GeoVax Ebola Vaccine
Summary June 10, 2019

Purpose The purpose of this document is to provide an overview of the GeoVax Ebola vaccine with intent to advance the product into clinical development.

The Vaccine The GeoVax Ebola vaccine, GEO-EM01, is an MVA-VLP vaccine against Ebola. It expresses the VP40 matrix protein and the GP glycoprotein from the Makona (most recent outbreak) strain of Ebola virus.

Results to Date GEO-EM01 was tested in guinea pigs and rhesus macaques for immunogenicity and efficacy against live virus challenge. In both animal models, it was immunogenic and protected 100% of animals against a relevant challenge virus after a single dose. Results of other MVA-vectored vaccines, including the GeoVax HIV vaccine, indicate that the recombinant MVA platform is extremely safe and highly immunogenic. There is high confidence and evidence that GEO-EM01 will be safe, immunogenic, and protective in humans.

Advantages Advantages of the GeoVax vaccine over the leading Ebola vaccine candidates are provided below.

Advantages over VSV (Merck/NewLink)

- Superior safety profile of MVA
- More extensive clinical experience with MVA than VSV
- Lack of immunological vector control, ability to immunize again using MVA
- Reduced need for cold chain
- Single product, no need for heterologous boost
- Protection after single dose

Advantages over Ad/MVA

While the VSV vaccine is appropriate for use in outbreak response, several characteristics of the vaccine (particularly reactogenicity) make it unsuitable for use in large preventive vaccination campaigns. ***GEO-EM01 is much better suited for routine vaccination and will fill this critical gap****.*

While the Ad/MVA combination is safer than the VSV vaccine and appears to be effective, the need for a heterologous

prime-boost regimen means that this will be an impractically complicated and expensive vaccine. ***GEO-EM01 provides a superior alternative***

Needs To advance GEO-EM01, funding (whether cash or in-kind) is required for these critical activities. The first two items (additional efficacy studies) are not required by FDA, but they are

important to demonstrate the value of the vaccine and the compelling need to advance it into the clinic. The following items (items #3 and higher) are prerequisites for a Phase 1 trial.

1. Efficacy studies in cynomolgus macaques. The cynomolgus macaque model is more widely used than the rhesus model for studies of preventive Ebola vaccines. Data in the cynomolgus macaque model are critical to demonstrate to key opinion leaders that the GeoVax vaccine is effective. *Estimated cost: $500K*

2. Efficacy studies against aerosol challenge. Ebola is a pathogen that could potentially be weaponized, and the bad actor would presumably attempt to deliver Ebola using an aerosol form of delivery. No vaccine has yet been shown to be safe and effective against aerosol Ebola challenge in animals. We believe that our vaccine could fill this critical gap. *Estimated cost N/A. This work would only be funded and performed by DoD.*

3. cGMP production of seed virus. A cGMP master seed virus is required for production of tox material and clinical trial material. *Estimated cost: $750K*

4. Production of tox material. A tox study is required for us to initiate clinical testing of this vaccine, and material for the tox study must be manufactured from the cGMP seed. *Estimated cost: $500K - $1.4M, depending on extent of process and analytical development done before tox lot production.*

5. Tox study. To enter our vaccine into Phase 1 testing, we must first perform an IND-enabling tox study. *Estimated cost: $300K*

6. cGMP production of Phase 1 clinical trial material. We need to produce our Phase 1 material so that we can submit an IND. *Estimated cost: $1.4M - $2.3M, depending on whether full process and analytical development done before tox lot production.*