, inclusive of all direct and indirect costs, storage, and shipping to designated Government facilities.

The manufactured prototype will be successful if:

- The prototype is safe and effective, as agreed to by the FDA either by licensure or under an EUA, or
- The Offeror demonstrates capability of manufacturing up to 100M doses for a targeted population within six (6) months of award.

2.1.5 SPECIAL REQUIREMENTS:

2.1.5.1 Export Control: Export Controls shall be in accordance with the Base Agreement.

2.1.5.2 Security and Classified Data: This project is Unclassified.

2.1.5.3 Acceptance of Deliverables: The Government will provide acceptance of all data deliverables within ten (10) calendar days of delivery. The Government will provide acceptance of all vaccine prototype deliverables within thirty (30) calendar days of delivery.

2.1.5.4 Travel: The following travel may be approved by the Government, upon request:

- Travel for face-to-face meetings with Government personnel and/or sub-contractors.
- Travel to provide oversight, audits, and/or data reviews with sub-contractors.
- Travel for program review meetings or Integrated Product Team (IPT) meetings, as requested by the Government.
- Travel to complete in-person FDA requested meetings.

Additional non-directed travel, necessary for the completion of the contracted work, may be permitted. The Offeror shall provide a breakout of expected travel in their proposal.

2.1.6 GOVERNMENT FURNISHED PROPERTY: Government Furnished Equipment, Contractor Acquired Government Furnished Property, and Contractor Acquired Government Owned Property are subject to negotiations during the award process. The contractor should identify necessary equipment and property in white paper submissions to this RPP.

2.1.7 FUNDING CONFIDENCE LEVEL:

CL-1 Highly Confident funds will be available.

2.1.8 AGREEMENTS OFFICER'S REPRESENTATIVE (AOR):
Name: TBD
Telephone:
E-mail:
Office Symbol: HHS/ASPR/BARDA

2.1.8.1 ALTERNATE AOR:
Name: TBD
Telephone:

E-mail:
Office Symbol: HHS/ASPR/BARDA

2.1.9 Requiring Activity:
Joint Mission - Department of Health and Human Services and Department of Defense to Combat COVID-19