Office of Biomedical Advanced Research and Development Authority (BARDA) Division of Research, Innovation & Ventures (DRIVe)

Special Instructions 015 Issuance for Easy Broad Agency Announcement (EZ-BAA) BAA-20-100-SOL-0002

The purpose of these Special Instructions are the following:

1) Add Area of Interest (AOI) #12 to the EZ-BAA:

AOI #12: Mitigating Long-term Effects (MILE) of Respiratory Distress

2) Remind potential Respondents that the following AOIs under the EZ-BAA are currently open and accepting abstract submissions:

AOI #2: Infection Severity and Solving Sepsis
AOI #6: Beyond the Needle
AOI #8: Bringing Laboratory Testing to the Home
AOI #9: Digital Health Tools for Pandemic Preparedness
AOI #10: Next Generation Sequencing (NGS)-based Agnostic Diagnostic for Respiratory RNA Virus Pathogens
AOI #11a: Home-based, Over-the-Counter Diagnostics for the Detection of SARS-CoV-2
AOI #11b: Enabling Technologies to Support Home-Based Diagnostics for SARS-CoV-2 Acute Infection
AOI #12: Mitigating Long-term Effects (MILE) of Respiratory Distress

3) Notify potential Respondents that any EZ-BAA contracts (above the micro-purchase threshold) awarded on or after November 14, 2021 will be subject to Class Deviation (2021-03) from the Federal Acquisition Regulation (FAR) Regarding Implementation of Executive Order 14042, Ensuring Adequate COVID Safety Protocols for Federal Contractors.

I. INTRODUCTION AND OVERVIEW INFORMATION

A. Development Opportunity Objective:

Under these Special Instructions 015, BARDA is adding AOI #12 as part of its EZ-BAA (BAA-20-100-SOL-0002). Under this AOI, we are seeking abstract submissions for the following:

AOI #12: Mitigating Long-term Effects (MILE) of respiratory distress

Lung injury or respiratory distress caused by infectious agents as seen in complications from common pathogens (e.g. influenza, pneumococcus), pandemics (SARS-CoV-2), or result of insult (e.g. radiation injury, chemical inhalation), can lead to hospitalizations and severe outcomes, including sepsis and acute respiratory distress syndrome (ARDS). These conditions can have long term consequences that linger beyond the initial recovery (i.e. discharge from the hospital). Therapeutic approaches are needed to improve long-term outcomes.

Interventional strategies primarily focus on the acute phase to the respiratory distress with the goal of recovery from critical care and/or mitigation of the infectious agent. However, many survivors of severe respiratory injury subsequently face the difficult challenge of long-term recovery. Long-term health consequences, risk of health deterioration or even mortality for previously hospitalized pneumonia, sepsis and/or ICU patients is well documented. For example, many COVID-19 patients requiring mechanical ventilation subsequently develop long-term sequelae, and both sepsis and ARDS survivors are disproportionately afflicted by sequelae of mental, physical, social and functional impairments for years following their initial hospitalization. Early interventional therapies are needed to reduce long-term symptoms and prevent hospital readmissions.

DRIVe is interested in host-targeted therapeutic product candidates as threat agnostic approaches to aid in mitigating long-term outcomes. DRIVe is interested in further study of host therapeutic product candidates that may be implemented early in the progression of acute lung injury to specifically reduce the long-term morbidity and mortality resulting from the initial injury or infectious insult. Of specific interest are candidates already in development for treating lung injury or another acute indication that can be adapted to include additional clinical research and analytics beyond their original primary/secondary endpoint(s) to explore impact on long-term outcomes as additional parameters. Analyses should assess the potential of the treatment to restore and/or maintain baseline health characteristics and/or to reduce hospital readmission. To be responsive to this topic, product candidates must have safely completed a phase I clinical trial with the FDA.

Proposals should consider the following:

- Include appropriate quantitative endpoints that reflect impact to longer-term (>3 months) health deterioration after recovery from the initial acute phase of illness. Potential long-term effects include, but are not limited to, physical stamina, cognitive function, mortality, hospital readmission, and should be compared to an untreated population following the same course of illness/infection.
- Patient enrollment and treatment should be limited to subjects experiencing respiratory distress or lung injury originating from a primary event/hospitalization. Of priority

interest, are products that have already demonstrated some efficacy against primary indication (e.g. acute phase of lung injury). Interventional agents should be administered during the initial hospital stay to demonstrate the long-term benefit.

- Include a rationale to support how the potential mechanism of action of the therapeutic may impact patient post-discharge health.
- Although not required, approaches able to predict/stratify patients that will be responsive to therapy and exhibit long term benefit, like endotyping, are of interest.
- Provide clear intended use statement for product in terms of population of interest, stage of lung injury for treatment, timing and route of administration targeted indication for the long-term consequences, and clinical setting for administration.
- Clinical studies should take into consideration the need to represent diverse populations and must be equitable in terms of enrollment, including diversity amongst race, ethnicity, and biological sex
- Address how the proposed study is different from or expands existing clinical trials of the candidate therapeutic.
- Address appropriate route(s) of administration as relevant to drug candidate dose and clinical setting.
- Only technologies focused on host-based approaches or clinical management approaches will be considered. BARDA has existing programs for pathogen-targeted approaches outside of this Area of Interest.
- Research should be considered translational science. Early stage or fundamental research will not be considered at this time.
- The investigational drug must have an IND filed and be on a clear path to achieving regulatory NDA or BLA with the FDA and information on regulatory approach and guidance to date should be provided.
- Proposals should provide evidence of pre-established agreements with proposed partners (i.e CROs, clinical sites, subcontractors) for relevant clinical studies, GMP manufacturers of product, etc.
- Proposals should include consideration of commercialization strategy outside the work proposed to this announcement. This may include other ongoing relevant research; establishment of partnerships with appropriate manufacturers; addressing the ability to scale, deploy, and distribute the product; intellectual property; and modeling the cost per unit, or reimbursement strategy.

The following are considered out of scope at this time:

- Pathogen-based or pathogen targeted products.
- Supportive care technologies that do not specifically improve clinical outcomes for patients.
- Exploratory research with no near-term translational application.
- Studies only targeting long-term outcomes of respiratory distress from chronic conditions, e.g. asthma, COPD.
- Product candidates that are intended for administration after the acute phase of injury (i.e. post-discharge).

B. Eligible Respondents & Scope Parameters:

These Special Instructions are open to all responsible sources as described in the EZ-BAA. Abstract submissions that do not conform to the requirements outlined in the EZ-BAA may

be considered non-responsive and will not be reviewed. To clarify, an entity must have an active registration with https://sam.gov at the time of submission to be reviewed. If not, submissions will not be reviewed and will be rejected. Please do not attempt to submit an abstract if your registration is not active in https://sam.gov.

IMPORTANT NOTE: Interested vendors are strongly encouraged to submit a request to schedule a market research call. This request should include the project title, key project staff, and a brief description of the proposed project. Please submit the requests to the following:

AOI #2: Infection Severity and Solving Sepsis (solvingsepsis@hhs.gov)
AOI #6: Beyond the Needle (beyondtheneedle@hhs.gov)
AOI #8: Bringing Laboratory Testing to the Home (homediagnostics@hhs.gov)
AOI #9: Digital Health Tools for Pandemic Preparedness (digitalhealth@hhs.gov)
AOI #10: NGS-based Agnostic Diagnostic for Respiratory RNA Virus Pathogens (NGS@hhs.gov)
AOI #11a: Home-based, Over-the-Counter Diagnostics for the Detection of SARS-CoV-2 (COVID19_homeDx@hhs.gov)
AOI #11b: Enabling Technologies to Support Home-Based Diagnostics for SARS-CoV-2 Acute Infection (COVID19_homeDx@hhs.gov)
AOI #12: Mitigating Long-term Effects (MILE) of Respiratory Distress (HostTx@hhs.gov)

AOI #2 will be open for abstract submissions through **5:00 PM ET on 15 January 2022,** unless otherwise extended.

AOIs #6, #8, and #9 will be open for abstract submissions through **5:00 PM ET on 03 February 2023**, unless otherwise extended.

AOI #10 will be open for abstract submissions through **5:00 PM ET on 30 November 2021,** unless otherwise extended.

AOIs #11a and #11b will be open for abstract submissions through **5:00 PM ET on 15 January 2022,** unless otherwise extended.

AOI #12 will be open for abstract submissions through **5:00 PM ET on 30 April 2022,** unless otherwise extended.

C. Number of Awards:

Multiple awards are anticipated and are dependent upon the program priorities, scientific/technical merit of submissions, how well submissions fit within the goals of the AOI, and the availability of funding. The program funding is subject to change based on the Government's discretion.

Additionally, award(s) expected to be made under these Special Instructions will be less than $750,000 in total Government funding. Funding is limited, so we encourage any interested vendors to reach out to the respective program as soon as possible before submitting an abstract.

D. Special Instructions Application Process:

These Special Instructions will follow the same submission process and review procedures as those established under the EZ-BAA. For complete details, please read the EZ-BAA solicitation in its entirety. DRIVe takes the protection of Respondent information very seriously to ensure that information is safeguarded in full compliance with all applicable regulations and law.

IMPORTANT NOTE: Awarded partners under each of these AOIs will be required to share any collected de-identified data in an effort to advance the field and knowledge. Interested partners are encouraged to commercialize their technology and algorithms but data collected through the use of Government funding will be made available through full Government purpose rights.