Possible Vaccine Availability Under EUA

### Vaccine A

**Candidate**: Vaccine A

**November 2020**
- The goal is to submit to the FDA late November to request EUA.
- Vaccine being produced concurrently with Phase 3 clinical trials.

**December 2020 - March 2021**
- Goal is to have 100 Million doses

**End of December 2021**
- Goal is to have 1.3 Billion doses

## Vaccine Packaging Overview

- 2ml type 1 glass preservative fee multidose vial (MDV)
- Each MDV has **0.45ml** frozen liquid vaccine product
- 5 doses per vial
- Single tray ("Pizza Box") holds 195 vials
- 975 doses per tray
- Tray (white Box) 229 x 229x40mm
- Minimum 1 tray (975 doses) or up to 5 trays (max 4875) stacked in a payload carton
- Payload carton submerged in 23 Kg dry ice pellets (10 mm-16 mm pellets)
- Thermal shipper ("Pizza Box") dimensions
  - Internal: 245mmx245mmx241mm
  - External: 400mmx400mmx560mm
- Total weight of the thermal shipper - 35 kg

## Vaccine Storage & Handling at the Point of Vaccination

**Ultra-Low Temperature Freezer**
- Can be stored at -70°C ± 10°C for 6 months

**Thermal Shipper**
- Must replenish dry ice within 24 hours of receiving shipment and again on day 5 & 10.
- The Thermal Shipper must only be opened twice per day and should be closed within 1 minute of opening.
- The shipper delivered with Real Time Monitoring (RTM) temperature logger, GPS enabled. This will be activated from the manufacturer to point of vaccination. It will then be disconnected.
- The thermal shipper will need to be returned to the manufacturer within 13 days.

**The Vaccine**
- Vaccine can be taken out of the tray (Pizza Box) and stored in refrigerator (at 2-8°C) and must be used within 5 days (discard unused doses after 5 days). This is the vaccine straight from the box that is NOT reconstituted.
- Once the vaccine is reconstituted using the diluent, it can be stored at room temperature (RT) and must be used within 6 hours (discard unused, reconstituted vaccine after 6 hours).

## Vaccine Administration

1. **Take the vaccine vial (0.45ml)** out of the Pizza Box or refrigerator
   - Let it thaw for 30 mins at room temperature
   - Gently invert the vaccine vial 10 times to homogenize the content
2. **Draw 1.8 ml of the provided Diluent** (saline provided in 3m vial) and combine it with the vaccine
   - Use 3 ml syringe/23-gauge needle
   - Invert 10 times again
3. **Draw 0.3 ml (one dose)** of the reconstituted vaccine
   - (using 1 ml syringe/21-23gauge needle)
   - **Total of 5 doses** in each reconstituted vial
4. Administer by intramuscular injection (IM) to 5 individuals (must be done within 6 hours)
5. Discard any remaining liquid in the vial

### Vaccine and Diluent
- **0.45 ml Vaccine**
- **1.8 ml Diluent**
- **2.25 ml Reconstituted Vaccine**
- **Dose 1 (0.3ml)**
- **Dose 2 (0.3ml)**
- **Dose 3 (0.3ml)**
- **Dose 4 (0.3ml)**
- **Dose 5 (0.3ml)**
- **Discard remaining vaccine**