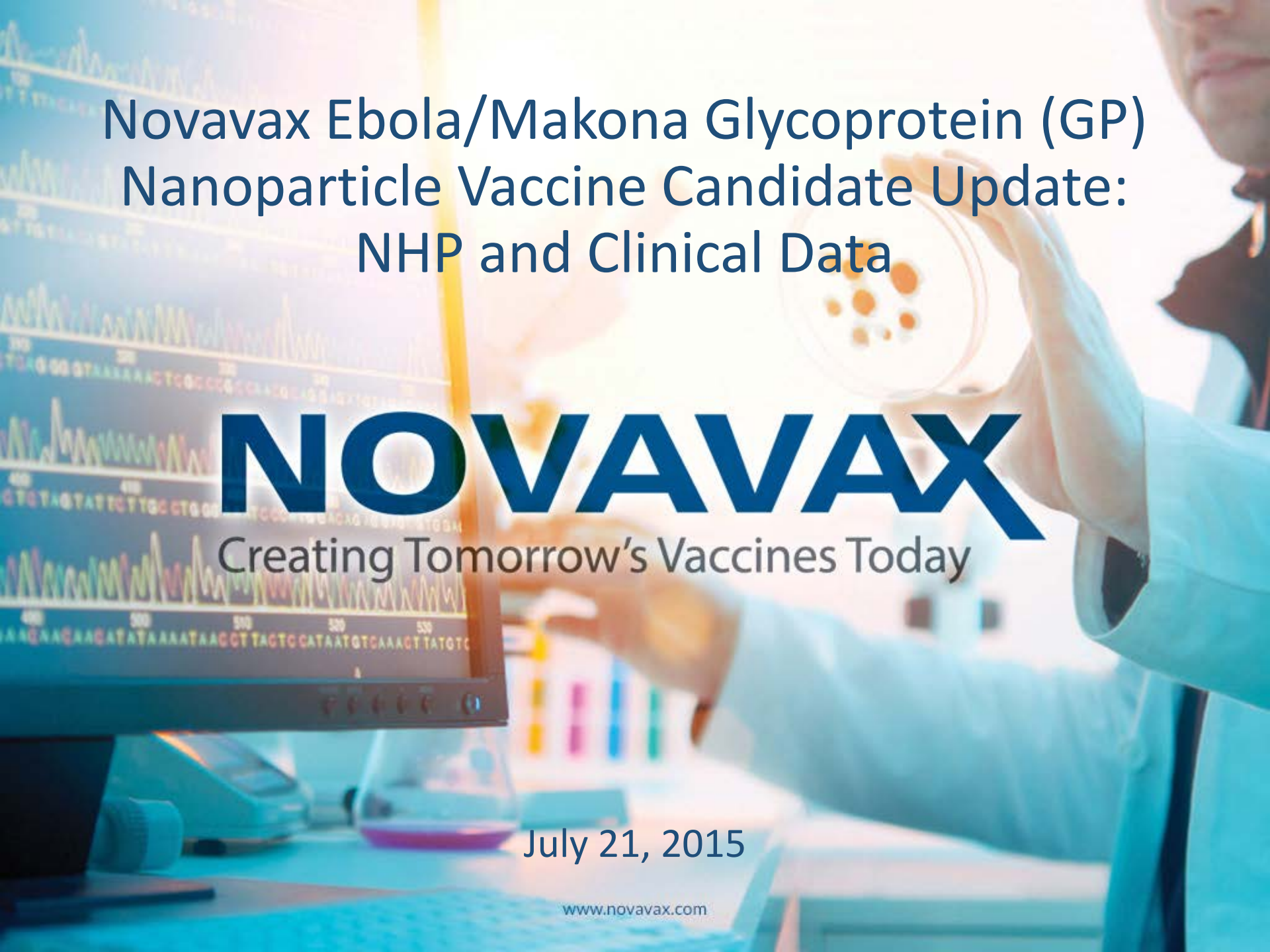
Novavax Ebola/Makona Glycoprotein (GP) Nanoparticle Vaccine Candidate Update: NHP and Clinical Data



July 21, 2015

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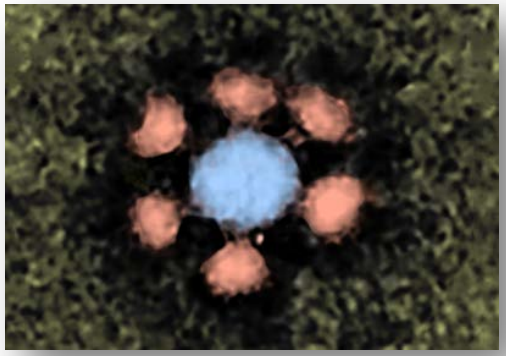
Novavax Ebola GP Nanoparticle Vaccine



- Ebola Zaire Makona GP Nanoparticle Vaccine
  - Recombinant, full length EBOV/Makona GP trimers
  - 30 – 40 nm spherical nanoparticles
- Matrix-M™ adjuvant
  - Nano-particulate saponin-based adjuvant
    - Promising stability in long-term pre-formulation with ZEBOV GP
  - EBOV-H-101 represents 8th clinical trial using Matrix-M
  - Most recently with flu H7N9-well tolerated, dose sparing, robust HAI
    - Adjuvant-induced cross-protection in avian influenza
  - Toxicology study completed prior to study initiation
    - Transient injection site, draining lymph node inflammatory response
    - No distant tissue findings

Novavax EBOV-H-101 Protocol

- Randomized, placebo-controlled, dose-escalating design with safety monitoring committee oversight
- Primary Objectives:
  - To accumulate a safety profile based on 7-day solicited reactogenicity, 84-day all AE profile, 1-year MAE and SAE profile, selected clinical labs
  - To demonstrate Matrix-M adjuvant effect on anti-GP IgG responses
  - To select the lowest antigen dose yielding a anti-EBOV GP IgG response not < the maximum feasible unadjuvanted dose
- Secondary Objectives:
  - To describe serum immune responses in terms of antibody titers competitive with known-neutralizing EBOV GP mab (13C6)
  - To describe antibody response kinetics in response to 1 and 2-dose regimens through one year
  - To compare Novavax anti-GP IgG with ELISA and neutralizing antibody responses from an external lab (University of Marburg)

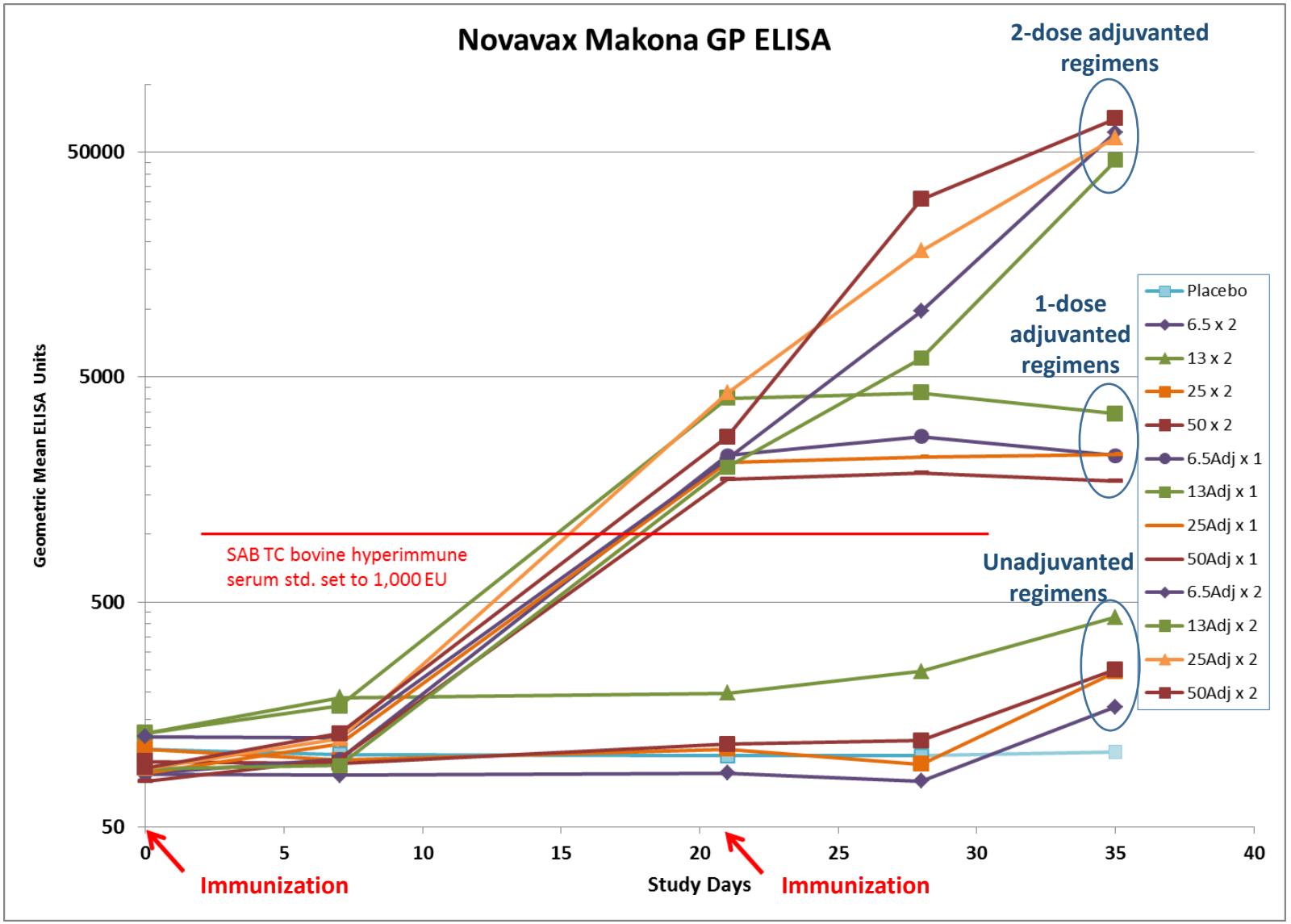
Novavax EBOV-H-101

Study Design							
Treatment Group	Day 0 Vaccination		Day 21 Vaccination		Subjects per Group		
	EBOV GP Antigen Dose	Matrix-M™ Adjuvant Dose	EBOV GP Antigen Dose	Matrix-M™ Adjuvant Dose	Stage 1	Stage 2	Stage 3
A	6.5µg	--	6.5µg	--	5	5	5
B	6.5µg	50µg	6.5µg	50µg	5	5	5
C	6.5µg	50µg	0µg (Placebo)	--	5	5	5
D	13µg	--	13µg	--	5	5	5
E	13µg	50µg	13µg	50µg	5	5	5
F	13µg	50µg	0µg (Placebo)	--	5	5	5
G	25µg	--	25µg	--	0	5	10
H	25µg	50µg	25µg	50µg	0	5	10
J	25µg	50µg	0µg (Placebo)	--	0	5	10
K	50µg	--	50µg	--	0	5	10
L	50µg	50µg	50µg	50µg	0	5	10
M	50µg	50µg	0µg (Placebo)	--	0	5	10
N	0µg (Placebo)	--	0µg (Placebo)	--	10	15	25
				Total Subjects per Stage	40	75	115
				Total Subjects		230	

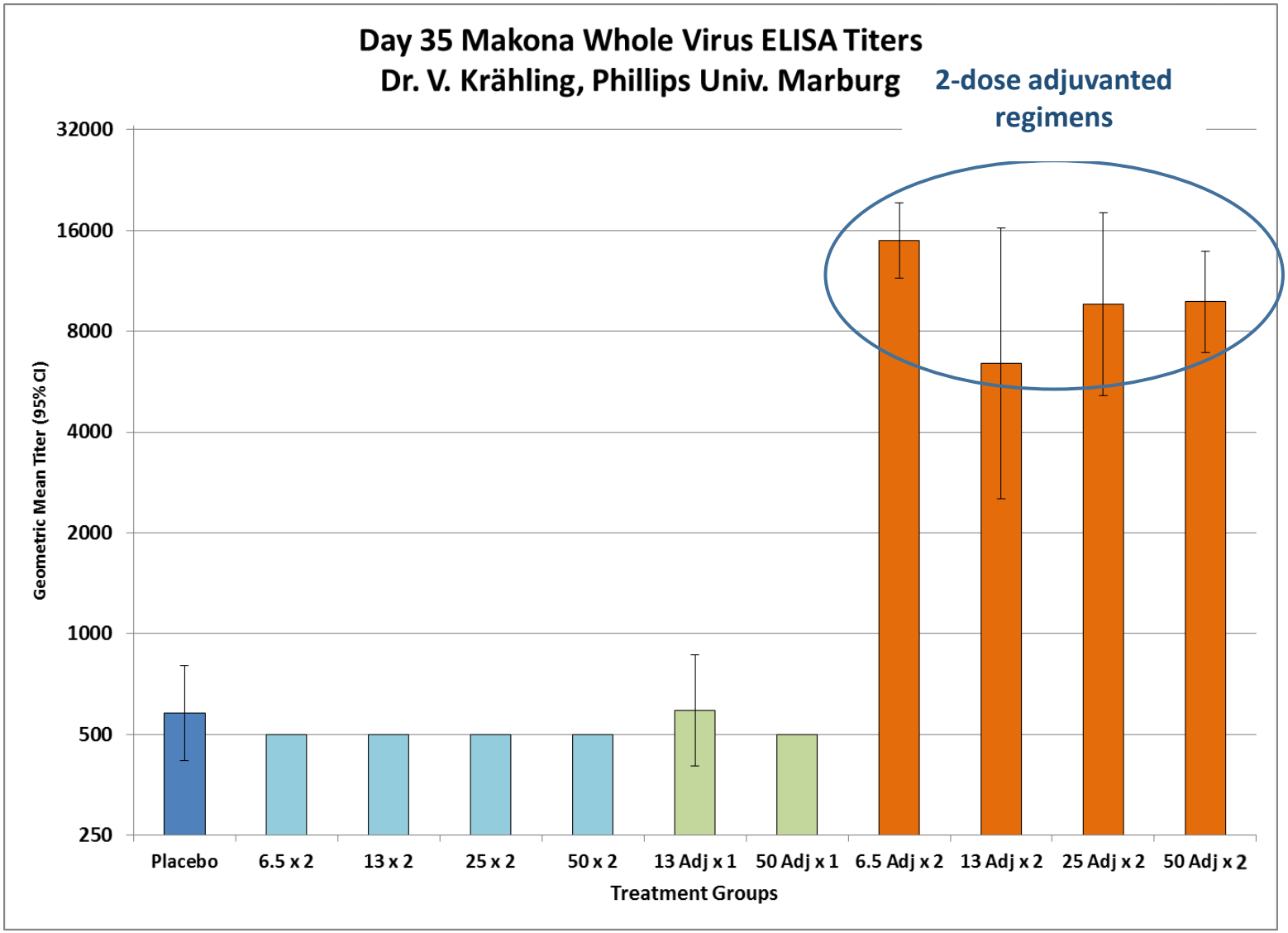
Novavax EBOV-H-101 Status

- Clinical trial material for phase I released Dec 2014
- 230 healthy young adults 18 to < 50 y.o., male and non-pregnant female; recruited in Australia.
- First subject dosed 10 Feb 2015
  - No stopping rules triggered during dose escalation
- Last subject received second dose April 2015
- Current data span days 0 – 35
  - Safety – all subjects
  - Novavax Makona GP ELISA – all per-protocol subjects
  - Inactivated Makona whole-virus capture ELISA provided by Dr. V. Krähling, Univ. Marburg. 100-subject randomly selected panel at day 35 spanning placebo and 10 of 12 active groups
- Pending, ~ 24 July, neutralization data on same 100 serum panel from University of Marburg (Dr. Becker).

Novavax ZEBOV Makona IgG ELISA Preliminary Results



Whole Virus ELISA Results



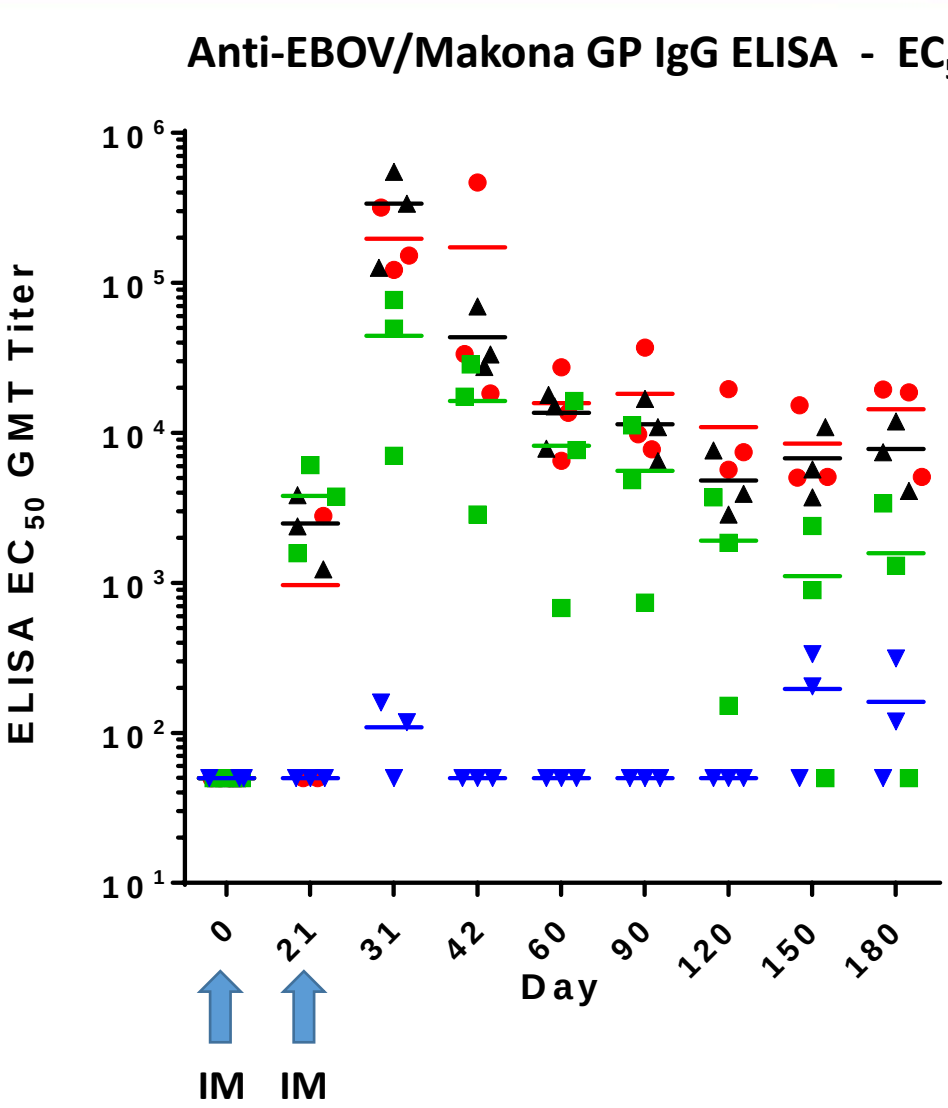
Novavax EBOV-H-101 Safety to Date

- Dose escalation completed without triggering stopping rules
- No attrition due to AE
- Local injection site pain
  - 8.3% of placebo recipients
  - 21.6% of unadjuvanted vaccine recipients
  - 60.0% of 1-dose adjuvanted vaccine recipients and 91.6% of 2-dose adjuvanted vaccine recipients
  - Predominantly mild
  - Transient
- Fever in 1 placebo recipient (2.1%), no 1-dose adjuvanted vaccine recipients and 3 in 2-dose adjuvanted vaccine recipients (5.0%)
  - None >38.9^{o}C
- Mild to moderate headache, myalgia, arthralgia and fatigue
- One SAE – active vaccinee with trauma secondary to auto accident
- Rates of severe; severe and related unsolicited AEs closely similar in active and placebo subjects

Preclinical NHP *Cynomolgus macaque* Challenge Summary

1. Texas Biomedical NOV2014-001- Complete
    - 5µg EBOV GP + Matrix
    - Immunization Day 0 and 21 (n=3)
    - 100% survival, challenged with 100 pfu wt ZEBOV Kikwit
2. OBRA/DMID/NIAID Stage one C25 - Complete
    - 5µg EBOV GP + Matrix
    - Immunization Day 0 and 42 (n=2) or Day 21 and 42 (n=2)
    - 100% survival, challenged with 100 pfu wt ZEBOV Kikwit
3. OBRA/DMID/NIAID Stage two C29 - Challenge result pending
    - 5µg or 1µg EBOV GP + Matrix (n=8)
    - 5µg EBOV GP + 5µg SUDV GP + Matrix (n=2)
    - Immunization Day 7 and 28
    - Challenged with 100 pfu wt virus ZEBOV Kikwit, 14 July 2015

Baboon Modeled Anti-EBOV GP IgG Response



Welliver et al,
Univ. of Oklahoma

- 5 µg EBOV GP + Matrix
- 60 µg EBOV GP + Matrix
- 60 µg EBOV GP + $AlPO_4$
- 60 µg EBOV GP

- Adjuvant effect
- Dose sparing
- Durability
- 13C6-like antibodies

Summary

- Full-length Recombinant Makona GP with Matrix-M adjuvant
- 100% protection against mortality in 2 NHP challenges to date, third in progress to identify failing dose
- Sustained IgG anti-GP responses in baboons
- Phase 1 data to date:
  - Adjuvant increases local and systemic reactogenicity, but symptoms are predominantly mild-moderate and transient
  - Approx. 3% vaccine-attributable incidence of mild-to-moderate fever in 2-dose adjuvanted vaccine groups
  - Approximately 10-fold antigen dose-sparing with Matrix-M (6.5 vs 50μg)
  - Two-dose adjuvanted regimens strongly immunogenic
  - Similar findings with Univ. Marburg Whole Virus ELISA
  - One-dose regimens readily detected, lower compared to two-dose
  - Neutralization data pending
- Further development of this vaccine is warranted