Statement of Work

Proposal Number: MTEC-20-09-COVID19-050
Organization: Centivax
Title: (b) (4) to COVID-19 for Immediate Clinical Use
ACURO and/or HRPO approval needed: ACURO Approvals Needed. HRPO Approval Needed if Option Year Funded.
EGS #: MT20009.050

Programmatic Relevance: Pandemic COVID-19 causes severe disease in 10-20% of the infected, requiring long hospitalization and causing a 10% mortality rate for those hospitalized. High virus transmissibility results in rapid outbreaks and exhaustion of hospital facilities and infection of staff. Currently, there are no FDA-approved vaccines or treatments for COVID-19. Although vaccines are under development, they cannot be used to treat the already sick and will not be ready until 2021. Thus, a therapeutic capable of immediate action and able to be used prophylactically to protect healthcare workers, the immunocompromised, the elderly, as well as infected individuals is critically needed.

Centivax (b) (4)

Antibodies have precedent of being extremely effective in combating viral outbreaks. Specifically, antibody therapeutics for Ebola transformed survival from 50% to over 94% for those who received the treatment early. Additionally, antibody therapeutics for rabies transform survival from 0% to nearly 100%. Antibody therapeutics are given to infants for RSV and as antivirals for HIV. Therefore, a SARS-CoV-2 antibody therapeutic will be effective where a vaccine is not. Reducing the COVID-19 mortality rate and decreasing recovery time in the hospital has the potential to significantly impact the crisis.

Non-clinical Data/Technical Abstract: Centivax (b) (4) From January 27th to March 30th, Centivax (b) (4) (b) (4) These parental antibodies were valuable in that they already had been well studied: they have been established to bind, neutralize, and protect against the SARS coronavirus. (b) (4) (b) (4) (b) (4) (b) (4) (b) (4)

(b) (4)

(b) (4) Our goals in this proposed study include:

- **Parallelized Potency characterization *in vitro* and *in vivo*:** (b) (4)
(b) (4)
(b) (4)
(b) (4)
- **Parallelized Safety and toxicity characterization *in-vitro* and *in-vivo*:** in parallel (b) (4)
(b) (4)
(b) (4)
(b) (4)
- **Plug-and-play Fc half-life extension and ADE elimination**: To further enhance the clinical value of our selected antibodies, (b) (4)
(b) (4)
(b) (4)
(b) (4).
- **Parallelized CMC/GMP production:** We are proposing ***Fast Track Development*** for (b) (4)
(b) (4) ***within a two month period*** from the start of this project (b) (4)
(b) (4)
(b) (4)
(b) (4)
(b) (4)
- **Combined Phase I/II clinical trial:** With FDA Emergency Use Approval and a final DoD GO decision, we will initiate a Phase I/II clinical trial by the end of summer on (b) volunteers to assess safety and efficacy of one lead monoclonal or oligoclonal pool of 1-2 mAbs, pending efficient IND review and approval. We are now in contact with FDA to arrange a pre-IND meeting.
- **Rapid Compassionate use/expanded access:** In parallel, we are seeking funding for manufacturing of sufficient GMP material to release at least (b) (4) in fall 2020 for widespread access immediately following the ***GO decision*** and positive safety and efficacy from Phase I/II (b) (4)
(b) (4)
(b) (4)

Manufacturing feasibility (b) (4)
(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

centivax

Figure 2. Centivax (b) (4)

Task Description: We will do (b) (4) . From the data generated, we will select the 1 or 2 most promising candidates for use in phase I/II clinical trials. To further enhance the clinical value of our selected antibodies (b) (4) (b) (4) . In parallel, (b) (4) (b) (4) The two most promising candidates will be produced in quantities needed for expedited Phase I/II clinical trials. As indicated, these (b) (4) more than 20 years ago, and are well known by the FDA. Rapid cGMP/IND/Phase I/II study design will be completed by the summer, pending efficient cGMP/IND review and approval. We anticipate Phase I/II studies to begin in July with wide-spread availability of therapeutic antibody released as compassionate use or in a Phase II/III design by September 2020. We are now in contact with FDA and have begun to begin product registration. The final expected deliverable from this project will be a final technical report to support a Go/No go decision for the product to enter a Phase I/II clinical trials for the treatment of COVID-19.

The scope of our effort is to demonstrate Centivax's (b) (4) (b) (4) (b) (4)

Project Objectives: Centivax's therapeutic is a ***complete solution to the requirements presented in this RPP***, and ***provides a GO/NO GO decision*** for continued Phase I/II clinical studies.

Objective 1: (b) (4)
Objective 2: (b) (4)
Objective 3: (b) (4)
Objective 4: (b) (4)
Objective 5: (b) (4)
Objective 6a: (b) (4)
Objective 6b: (b) (4)
Objective 7: (b) (4)

Table 2: Anticipated Outcomes (Does not include Labor Costs)

Objective	Task	Deliverable	Time
1	(b) (4)	(b) (4)	2-3 weeks
2	(b) (4)	(b) (4)	2-4 weeks

3	(b) (4)	(b) (4)	2-4 weeks
4	(b) (4)	(b) (4)	2 weeks
5	(b) (4)	(b) (4)	10 weeks
Option 6a	(b) (4)	(b) (4)	8 Weeks
Option 6b	(b) (4)	(b) (4) (b) (4) (b) (4)	3-9 Months

Milestone Payment schedule

Based on the information provided by MTEC, CentiVax proposes to apply the following resources charged at the prices indicated below to meet the project objectives. Should CentiVax's needs change, this will be updated accordingly in a subsequent amendment to this Statement of Work.

Milestone Payment Schedule					
MTEC Milestone Number	**Objective Number**	**Task**	**Due Date**	**Government Funds**	**Total Funding**
1	N/A	Initiation of the program	7/5/20	$(b) (4)	$(b) (4)
2	1	Submission for ACURO approvals	TBD	(b) (4)	(b) (4)
3	1	Receipt of ACURO Approvals	TBD	(b) (4)	(b) (4)
4	1	(b) (4) (b) (4)	7/5/20	$(b) (4)	$(b) (4)
5	2	(b) (4)	7/20/20	$(b) (4)	$(b) (4)
6	3	(b) (4)	7/5/20	$(b) (4)	$(b) (4)
7	4	(b) (4)	7/30/20	$(b) (4)	$(b) (4)

8	N/A	Quarterly Report 1 (April-June Technical and Business Reports)	7/25/20	(b) (4)	(b) (4)
9	5	Regulatory Toxicology Study (CRL)	8/30/20	$(b) (4)	$(b) (4)
10	N/A	Annual Technical Report, Final Technical Report, and Final Business Status Report	1/25/21	(b) (4)	(b) (4)
		Total		$(b) (4)	**$1,206,824**

DATA RIGHTS ASSERTIONS

Government Purpose Data Rights.