UNCOMPROMISING INTEGRITY ✦ RESPECT FOR ALL ✦ COMMITTED TO EXCELLENCE ✦ ALWAYS READY ✦

JPEO-CBRND

EFFORTS ON THE PLAGUE rF1V VACCINE SINCE 2018

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AUGMENTING VACCINE CAPABILITIES THROUGH BIOLOGICAL RESPONSE MODIFIER (BRM) CO-ADMINISTRATION

Background

- Pathway to licensure via FDA Animal Rule using pneumonic NHP model
- Recombinant F1-V protein from *Y. pestis* in aluminum-based adjuvant
- GMP manufactured in single dose vials; Stable at 4ºC for >12 years
- Completed a Phase 1 and two Phase 2 clinical trials (CT)
- Safe, well-tolerated, and highly immunogenic in >95% of vaccinated subjects (n = 849)
- Vaccination schedule shown with three doses across six months

WHO Meeting 2018

2019

Non-clinical Studies
- Confirms the correlate of protection is the serum F1-V ELISA titer
- Confirms rF1V vaccine efficacy at ≥71% against lethal challenge

2020

Manufacturing
Completed GMP manufacturing of rF1V vaccine clinical trial material

Contract Award
DoD awarded contract to Dynavax to improve the rF1V vaccine's duration and onset of protection

2021

Phase II Begins
Part 1 of the adaptive CT initiated to evaluate co-administration of CpG 1018®

2022

Phase II Part 2 Begins
Part 2 of the adaptive CT initiated with a single co-administration method

2023

Where we are Today

- Phase 2 clinical trial fully enrolled
- Phase 2 Part 2 will complete in early 2024
  - Condensed 2 dose schedule
- GMP rF1V vaccine in storage and continued stability testing
- Dynavax has available GMP CpG 1018® for single use dosing

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DYNAVAX TECHNOLGIES

PARTNER SLIDES TO FOLLOW

Dynavax Technologies rF1V-1018: A Plague Vaccine For Rapid Response

OCT 12, 2023

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Overview: rF1V-1018: A Plague Vaccine For Rapid Response

- CpG 1018® adjuvant (**Dynavax Technologies Corporation**) is a TLR9 agonist promoting T-helper 1 immune responses used in HEPLISAV-B® (2 doses over 1 month) and 5 COVID-19 vaccines which have received EUA or full approvals worldwide.

- The rF1V antigen has been developed as an investigational plague vaccine by MCS JVAP (US Department of Defense) requiring 3 doses over 6 months.

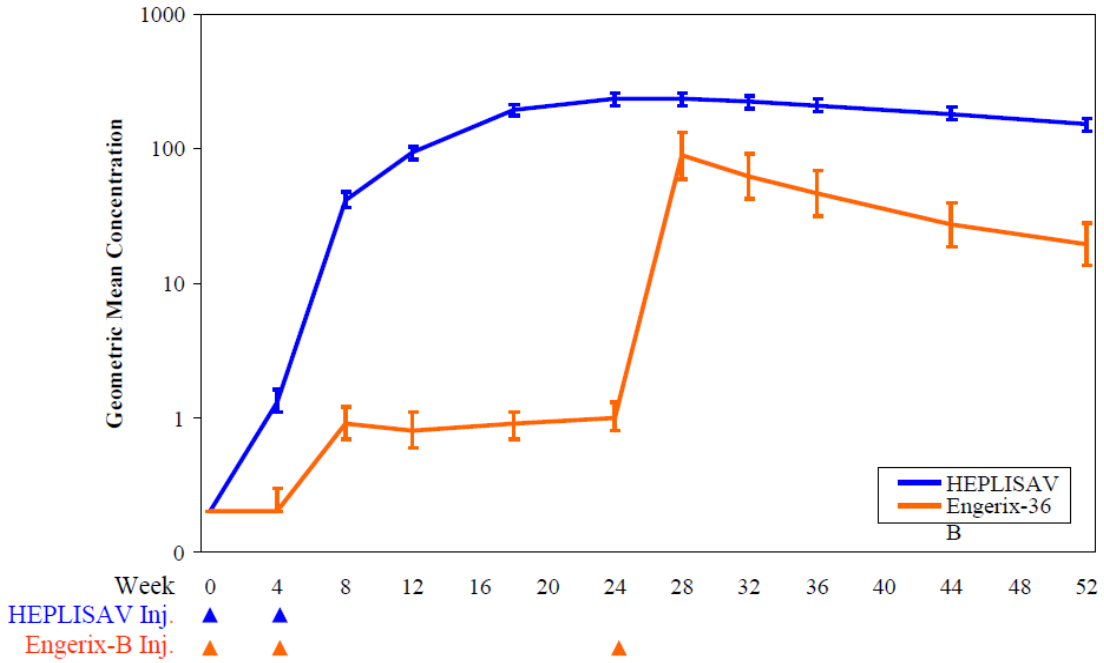
- In collaboration with the US DoD*, Dynavax is evaluating an improved plague vaccine **rF1V-1018** utilizing Dynavax's proprietary CpG 1018® adjuvant

- **rF1V-1018** is currently in a **Phase 2** human trial (N=200)
  - rF1V-1018 (2 doses, 1 month apart) is being compared to the legacy rF1V antigen-only vaccine (3 doses over 6 months)
  - CpG 1018® induces a **more rapid and higher response,** greater than two-fold higher antibody response after two doses.

- **Improved** vaccine **rF1V-1018** is
  - Being developed to provide protection with **2 doses IM, 1 month apart**
  - Intended to enable rapid response
  - Has **potential** for use in civilian context in **endemic areas**

*Funding from MCS JVAP Contract W911SR-21-9-0011 is acknowledged

CpG 1018® Adjuvant Enables Higher and More Persistent Antibody Responses in HEPLISAV-B® Adult Hepatitis B Vaccine



- 0, 4-week schedule
- HEPLISAV-B® : 48 weeks after last dose, declined 1.5-fold from peak
- Engerix-B: 28 weeks after last dose, declined 4.6-fold from peak
- HEPLISAV-B® induced superior anti-HBsAg antibodies at all visits
- Similar reactogenicity and safety profile for both vaccines

Reference: Heyward. Vaccine. 31 (2013) 5300–5305

DYNAVAX

CLOVER COVID Vaccine Efficacy Study

Subunit Vaccine containing Spike protein + CpG 1018® Adjuvant

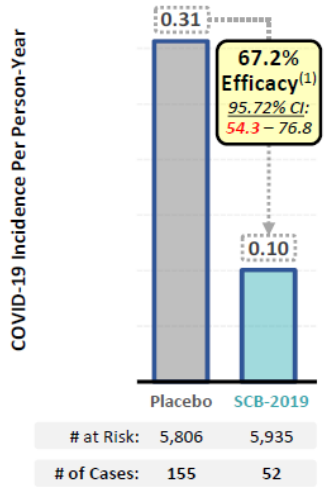
SPECTRA: Primary and key secondary efficacy objectives were met

- ✓ **Primary Endpoint is met:** VE against COVID-19 of any severity is 67.2% (LL of 95.72% CI >30%)
- ✓ **Key Secondary Endpoint 1 is met:** VE against moderate-to-severe COVID-19 is 83.7% (LL of 97.86% CI >0%)
- ✓ **Key Secondary Endpoint 2 is met:** VE against severe COVID-19 is 100% (LL of 97.86% CI >0%)

100% of strains were variants.
Efficacy against gamma = 92%

COVID-19 of Any Severity[1]

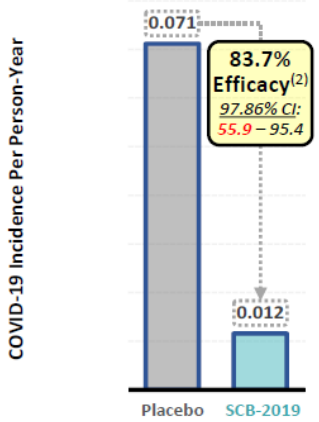
Efficacy Against: **Any Strain**



	Placebo	SCB-2019
# at Risk:	5,806	5,935
# of Cases:	155	52

Moderate-to-Severe COVID-19[2]

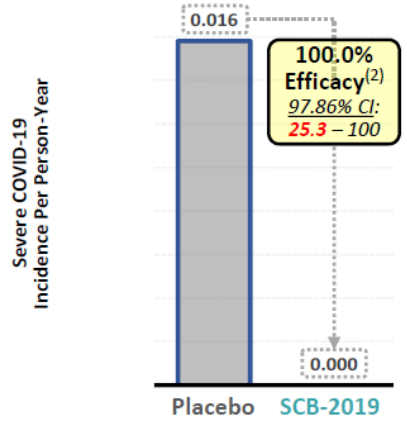
Efficacy Against: **Any Strain**



	Placebo	SCB-2019
# at Risk:	5,806	5,935
# of Cases:	36	6

Severe COVID-19[2]

Efficacy Against: **Any Strain**



	Placebo	SCB-2019
# at Risk:	5,806	5,935
# of Cases:	8	0

Notes: Figures show data for PCR-confirmed COVID-19 at ≥14 days after second dose in baseline seronegative participants.
(1) Predefined success criteria for primary endpoint: Lower Limit of 95.72% confidence interval exceeds 30%.
(2) Predefined success criteria for key secondary endpoints: Lower Limit of 97.86% confidence interval exceeds 0%.

Reference: Bravo. Lancet. 22 (2022) 990-1001

rF1V-1018 Plague Vaccine: Phase 2 Clinical Study

Protect with fewer doses in less time

Dynavax Phase 2 – Compares rF1V antigen + CpG 1018® adjuvant (2 doses, 1 month apart) to the historical DoD antigen rF1V-only regimen (3 doses, 6 months) (NCT05506969)

Part 1 (N=60) completed Jan 2023

- Compare CpG 1018 co-administration vs. mixing at time of use
- Successfully met primary endpoint
- Both CpG 1018 adjuvanted arms demonstrated a greater than two-fold increase in antibodies over the alum adjuvanted control arm after two doses

Part 2 (N=140) ongoing through 2024

- Study continues with CpG 1018 mixed at time of use

Summary and Next Steps

- A Phase 2 plague vaccine, rF1V-1018 is intended to protect with fewer doses in less time
  - Includes clinically validated antigen rF1V with CpG 1018® a proven adjuvant.

- Preliminary analysis from Phase 2 study shows rF1V-1018 results in a rapid and higher antibody response with 2 doses IM in 1 month.

- NHP challenge studies are underway to generate correlates of protection data that may be used under FDA Animal rule for near term use under EUA and future approvals.

- Furthermore, with its potential for more rapid and higher immune responses, rF1V-1018 may be considered for future clinical studies in endemic settings.

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