Statement of Work

Proposal Number: MTEC-20-09-COVID19-079
Organization: Inhalon Biopharma, Inc.
Title: Production and Phase 1/2a trial of Inhaled Immunotherapy for COVID‐19
ACURO and/or HRPO approval needed: ACURO and HRPO

All FDA communication and documentation related to this award will be provided to the government.

Introduction/Background

This Statement of Work was prepared to meet the submission deadline because of the urgency of the current pandemic. We are providing an abbreviated Statement of Work that will be expanded should Inhalon be considered for an award.

Scope/Project Objective
The technology objective is to develop a treatment for Service members and the general population diagnosed with COVD-19 which can also be used to prevent SARS-CoV-2 infections. The objectives of this proposal are to demonstrate proof-of-concept safety and efficacy in a Phase 1/2a clinical study of an inhaled treatment that can be widely deployed and self-administered.

The major milestones are:

- Demonstrate efficacy in a hamster challenge model using live SARS-CoV-2 virus
- Demonstrate stability and desired properties for nebulized IN-005
- Manufacture (b) (4) of drug product for the clinical study
- Submit IND for a Phase 1/2a clinical study
- Complete enrollment of (b)(4) COVID-19 patients in a Phase 1/2a study

Requirements
Below are the requirements for meeting the proposed objectives:

1. **Regulatory** – obtain FDA approval to conduct a Phase 1/2a study for IN-005
   1.1. Pre-IND Meeting – submit a pre-IND meeting request to FDA outlining key topics to be discussed prior to making IND submission.
   1.2. IND Submission – Submit IND to authorize the start of a Phase 1/2a clinical study.
   1.3. IND Approval – FDA agrees to initiating the Phase 1/2a study

2. **Nonclinical** – generate a robust data set from experiments to support use of IN-005 in humans
   2.1. Antibody characterization – characterize IN-005 with analytical tests showing (b) (4) .
   2.2. Nebulization characterization – characterize the aerosolized IN-005 .
   2.3. (b) (4) challenge study – demonstrate efficacy in a placebo-controlled study of (b) (4) .
   2.4. Tissue cross-reactivity study – determine the cross-reactivity properties of IN-005 to (b) (4) .
   2.5. Rat toxicology study – acute tox study to show safety

3. **Clinical Trial Material** – produce GMP drug product for use in a Phase 1/2a study

3.1. Research material – acquire GLP IN-005 for preclinical studies
3.2. Clinical trial material – produce (b) (4) of GMP drug product
    3.2.1. Produce IN-005 – (b) (4) .
    3.2.2. Vialed Drug Product – IN-005 will be release tested, filled in vials and kitted for deliver to clinical sits.
3.3. (b) (4) Cell Line Development – develop (b) (4) cell line (b) (4) in order to scale up after the Phase 1/2a study completes.

4. **Phase 1/2a Clinical Study** – determine the safety profile for IN-005 and obtain preliminary efficacy data
4.1. Study Protocol
    4.1.1. Prepare Protocol Synopsis for Pre-IND meeting
    4.1.2. Full study protocol for IND submission
4.2. Plans and SOPs – create required plans for carrying out the clinical study under FDA and state regulations
    4.2.1. Clinical Monitoring Plan
    4.2.2. Quality Plan
    4.2.3. Data Management Plan
    4.2.4. Statistical Analysis Plan
    4.2.5. Drug Safety SOPs
4.3. Databases – create databases for conducting the clinical study
    4.3.1. Clinical Database
    4.3.2. Safety/Argus Database
4.4. Clinical Sites – screen and recruit clinical sites
    4.4.1. Put in place contracts
    4.4.2. Obtain IRB approvals
    4.4.3. Site initiation and training
4.5. Conduct in-patient study
    4.5.1. First subject screened, randomized and enrolled
    4.5.2. Complete 50% patient enrollment
    4.5.3. Complete 100% patient enrollment
    4.5.4. Last patient visit
    4.5.5. Monitor site activities and compliance
4.6. Report
    4.6.1. Close out sites
    4.6.2. Preliminary database lock
    4.6.3. Report topline results

Deliverables

- Report of efficacy of IN-005 in (b) (4) study
- Report of IN-005 nebulization characterization
- Report of tissue cross-reactivity studies
- Report of (b) (4) study
- (b) (4) to scaleup for Phase 2/3 clinical studies
- IND submission
- Report of topline clinical results from the Phase 1/2a study

Milestone Payment Schedule

MTEC Milestone Number	Task Number	Significant Event /Accomplishment	Due Date	Government Funds	Cost Share	Total Funding
1	N/A	Project Kickoff	7/13/2020	$39,780		$39,780
2	4.1.1	Protocol Synopsis	7/15/2020	$0		$0
3	1.1	Pre-IND Submission	7/22/2020	$0		$0
4	3.1	Acquire research material	7/27/2020	$0		$0
5	N/A	Monthly Project Management	8/1/2020	(b) (4)		(b) (4)
6	N/A	Monthly Admin, QA, Regulatory, ClinOps	8/1/2020	(b) (4)		(b) (4)
7	3.2.1	Start Drug Substance Manufacturing	9/1/2020	(b) (4)		(b) (4)
8	N/A	Submission for ACURO Approval	9/1/2020	$0		$0
9	2.1	Antibody Characterization	9/15/2020	(b) (4)		(b) (4)
10	N/A	Monthly Project Management	10/1/2020	(b) (4)		(b) (4)
11	N/A	Monthly Communications	10/1/2020	(b) (4)		(b) (4)
12	N/A	Monthly Admin, QA, Regulatory, ClinOps	10/1/2020	(b) (4)		(b) (4)
13	2.2	Nebulization Characterization	10/1/2020	(b) (4)		(b) (4)
14	4.2.1	Clinical Monitoring Plan	10/1/2020	$0		$0
15	4.2.2	Quality Plan	10/1/2020	(b) (4)		(b) (4)
16	4.2.4	Statistical Analysis Plan	10/1/2020	(b) (4)		(b) (4)
17	4.1.2	Full Clinical Study Protocol	10/1/2020	(b) (4)		(b) (4)
18	3.2.1	Release of Drug Substance	10/1/2020	(b) (4)		(b) (4)
19	2.4	Tissue Cross-reactivity Studies Report	10/1/2020	(b) (4)		(b) (4)
20	2.5	(b) (4)	10/1/2020	(b) (4)		(b) (4)
21	2.3	(b) (4) Challenge Model	10/5/2020	$0		$0
22	4.4.1	Clinical Site Contracts	10/8/2020	(b) (4)		(b) (4)
23	4.2.3	Data Management Plan	10/17/2020	(b) (4)		(b) (4)
24	4.3.2	Safety/Argus Database	10/17/2020	(b) (4)		(b) (4)
25	4.2.5	Drug Safety SOPs	10/17/2020	$0		$0
26	4.4.2	IRB Approvals	10/22/2020	(b) (4)		(b) (4)
27	N/A	Submission for HRPO Approval	10/22/2020	$0		$0
28	N/A	Quarterly Report 1 (June – September, Technical and Business Reports)	10/25/2020	$0		$0

29	3.2.2	Release of Drug Product	10/30/2020	(b) (4)		(b) (4)
30	4.3.1	Clinical Database	10/30/2020	(b) (4)		(b) (4)
31	N/A	Monthly Project Management	11/1/2020	(b) (4)		(b) (4)
32	N/A	Monthly Communications	11/1/2020	(b) (4)		(b) (4)
33	N/A	Monthly Admin, QA, Regulatory, ClinOps	11/1/2020	(b) (4)		(b) (4)
34	1.2	Submission of IND Application to US FDA	11/6/2020	(b) (4)		(b) (4)
35	N/A	Nebulizers	11/6/2020	(b) (4)		(b) (4)
36	1.3	FDA trial authorization	11/7/2020	(b) (4)		(b) (4)
37	4.4.3	Site Initiation and Training	11/8/2020	(b) (4)		(b) (4)
38	4.5.1	1st subject screened, randomized and enrolled in study.	11/8/2020	$0		$0
39	N/A	Monthly Project Management	12/1/2020	(b) (4)		(b) (4)
40	N/A	Monthly Communications	12/1/2020	(b) (4)		(b) (4)
41	N/A	Monthly Admin, QA, Regulatory, ClinOps	12/1/2020	(b) (4)		(b) (4)
42	N/A	Monthly Site Monitoring	12/1/2021	(b) (4)		(b) (4)
43	N/A	Medical Monitoring	12/1/2021	(b) (4)		(b) (4)
44	N/A	Safety Reporting	12/1/2021	(b) (4)		(b) (4)
45	N/A	Monthly Project Management	1/1/2021	(b) (4)		(b) (4)
46	N/A	Monthly Communications	1/1/2021	(b) (4)		(b) (4)
47	N/A	Monthly Admin, QA, Regulatory, ClinOps	1/1/2021	(b) (4)		(b) (4)
48	N/A	Monthly Site Monitoring	1/1/2021	(b) (4)		(b) (4)
49	N/A	Medical Monitoring	1/1/2021	(b) (4)		(b) (4)
50	N/A	Safety Reporting	1/1/2021	(b) (4)		(b) (4)
51	N/A	Quarterly Report 2 (October – December, Technical and Business Reports)	1/25/2021	$0		$0
52	N/A	Monthly Project Management	2/1/2021	(b) (4)		(b) (4)
53	N/A	Monthly Communications	2/1/2021	(b) (4)		(b) (4)
54	N/A	Monthly Admin, QA, Regulatory, ClinOps	2/1/2021	(b) (4)		(b) (4)
55	N/A	Monthly Site Monitoring	2/1/2021	(b) (4)		(b) (4)
56	N/A	Medical Monitoring	2/1/2021	(b) (4)		(b) (4)
57	N/A	Safety Reporting	2/1/2021	(b) (4)		(b) (4)
58	3.3	(b) (4) development	2/1/2021	(b) (4)		(b) (4)

59	4.5.2	Complete 50% patient enrollment	2/3/2021	(b) (4)		(b) (4)
60	N/A	Monthly Project Management	3/1/2021	(b) (4)		(b) (4)
61	N/A	Monthly Communications	3/1/2021	(b) (4)		(b) (4)
62	N/A	Monthly Admin, QA, Regulatory, ClinOps	3/1/2021	(b) (4)		(b) (4)
63	N/A	Monthly Site Monitoring	3/1/2021	(b) (4)		(b) (4)
64	N/A	Medical Monitoring	3/1/2021	(b) (4)		(b) (4)
65	N/A	Safety Reporting	3/1/2021	(b) (4)		(b) (4)
66	4.5.3	Complete 100% patient enrollment	3/3/2021	(b) (4)		(b) (4)
67	4.5.4	Last patient visit	3/13/2021	$0		$0
68	4.6.1	Close out sites	3/13/2021	(b) (4)		(b) (4)
69	4.6.2	Preliminary Database Lock	3/13/2021	$0		$0
70	4.6.3	Topline study results	3/25/2021	(b) (4)		(b) (4)
71	N/A	Monthly Project Management	4/1/2021	(b) (4)		(b) (4)
72	N/A	Monthly Communications	4/1/2021	(b) (4)		(b) (4)
73	N/A	Monthly Admin, QA, Regulatory, ClinOps	4/1/2021	(b) (4)		(b) (4)
74	N/A	Monthly Site Monitoring	4/1/2021	(b) (4)		(b) (4)
75	N/A	Medical Monitoring	4/1/2021	(b) (4)		(b) (4)
76	N/A	Safety Reporting	4/1/2021	(b) (4)		(b) (4)
77	N/A	Final Reports	4/5/2021	$0		$0
			Total	**$4,956,163**		**$4,956,163**