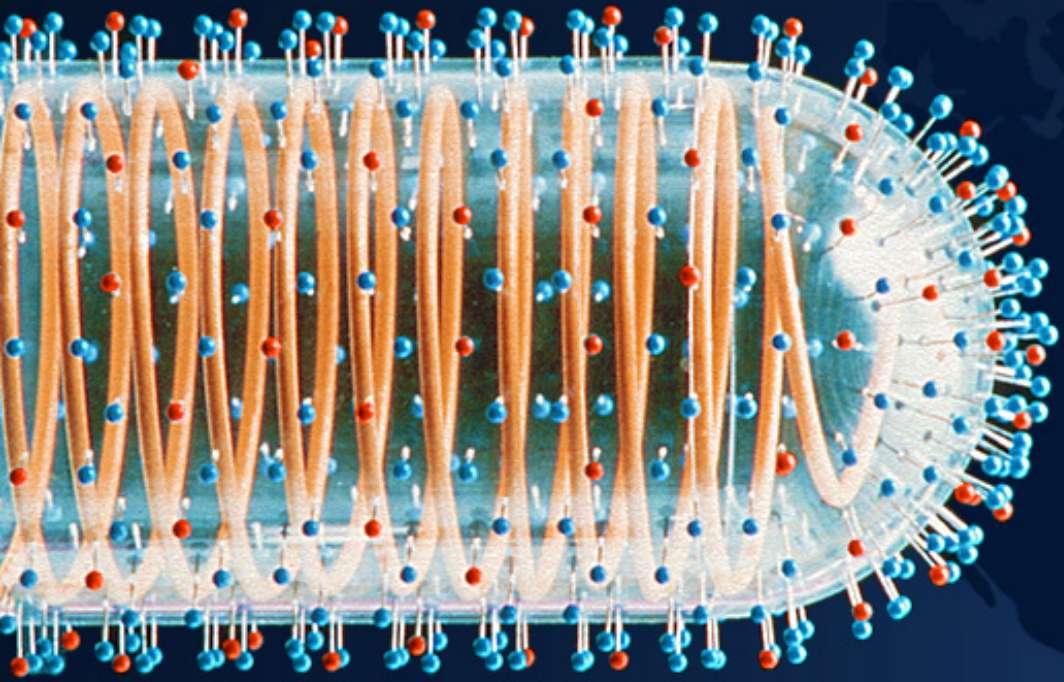
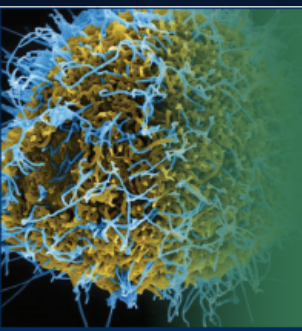
PROFECTUS BIOSCIENCES



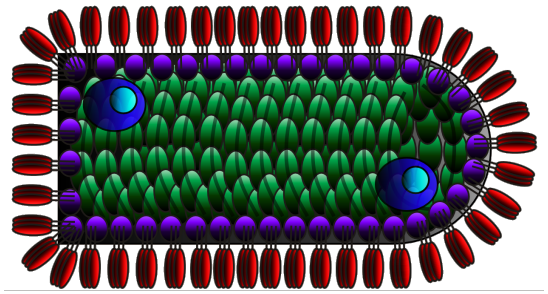
Filovirus rVSV Vaccines

- **Michael A. Egan, Ph.D.**
- Director of Immunology



Hemorrhagic Fever Viruses

December 4–8, 2016 | Hilton Santa Fe Historic Plaza Hotel | Santa Fe, New Mexico | USA



Presentation Outline:

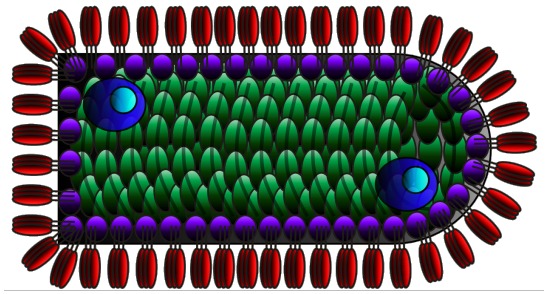
1.) Background on the VesiculoVax™ Vaccine Platform

2.) Ability of a Single Dose Tri-valent VesiculoVax™ panFilo Vaccine to protect against EBOV, SUDV and MARV challenge

3.) Phase I Safety and Immunogenicity of the mono-valent VesiculoVax™ EBOV Vaccine

4.) Identification of a Correlate of Protection Against Aerosol MARV challenge in NHPs

5.) Future Plans



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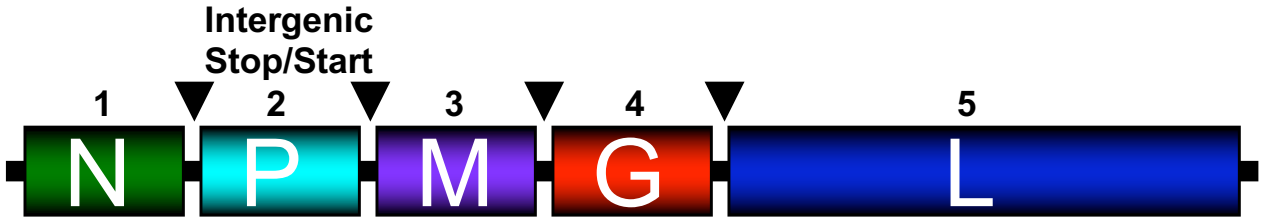
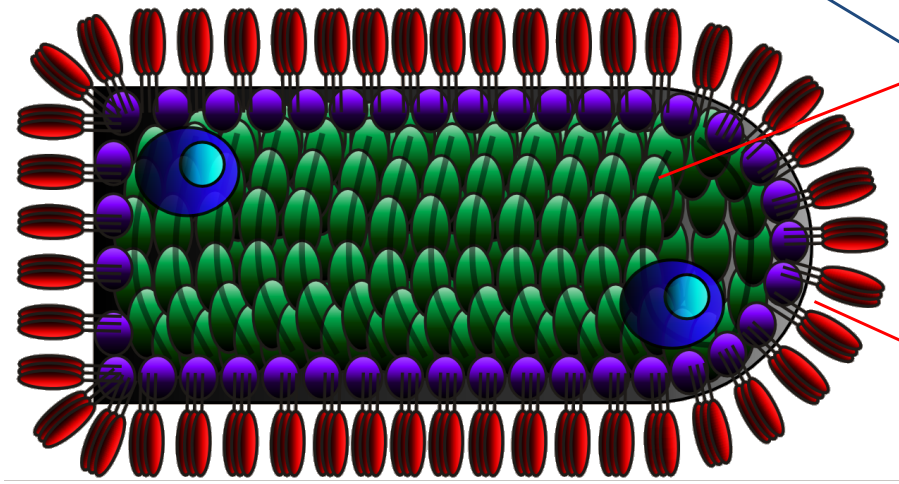
VesiculoVax™: A Family of Vaccine Vectors





RNA genome
- Nonsegmented,
- Single-stranded
- Negative-sense

Envelope

G protein
- Mediates cell attachment
- Target of neutralizing antibodies

Nucleocapsid

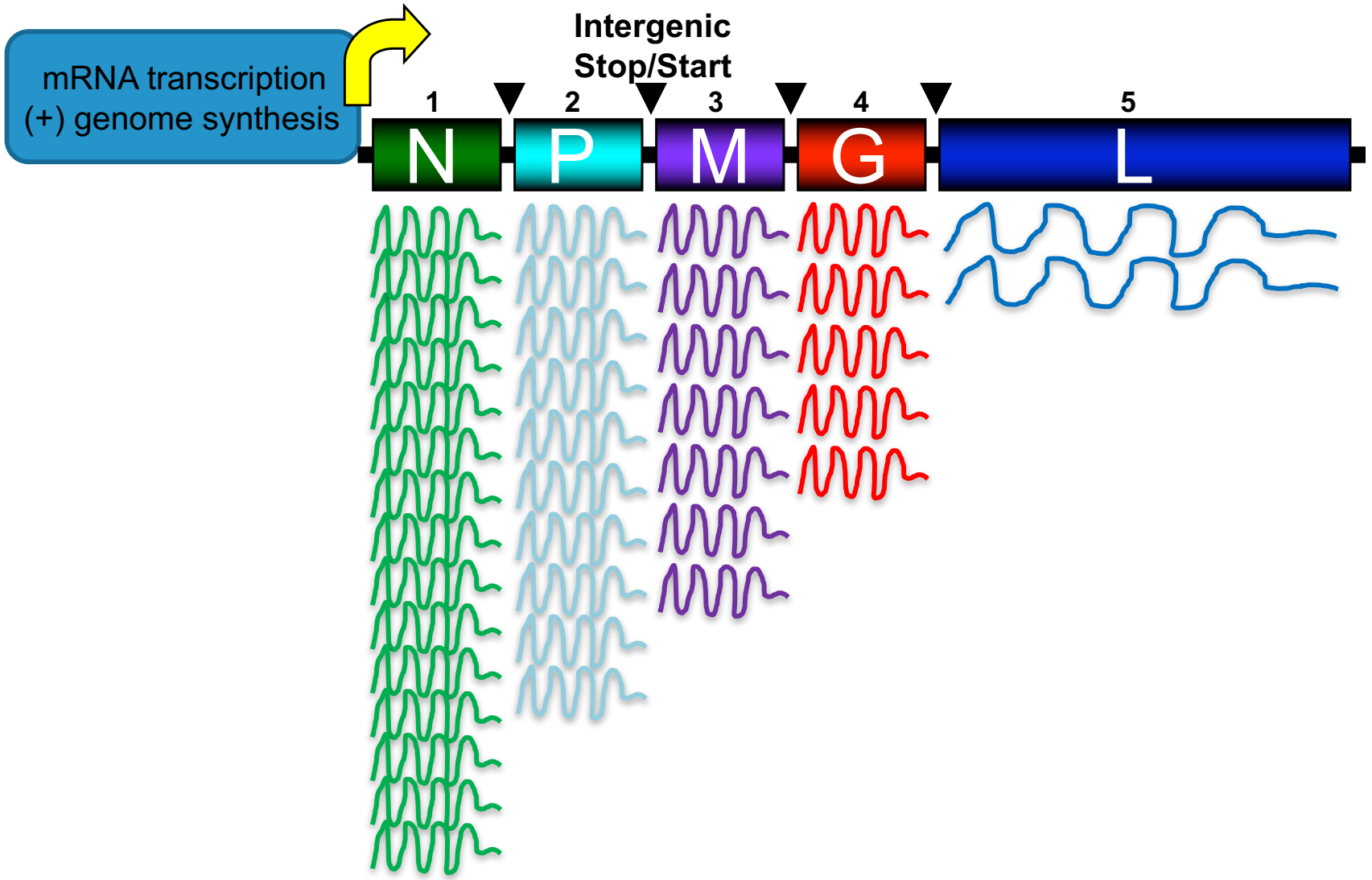
Phosphoprotein

Matrix protein

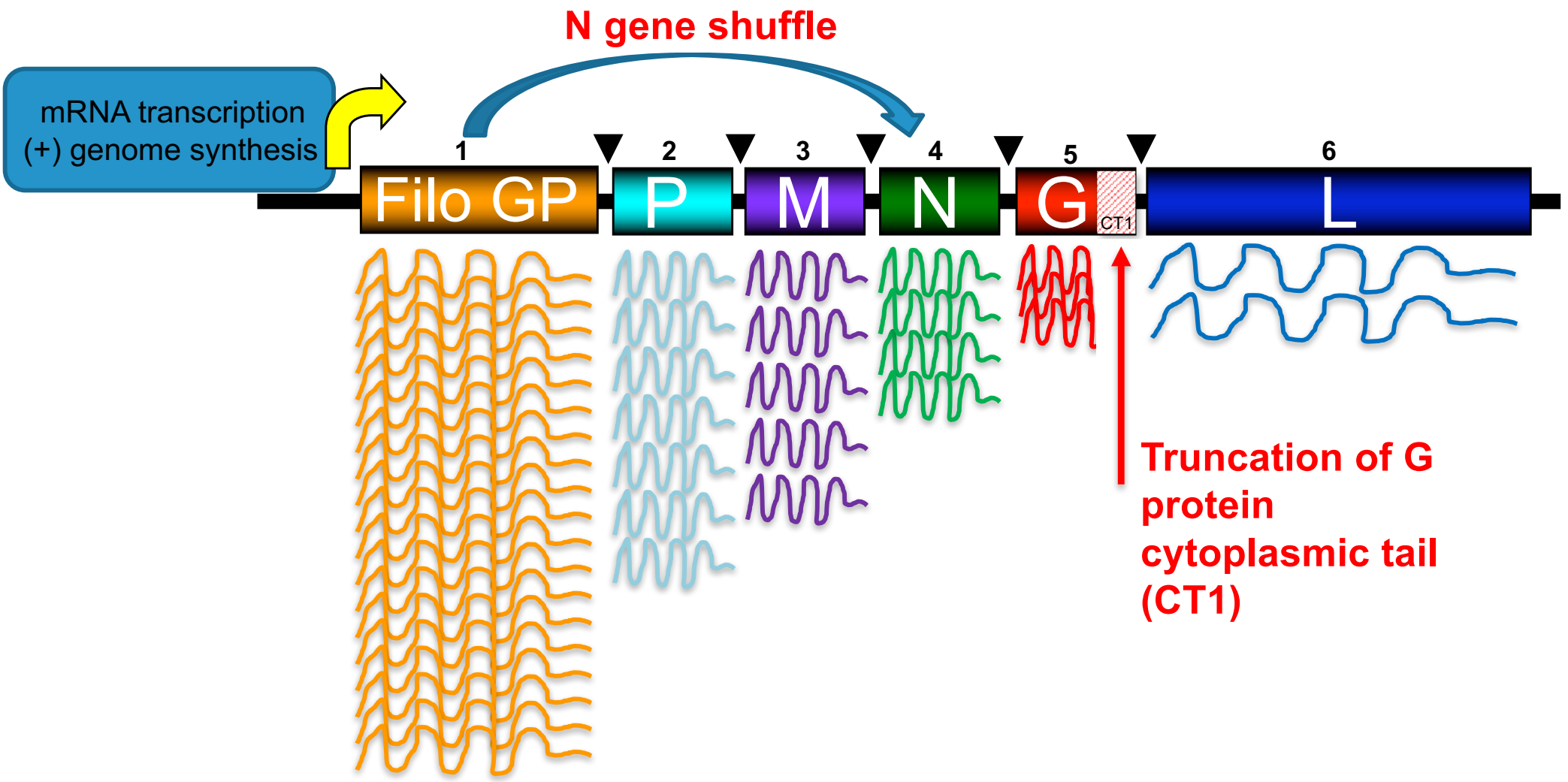
G protein

Large protein (RNA Pol)

The Vesiculovirus mRNA Transcriptional Gradient



Using the Vesiculovirus mRNA Transcriptional Gradient to Attenuate the Vector and Overexpress a Gene of Interest



VesiculoVax™ Vectored Vaccines

Single Stranded/Non-segmented/Negative-sense RNA Viruses

- Small simple genome, large capacity for inserting multiple foreign genes
- Modulation of antigen expression controlled by gene position
- Synergistic attenuating mutations:
  - [N gene shuffle (N4) & G protein CT truncation (CT1)
- **Family of non-cross-reactive (both B and T cell) vectors**
  - Four reduced to practice and three under development

Immunogenicity

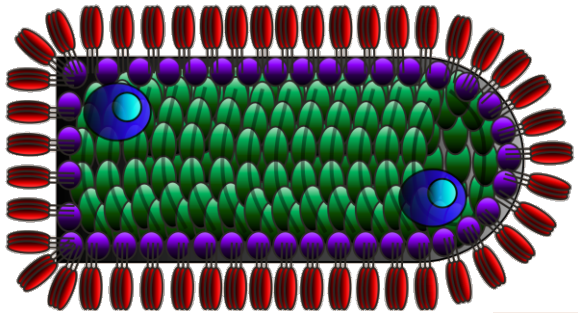
- Replication competent vectors
- Targets antigen-presenting cells
- Attenuating mutations **increase** immunogenicity

Manufacturing

- Propagates efficiently in PBS certified Vero production cell line
- GMP Manufacturing and purification processes in place

Vector Immunity

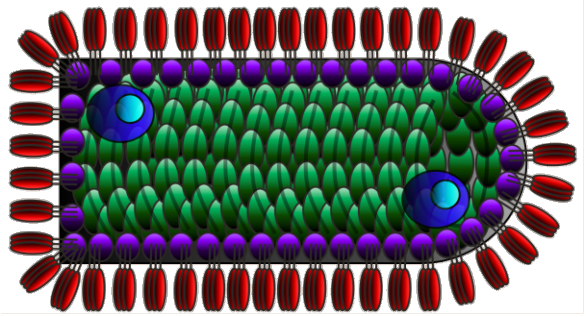
- Little pre-existing immunity in the human population
- Clinical demonstration of effective homologous boosting

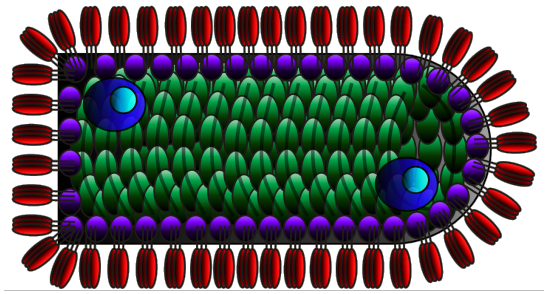


VesiculoVax™ Vectored Vaccines

rVSV N4CT1 Clinical Status

- **HVTN-090**
  - FIM dose escalation, N=60, 10^4 – 10^8 PFU
  - 100% seroconversion, 63% ELISpot response rate, **homologous boosting induces anamnestic response**
  - Safe and well tolerated, no vaccine-related SAE
- **HVTN-087**
  - pDNA prime / rVSV boost, N=100, 10^8 PFU
  - 92% CD4 ICS response rate, 58% CD8 ICS response rate, highest ICS response rate in any HVTN trial
  - Safe and well tolerated, no vaccine-related SAE
- **TheraVax**
  - pDNA prime / rVSV boost, N=30, 10^7 PFU
  - Study is on-going
  - Safe and well tolerated, no vaccine-related SAE
- **HVTN-112**
  - pDNA prime / rVSV boost, N=15, 10^7 PFU
  - Study is on-going
- **EBOV-001**
  - FIM dose escalation, N=39, 10^4 – 10^6 PFU
  - Study is on-going





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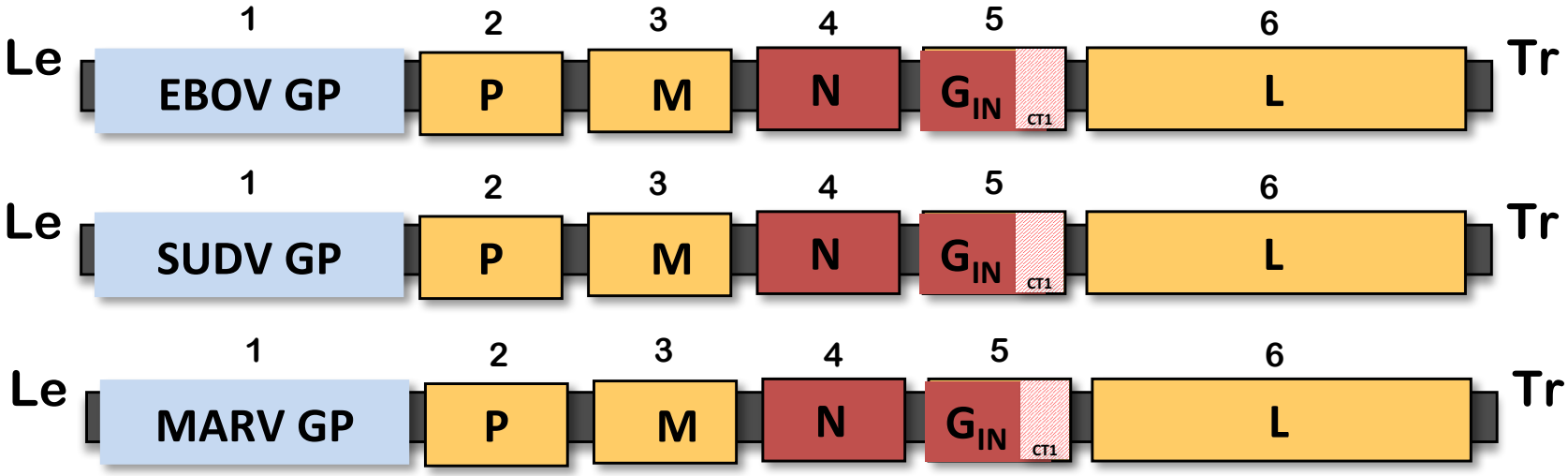
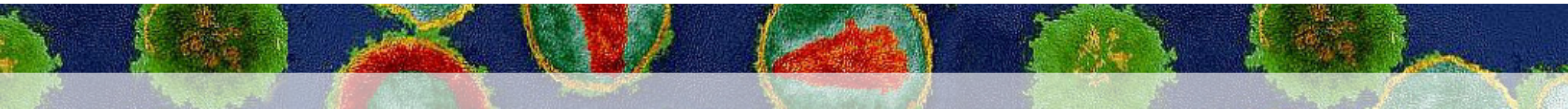
rVSV Vectored Tri-Valent Filovirus Vaccine Candidate

rVSVN4CT1-panFiloGP

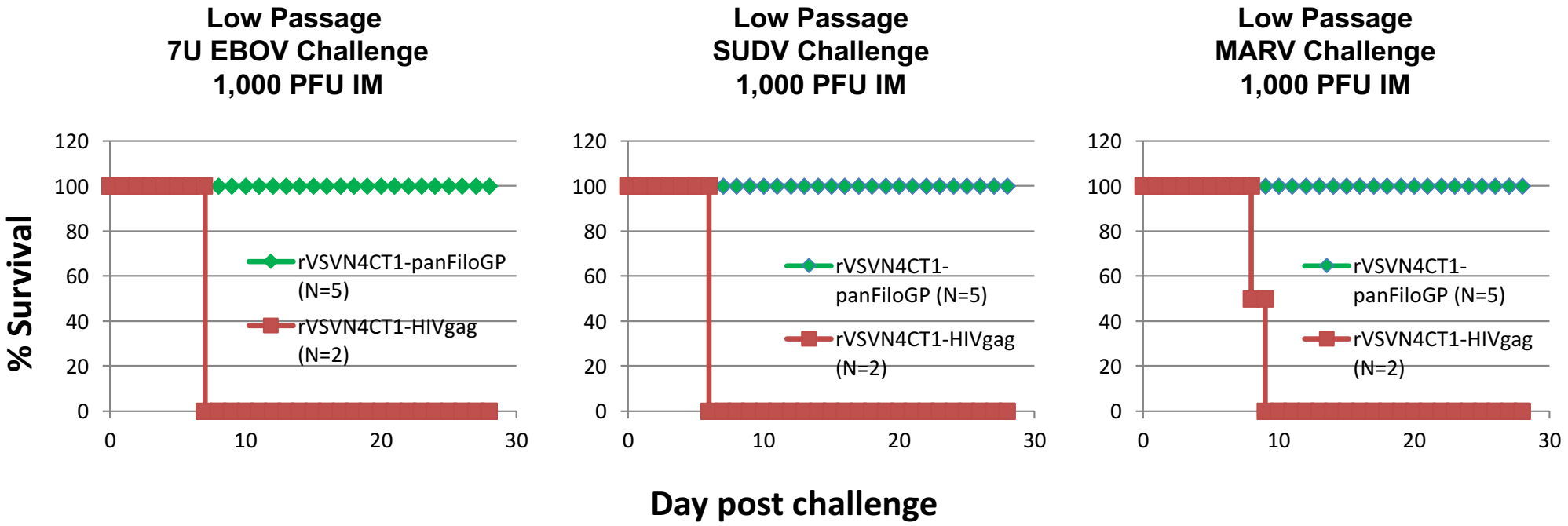


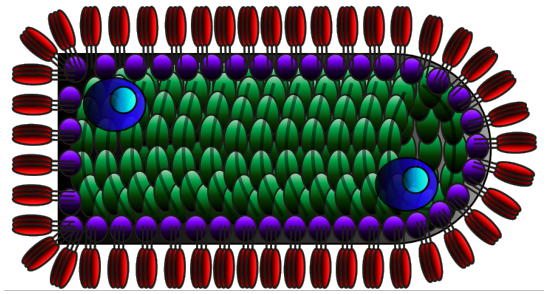


Single Dose NHP Immunogenicity/Efficacy Trial of Tri-Valent rVSVN4CT1-panFilovirus Vaccine

Iteration	Group	Vaccine	Dose (PFU)	Animals		Vacc. Day	1,000 PFU IM Virus Challenge Day 28
				M	F		
1	1	Tri-val N4CT1 panFiloGP(a1)	3×10^7	3	2	0	EBOV (Kikwit)
	2	N4CT1-HIVgag(s1)	3×10^7	1	1		
2	3	Tri-val N4CT1 panFiloGP(a1)	3×10^7	3	2	0	SUDV (Gulu)
	4	N4CT1-HIVgag(s1)	3×10^7	1	1		
3	5	Tri-val N4CT1 panFiloGP(a1)	3×10^7	3	2	0	MARV (Angola)
	6	N4CT1-HIVgag(s1)	3×10^7	1	1		

Efficacy of a Single Dose Tri-Valent rVSVN4CT1-panFilovirus Vaccine in NHPs





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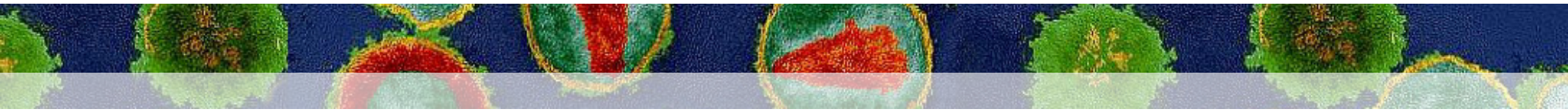
A Phase 1 Clinical Trial to Evaluate the Safety and Immunogenicity of a Monovalent Ebola Zaire Vaccine (rVSVN4CT1-EBOVGP1) Delivered by Intramuscular Injection in Healthy Adult Subjects

IND No.: BB-IND-16670

Phase: 1
Protocol Number: rVSV-EBOV-01

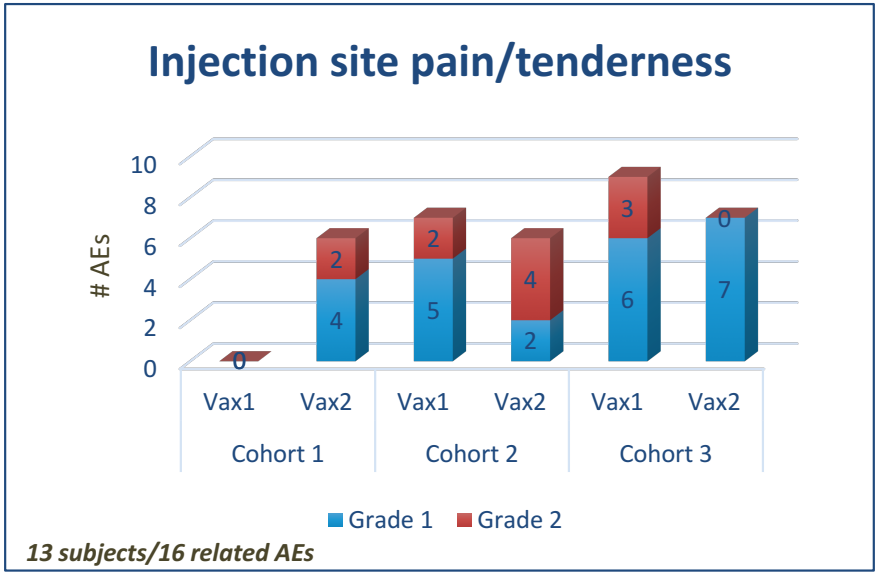


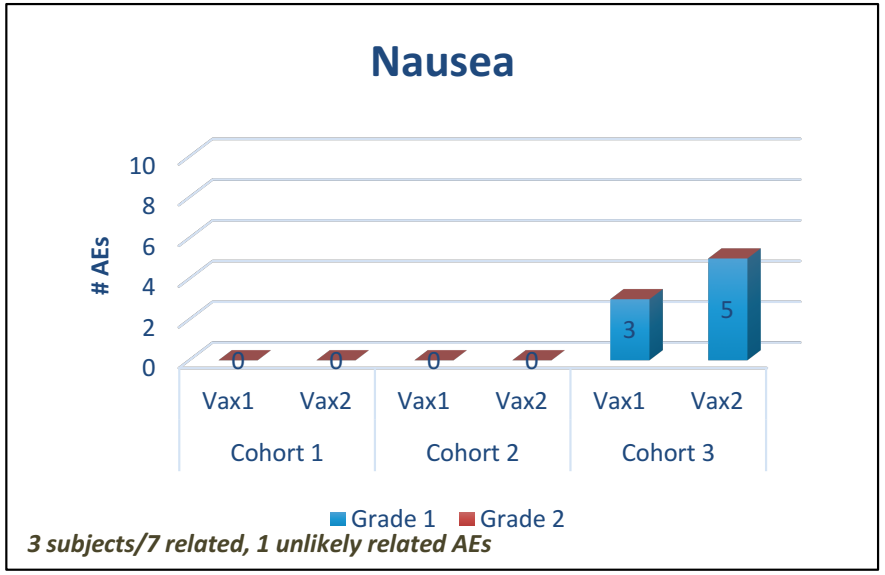
Protocol Number: rVSV-EBOV-01

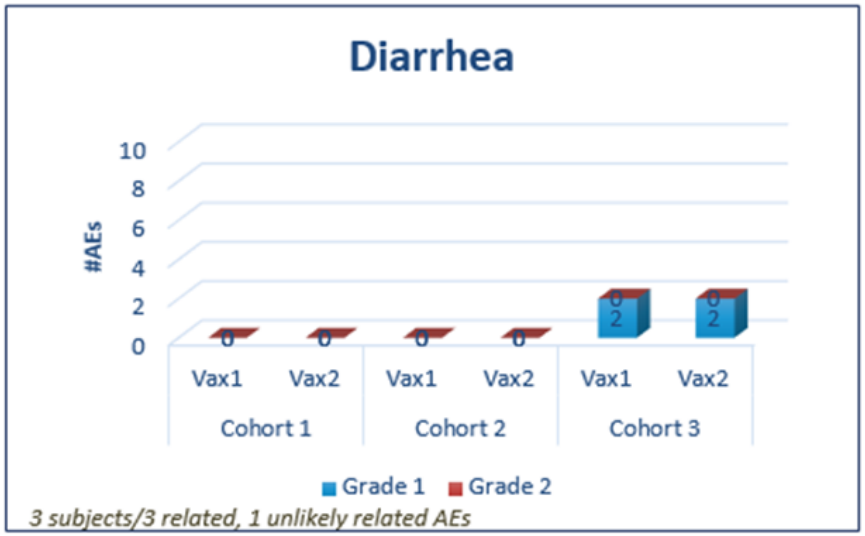
Phase 1 Dose Escalation and Vaccination Schedule in Months (Days)				
Study Arm	**N**	**Dose**	**Month 0 (Day 0)**	**Month 1 (Day 28)**
Group 1	10	2.5 x 10^4 PFU	rVSVN4CT1-EBOVGP1	rVSVN4CT1-EBOVGP1
	3	—	control (saline)	control (saline)
Group 2	10	2.5 x 10^5 PFU	rVSVN4CT1-EBOVGP1	rVSVN4CT1-EBOVGP1
	3	—	control (saline)	control (saline)
Group 3	10	2.0 x 10^6 PFU	rVSVN4CT1-EBOVGP1	rVSVN4CT1-EBOVGP1
	3	—	control (saline)	control (saline)
Total	39 (30 vaccine/9 placebo)			

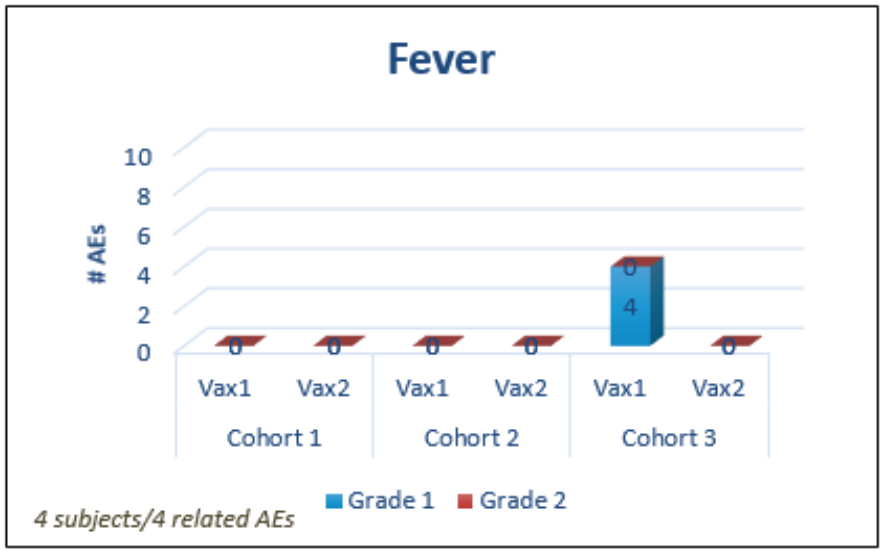
Notes: All immunizations will be administered IM in the deltoid; for Groups 1 and 2 each dose will be delivered bi-laterally as 2 x 0.5 mL inoculations, and for Group 3 as 2 x 1.0 ml inoculations; CoA = Certificate of Analysis; PFU = plaques forming units.

Protocol Number: rVSV-EBOV-01: Adverse Events



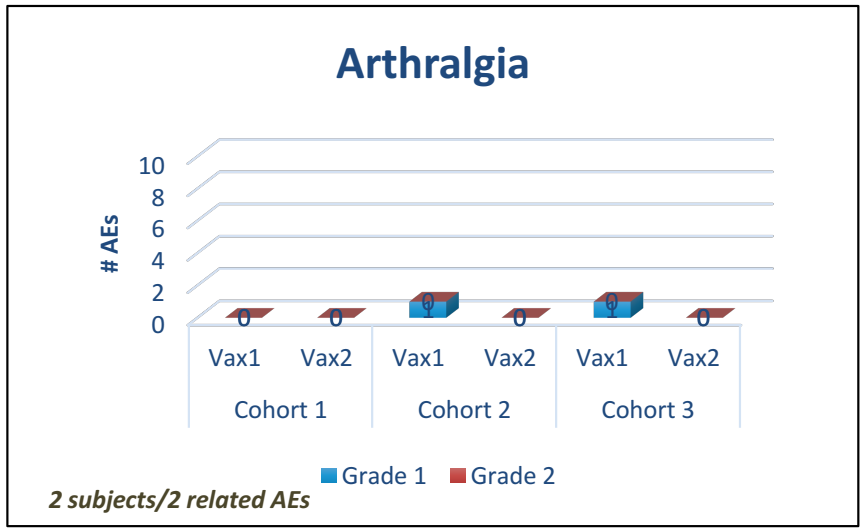




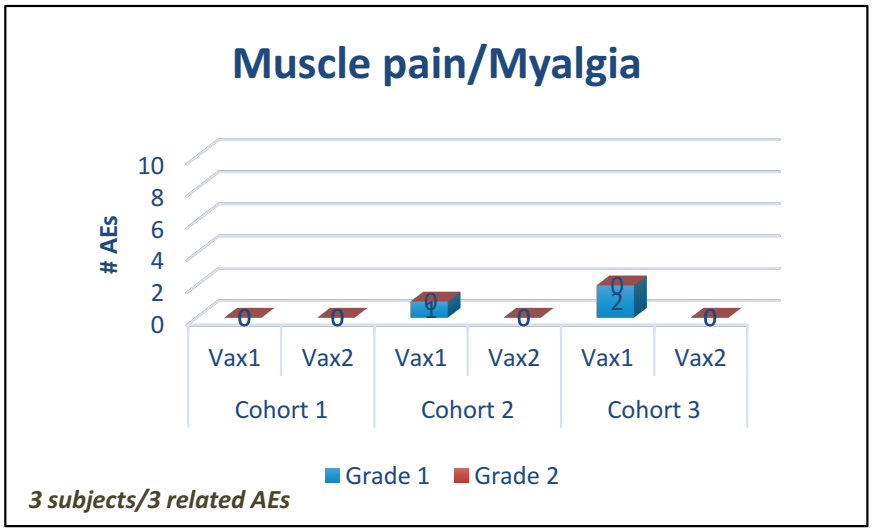


From blinded data (Active and Placebo), *excluding* AEs considered unrelated.

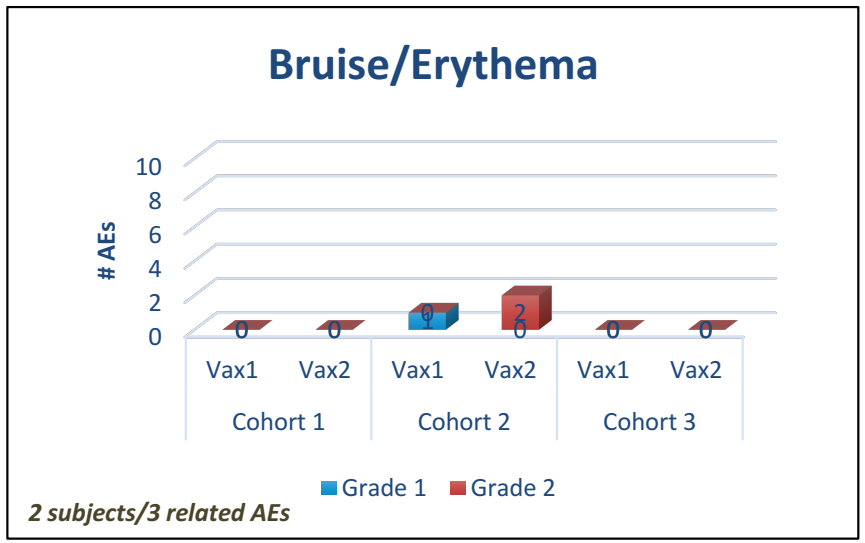
Protocol Number: rVSV-EBOV-01: Adverse Events



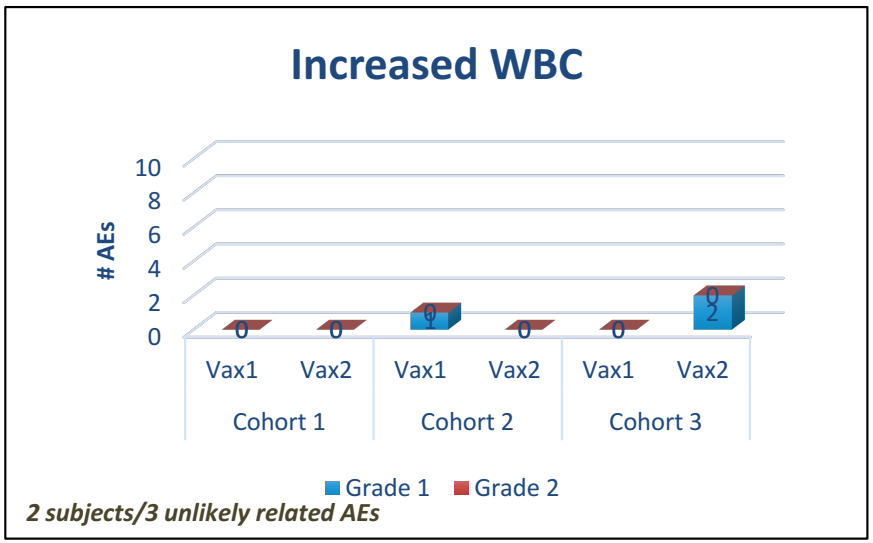
2 subjects/2 related AEs



3 subjects/3 related AEs



2 subjects/3 related AEs



2 subjects/3 unlikely related AEs

Protocol Number: rVSV-EBOV-01

Detection of Disseminated Vaccine Virus (Blinded)

Sample Day	Blood		Urine		Saliva	
	RT-qPCR (LOQ=1.36x10^3 copies/mL)	Culture Confirmed (LOD=100 PFU/0.1 mL)	RT-qPCR (LOQ=6.43x10^3 copies/mL)	Culture Confirmed (LOD=100 PFU/0.1 mL)	RT-qPCR (LOQ=8.30x10^2 copies/mL)	Culture Confirmed (LOD=100 PFU/0.1 mL)
0 (Prime)	0/39	NA	0/39	NA	0/39	NA
1	1[a]/39	Neg	0/39	NA	0/39	NA
3	0/39	NA	0/39	NA	0/39	NA
7	0/39	NA	0/39	NA	0/39	NA
14	0/39	NA	0/39	NA	0/39	NA
28 (Boost)	0/39	NA	0/39	NA	0/39	NA
29	0/38	NA	0/38	NA	0/38	NA
31	0/38	NA	0/38	NA	0/38	NA
35	0/38	NA	0/38	NA	0/38	NA
42	0/38	NA	0/38	NA	0/38	NA
56	0/38	NA	0/38	NA	0/38	NA

PROFECTUS BIOSCIENCES

[a]2.66 x 10^3 copies/mL

Protocol Number: rVSV-EBOV-01

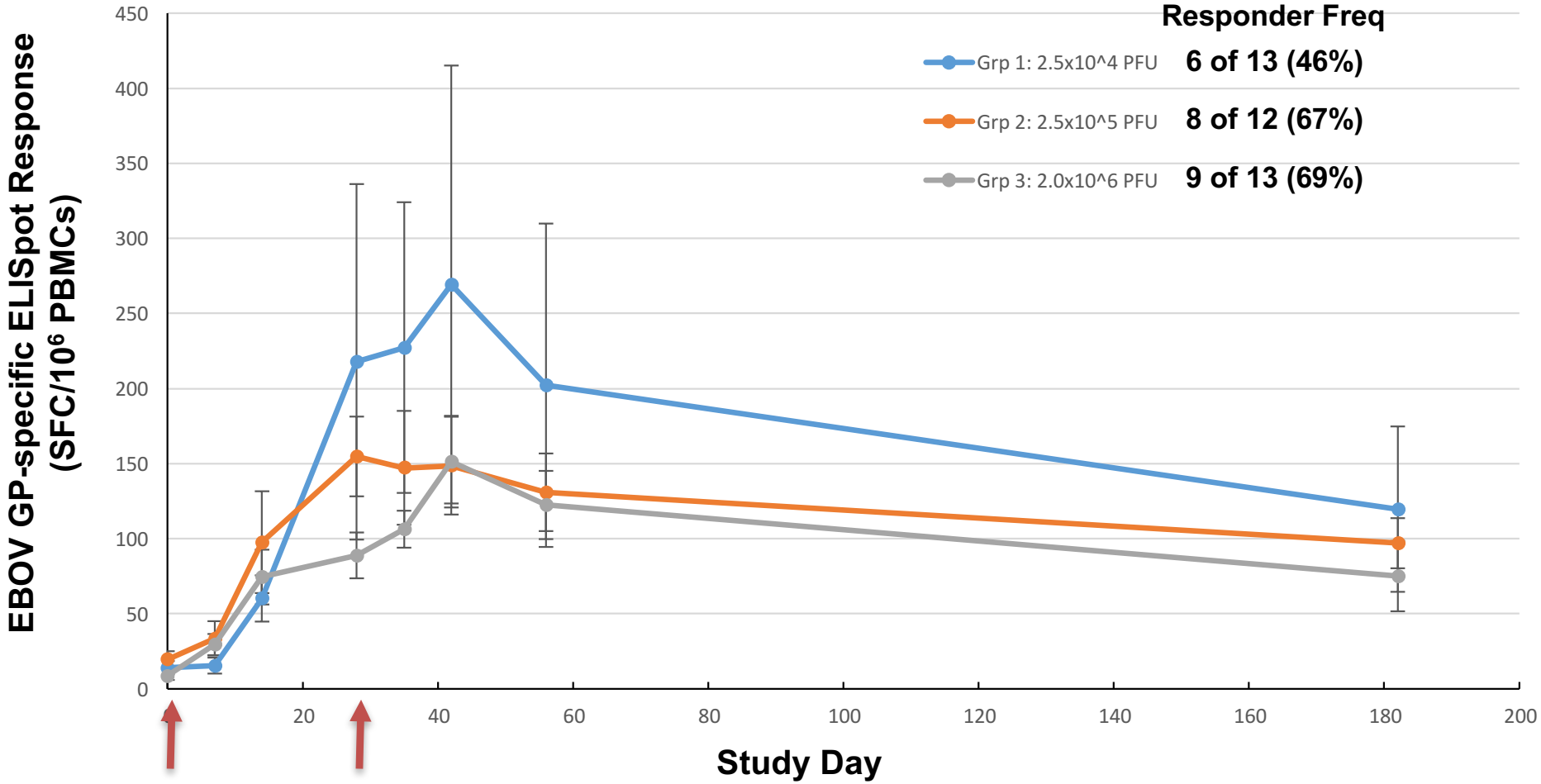
EBOV GP-specific ELISpot analysis conducted by Profectus BioSciences

Cryo-preserved PBMCs were collected at the following time points for ELISpot analysis:

Visit 2:	Day of 1st vaccination
Visit 5:	1 week post 1st vaccination
Visit 6:	2 weeks post 1st vaccination
Visit 7:	Day of 2nd vaccination
Visit 10:	1 week post 2nd vaccination
Visit 11:	2 weeks post 2nd vaccination
Visit 12:	4 weeks post 2nd vaccination
Visit 13:	22 weeks post 2nd vaccination

Protocol Number: rVSV-EBOV-01

BLINDED EBOV GP-specific cell mediated immune (CMI) responses over time by IFN-gamma ELISpot assay



Human ELISpot assay positivity criteria:

- ≥ Assay LOB (80 SFC/10^6 PBMCs for EBOV GP)
- ≥ 2x baseline visit 2 response

PROFECTUS BIOSCIENCES

Protocol Number: rVSV-EBOV-01

EBOV GP-specific ELISA analysis conducted by Battelle

Serum was collected at the following time points for ELISA analysis:

Visit 2:	Day of 1st vaccination
Visit 5:	1 week post 1st vaccination
Visit 6:	2 weeks post 1st vaccination
Visit 7:	Day of 2nd vaccination
Visit 10:	1 week post 2nd vaccination
Visit 11:	2 weeks post 2nd vaccination
Visit 12:	4 weeks post 2nd vaccination
Visit 13:	22 weeks post 2nd vaccination

Protocol Number: rVSV-EBOV-01

EBOV GP-specific ELISA responses

Cohort #1: 2.5x10^4 PFU dose level

V2: baseline
V5: 1wk post 1st vacc
V6: 2wk post 1st vacc
V7: 4wk post 1st vacc
V10: 1wk post 2nd vacc
V11: 2wk post 2nd vacc
V12: 4wk post 2nd vacc
V13: 22wk post 2nd vacc

Study 3671-100062783 **QA Reviewed ELISA Data**

Friday, November 11, 2016

Zaire (ELISA Units/mL)								
Sample ID	Visit 2	Visit 5	Visit 6	Visit 7	Visit 10	Visit 11	Visit 12	Visit 13
101-001	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
101-002	0.00	0.00	0.00	100.77	296.76	359.06	224.23	166.76
101-003	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
101-004	0.00	0.00	0.00	94.43	1151.41	1368.36	989.06	173.17
101-005	0.00	0.00	0.00	77.26	834.90	1156.26	911.86	764.14
101-006	0.00	0.00	0.00	336.14	1234.69	1221.93	1581.51	2422.92
101-007	0.00	0.00	0.00	0.00	842.88	1448.94	754.44	113.92
101-008	0.00	0.00	0.00	235.38	1066.67	2424.52	1676.85	508.24
101-009	0.00	0.00	0.00	0.00	2011.66	1936.73	647.01	66.90
101-010	0.00	0.00	0.00	651.36	1785.12	2502.64	3124.65	1176.90
101-011	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
101-012	0.00	0.00	54.81	205.51	2385.83	3162.68	1535.62	122.81
101-013	0.00	0.00	0.00	0.00	217.22	447.36	415.22	0.00
AVG	0.00	0.00	4.22	130.84	909.78	1232.96	912.34	424.29
SE	0.00	0.00	4.22	52.95	222.12	291.59	248.51	193.61

Responder Freq **10 of 13 (77%)**

Protocol Number: rVSV-EBOV-01

EBOV GP-specific ELISA responses

Cohort #2: $2.5x10^5$ PFU dose level

Study 3671-100062783 **QA Reviewed ELISA Data**

Friday, November 11, 2016

V2: baseline
V5: 1wk post 1st vacc
V6: 2wk post 1st vacc
V7: 4wk post 1st vacc
V10: 1wk post 2nd vacc
V11: 2wk post 2nd vacc
V12: 4wk post 2nd vacc
V13: 22wk post 2nd vacc

Zaire (ELISA Units/mL)								
Sample ID	Visit 2	Visit 5	Visit 6	Visit 7	Visit 10	Visit 11	Visit 12	Visit 13
101-015	0.00	0.00	0.00	119.54				
101-016	0.00	0.00	0.00	286.47	677.04	1001.72	633.79	229.18
101-017	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
101-018	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
101-021	0.00	0.00	0.00	172.17	1712.36	2726.14	2156.22	550.31
101-022	0.00	0.00	0.00	155.56	1928.72	3896.73	2053.26	623.20
101-023	71.55	89.94	162.74	273.88	2490.43	3833.38	1799.97	309.77
101-024	0.00	0.00	0.00	563.88	9704.14	13522.67	4183.83	639.84
101-025	0.00	0.00	0.00	0.00	135.56	246.09	276.02	241.48
101-026	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
101-027	0.00	0.00	197.02	1293.67	7727.87	5015.19	3718.28	2421.44
101-029	0.00	0.00	0.00	473.86	2792.56	4611.89	2869.49	327.92
101-030	0.00	0.00	0.00	329.61	841.81	1089.97	663.62	266.86
AVG	5.50	6.92	27.67	282.20	2334.21	2995.31	1529.54	467.50
SE	5.50	6.92	18.84	98.54	878.44	1061.68	414.03	181.81

Responder Freq **10 of 13 (77%)**

Protocol Number: rVSV-EBOV-01

EBOV GP-specific ELISA responses

Cohort #3: $2.0x10^6$ PFU dose level

Study 3671-100062783 **QA Reviewed ELISA Data**

Friday, November 11, 2016

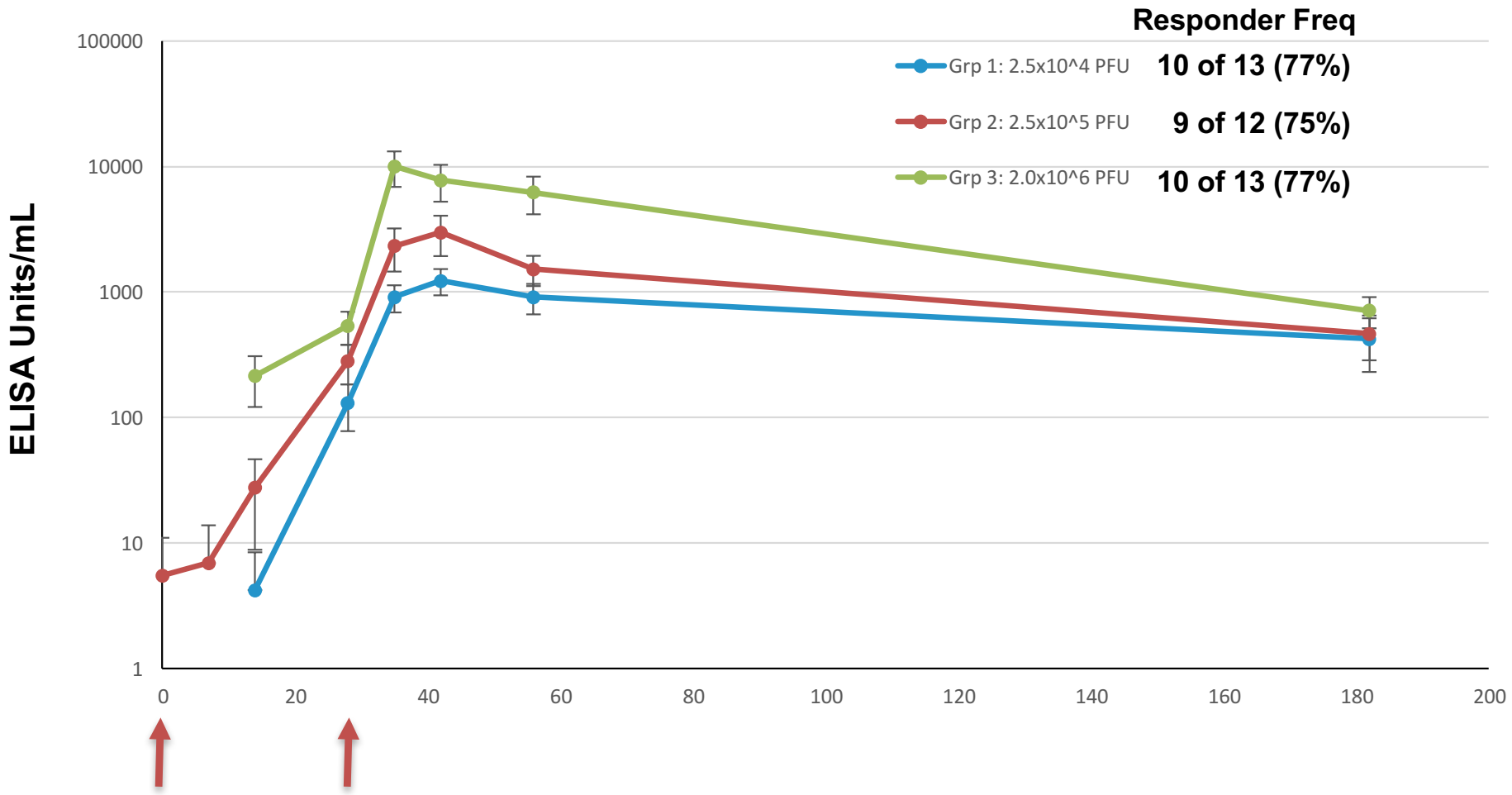
V2: baseline
V5: 1wk post 1st vacc
V6: 2wk post 1st vacc
V7: 4wk post 1st vacc
V10: 1wk post 2nd vacc
V11: 2wk post 2nd vacc
V12: 4wk post 2nd vacc
V13: 22wk post 2nd vac

Zaire (ELISA Units/mL)								
Sample ID	Visit 2	Visit 5	Visit 6	Visit 7	Visit 10	Visit 11	Visit 12	Visit 13
101-032	0.00	0.00	75.12	159.13	2900.37	5873.97	5917.56	
101-034	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
101-035	0.00	0.00	219.80	594.28	23406.12	6059.19	4413.87	459.59
101-036	0.00	0.00	140.96	390.89	8953.39	34705.93	15424.24	2372.94
101-037	0.00	0.00	82.37	317.43	2381.69	4542.56	1953.16	307.52
101-038	0.00	0.00	64.98	151.93	3284.03	2464.43	2045.51	517.12
101-039	0.00	0.00	1225.45	1365.95	14570.96	6982.50	6353.86	1373.12
101-042	0.00	0.00	0.00	155.82	2707.41	5911.33	2958.91	285.57
101-043	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
101-044	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
101-045	0.00	0.00	457.43	971.22	31026.51	11181.75	26349.20	1258.11
101-046	0.00	0.00	379.85	1268.24	30172.53	13303.51	10085.23	1004.14
101-049	0.00	0.00	146.16	1614.27	11170.07	10175.08	5596.04	972.91
AVG	0.00	0.00	214.78	537.63	10044.08	7784.63	6238.27	712.59
SE	0.00	0.00	93.43	159.03	3161.09	2536.74	2073.85	198.16

Responder Freq **10 of 13 (77%)**

Protocol Number: rVSV-EBOV-01

BLINDED Mean EBOV GP-specific ELISA responses over time

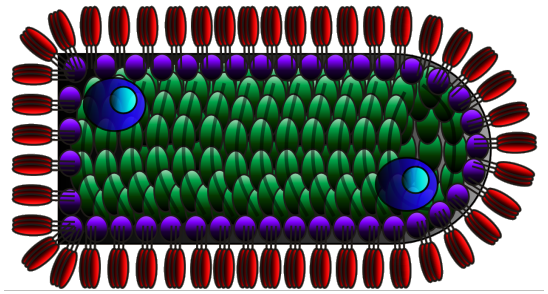


PROFECTUS BIOSCIENCES

rVSV-EBOV-01 Summary

- **Safe and well-tolerated at all tested doses**
  - No vaccine-related AEs greater than grade 2
  - 13/39 reported mild to moderate injection site tenderness
  - No other AEs reported in more than 5/39 subjects
  - Vaccine shedding:
    - 1 blood sample PCR positive, culture negative
    - PCR and culture of urine and saliva, universally negative

- **Immunogenic at all tested doses and blinded data consistent with:**
  - CMI responses by IFNγ ELISpot
    - Response rates of 60-80% post dose 1 and 80-90% post dose 2
  - Antibody responses by ELISA
    - Response rates of 70-100% post dose 1 and 100% post dose 2



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4.) Identification of a Correlate of Protection Against Aerosol MARV challenge in NHPs

5.) Future Plans

Identification of a Correlate of Protection Against Aerosol MARV challenge in NHPs

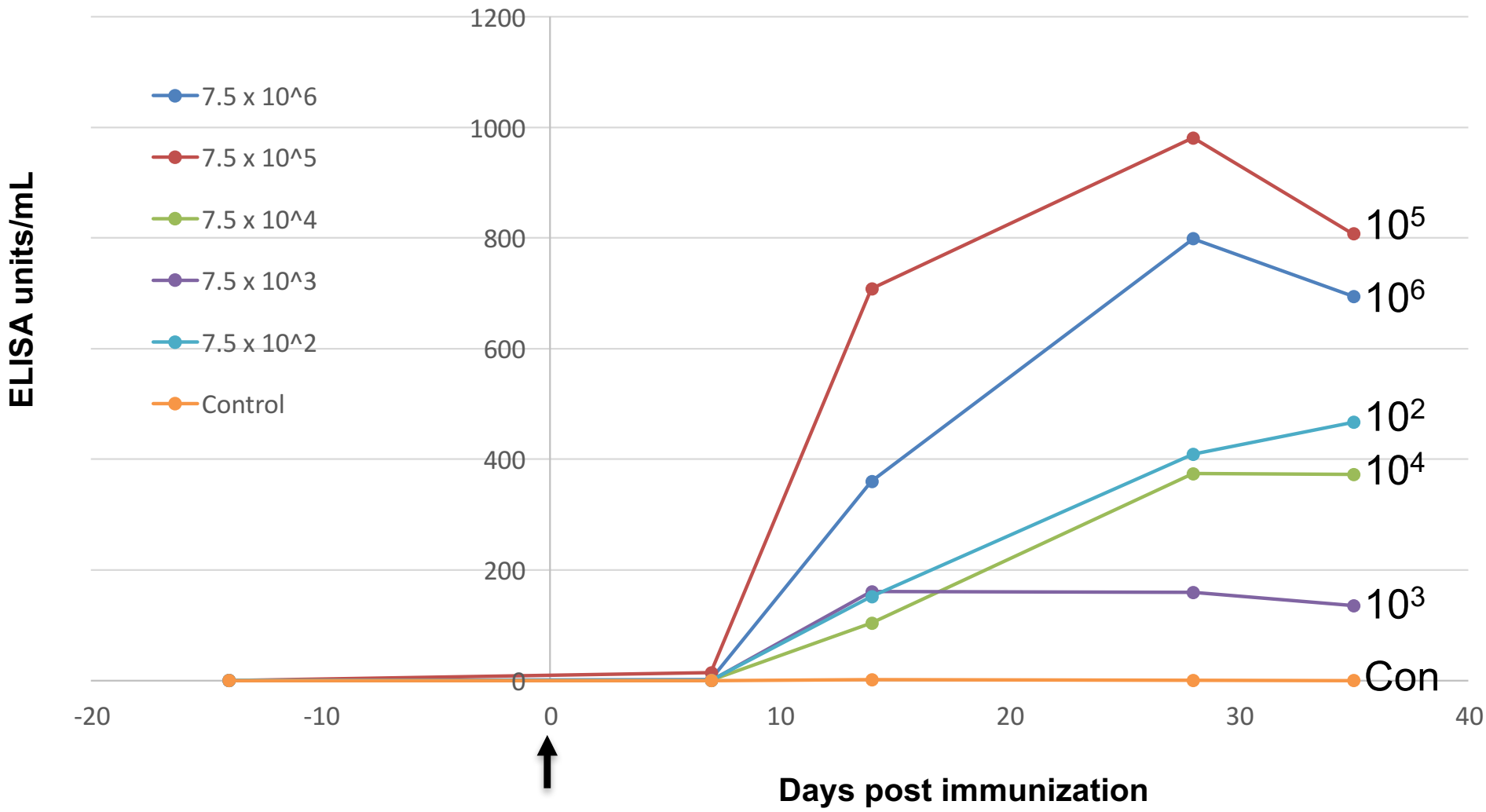
Group	Number of NHPs	Dosing Material	Vaccine Dosage (PFU)	Vaccination (Day/Route)	Challenge 1,000 PFU MARV (Day/Route)
1	5	Tri-val rVSVN4CT1 panFiloGP(a1)	7.5×10^6	0 / IM	42 / Aerosol
2	5		7.5×10^5		
3	5		7.5×10^4		
4	5		7.5×10^3		
5	4		7.5×10^2		
6	2	N4CT1-HIVgag(s1)	7.5×10^6		

N=26

Goal: to achieve a wide range of:

- MARV GP-specific immune responses
- Post MARV challenge protection

Anti-EBOV GP ELISA titers



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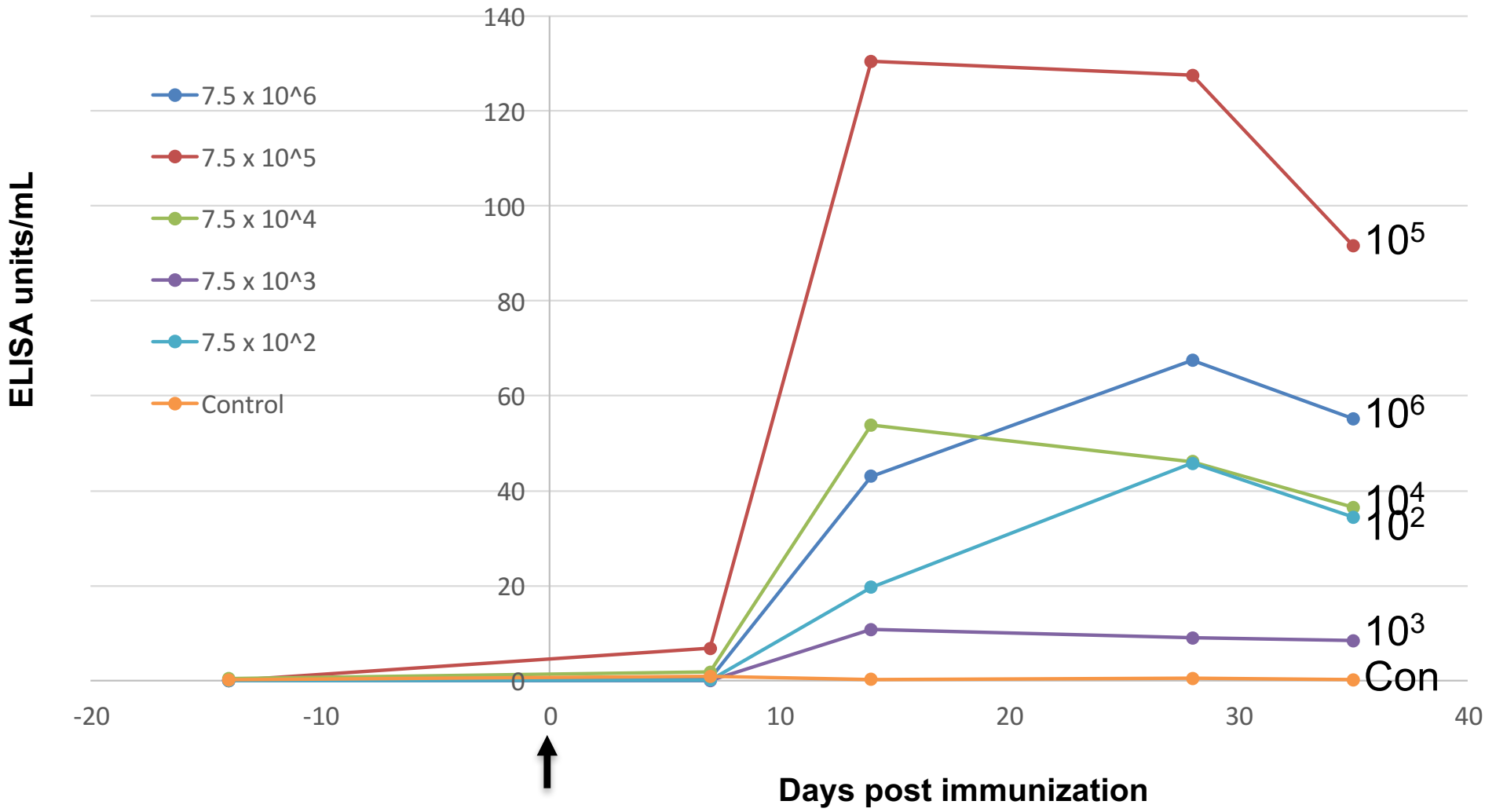
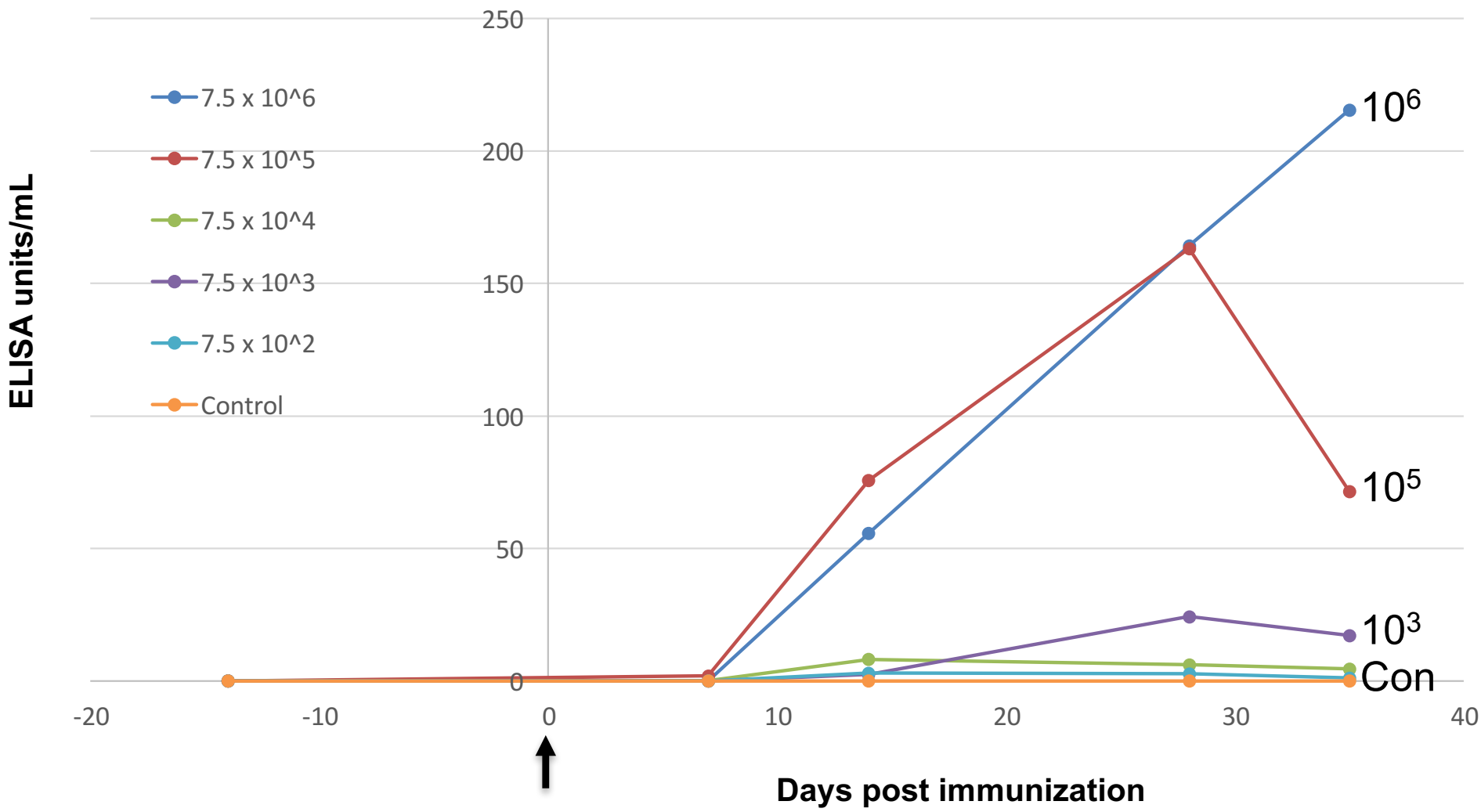
Anti-SUDV GP ELISA titers



Anti-MARV GP ELISA titers



PROFECTUS BIOSCIENCES

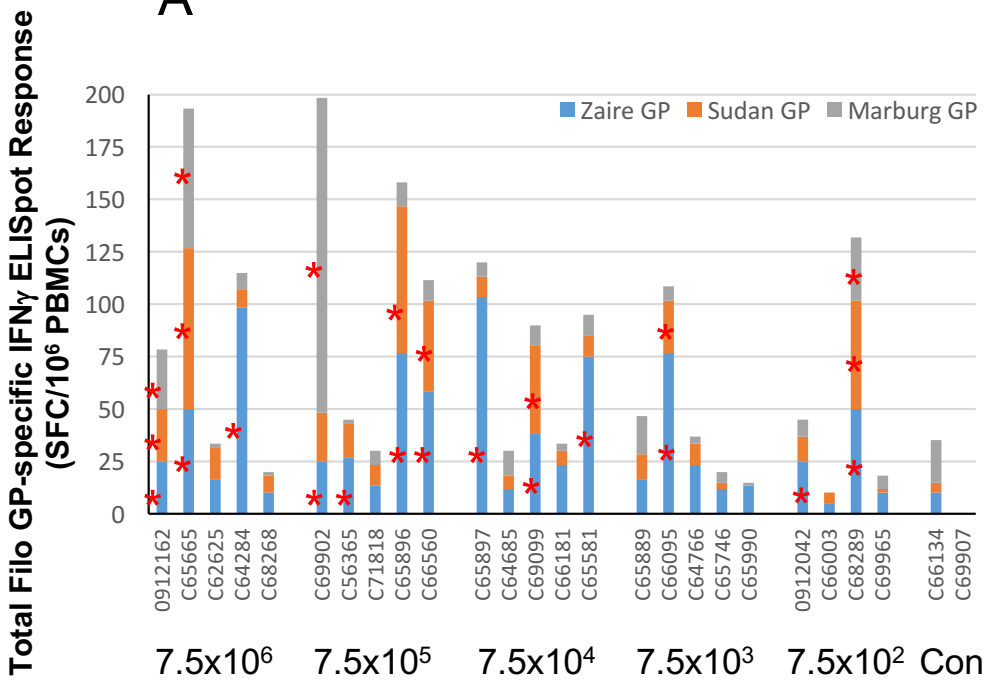
FiloGP-specific Neutralizing Ab Responses* (PRNT50) at Day 35

Vaccine	Dose	Group	Animal ID	PRNT50 - Day 35		
				Ebov	Sudv	Marv
Tri-val N4CT1(6)GP(a1)	7.5×10^6	1	0912162	**147.0**	29.7	**34**
		1	C65665	**77.6**	37.9	**27**
		1	C62625	16.5	21.7	10
		1	C64284	**75.3**	23.3	10
		1	C68268	**91.0**	35.8	10
Tri-val N4CT1(6)GP(a1)	7.5×10^5	2	C69902	22.9	29.8	10
		2	C56365	**178.1**	**41.2**	**24**
		2	C71818	**31.4**	27.4	10
		2	C65896	**121.5**	26.2	19
		2	C66560	**110.0**	24.3	12
Tri-val N4CT1(6)GP(a1)	7.5×10^4	3	C65897	**58.5**	19.5	10
		3	C64685	19.8	**48.4**	10
		3	C69099	10.9	16.4	10
		3	C66181	22.9	29.8	10
		3	C65581	24.2	24.5	10
Tri-val N4CT1(6)GP(a1)	7.5×10^3	4	C65889	16.4	16.5	10
		4	C66095	**37.9**	17.7	10
		4	C64766	**40.0**	22.5	10
		4	C65746	17.5	13.0	10
		4	C65990	19.6	15.1	10
Tri-val N4CT1(6)GP(a1)	7.5×10^2	5	0912042	**40.7**	15.9	10
		5	C66003	23.4	17.2	10
		5	C68289	19.0	17.0	10
		5	C69965	**35.6**	10.5	10
N4CT1-HIVgag(s1)	7.5×10^6	6	C66134	20.2	16.8	10
		6	C69907	10.9	16.2	10

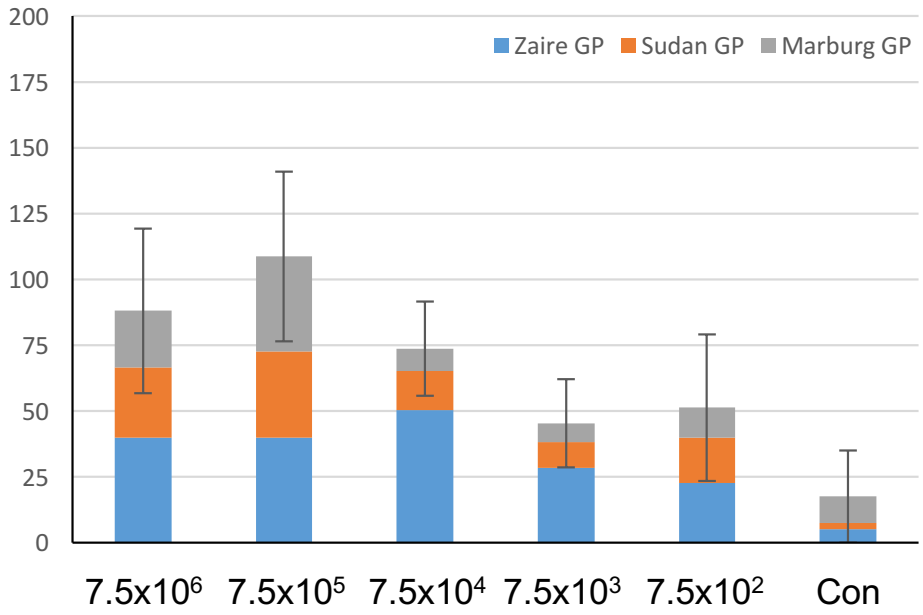
* Research assay

D35 (5wks post immunization) anti-Filo GP IFNγ ELISpot response

A

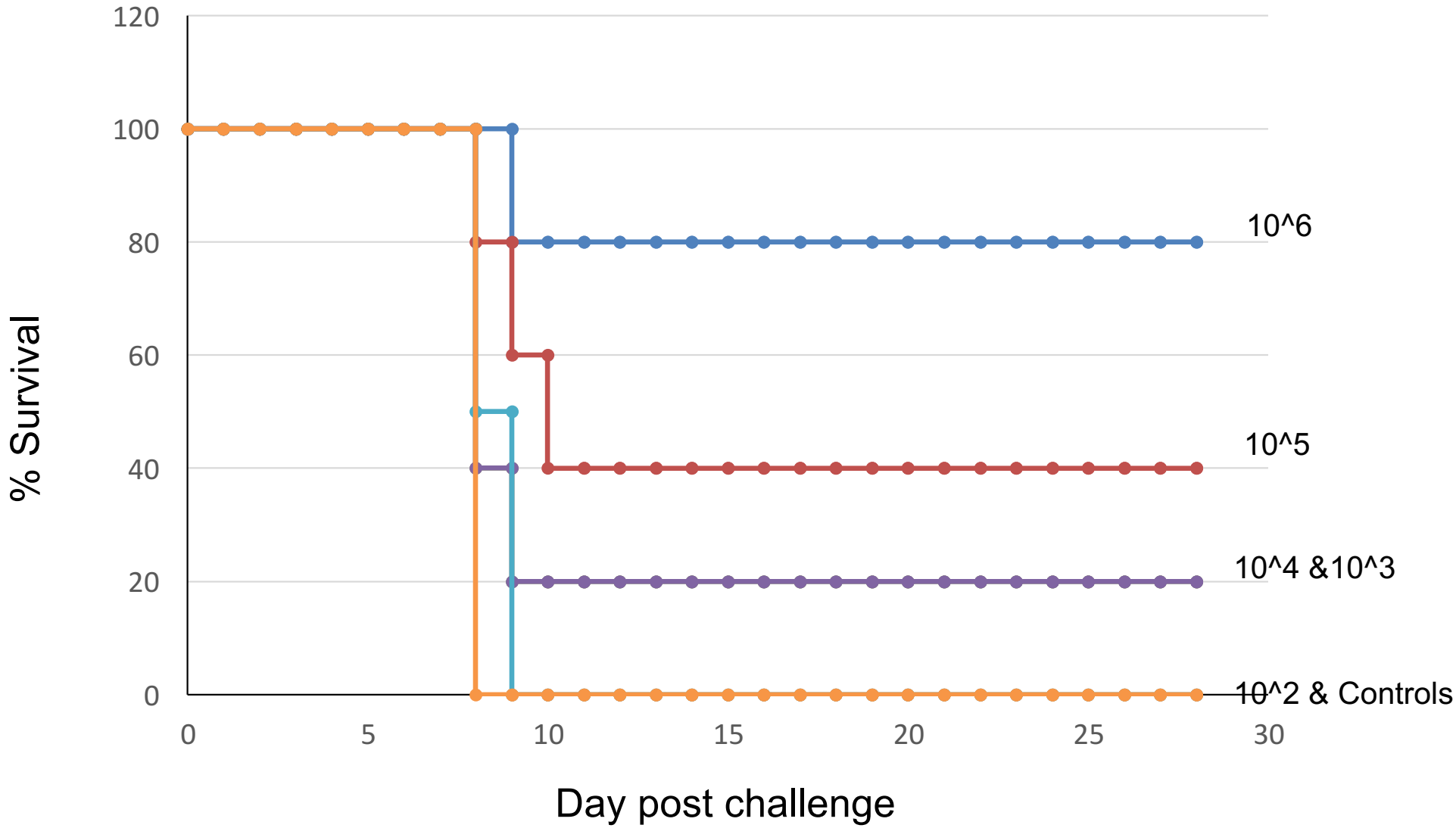


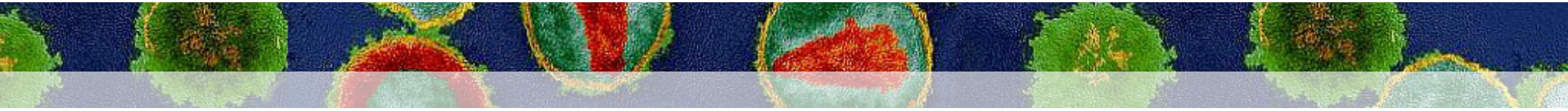
B



	7.5x10⁶	7.5x10⁵	7.5x10⁴	7.5x10³	7.5x10²	Con
Responder Freq	3/5 (60%)	4/5 (80%)	3/5 (60%)	1/5 (20%)	2/4 (50%)	0/2 (0%)

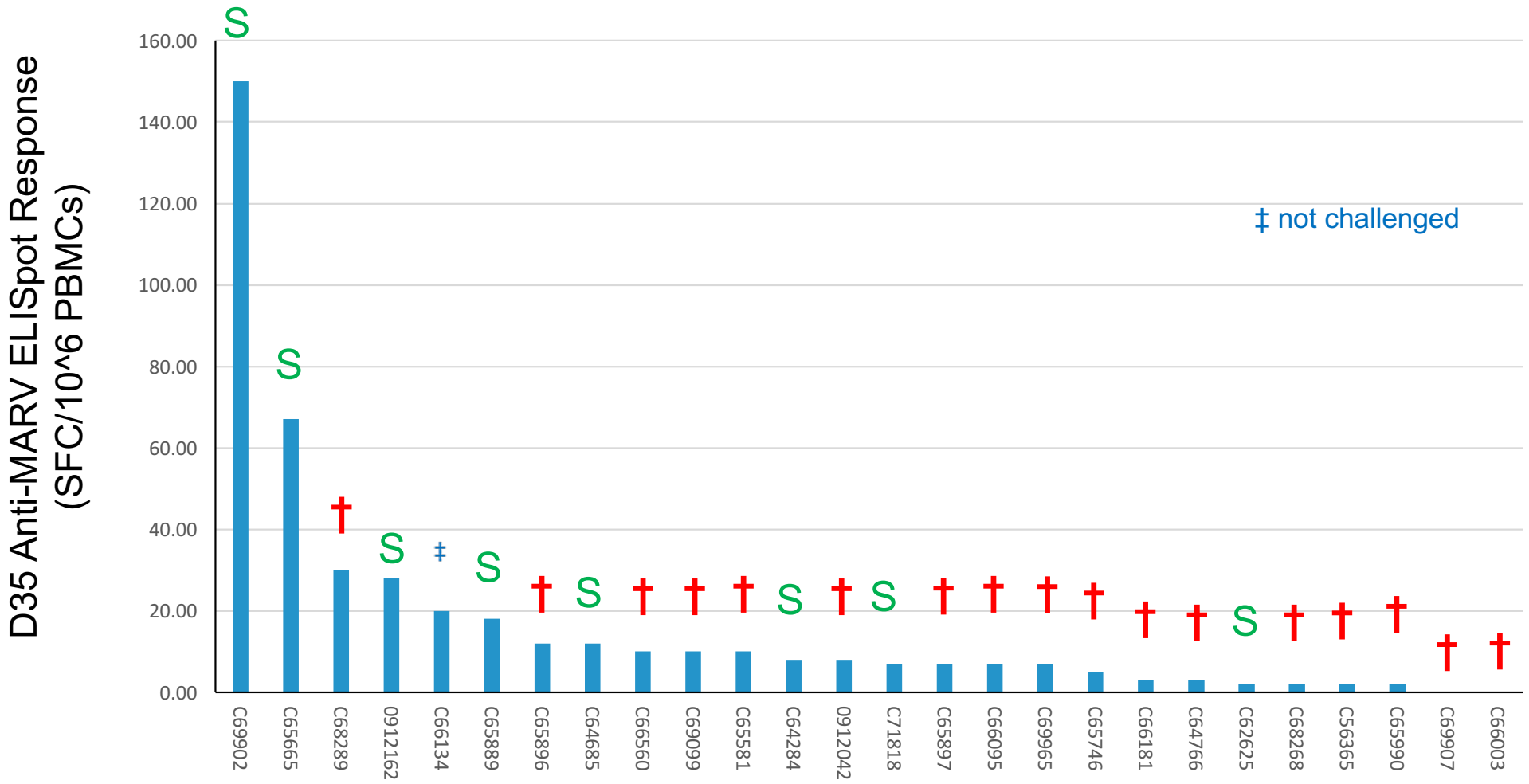
Post Challenge Survival (1,000 PFU AE MARV)



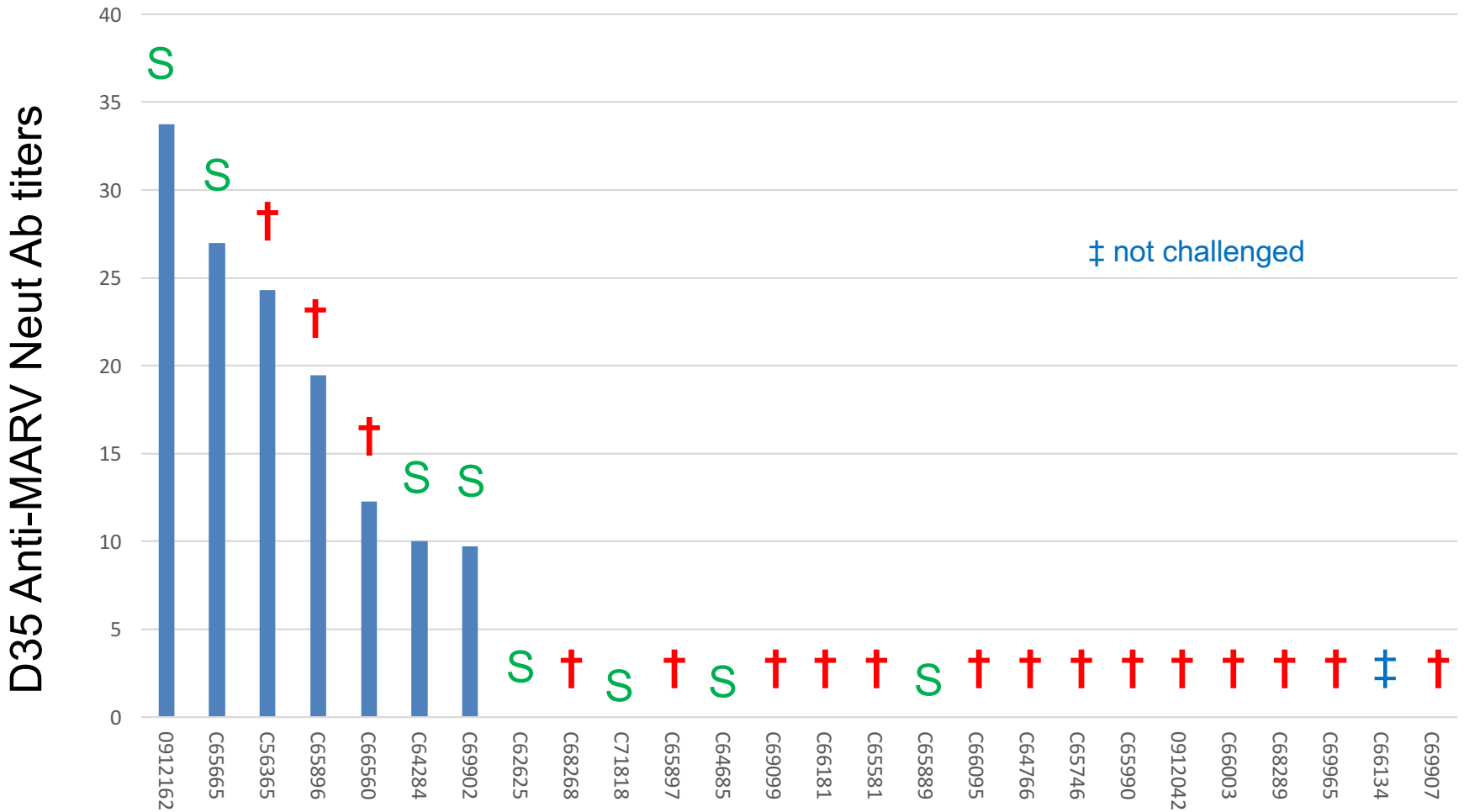


Determining a Correlate of Protection against 1,000 PFU AE MARV Challenge

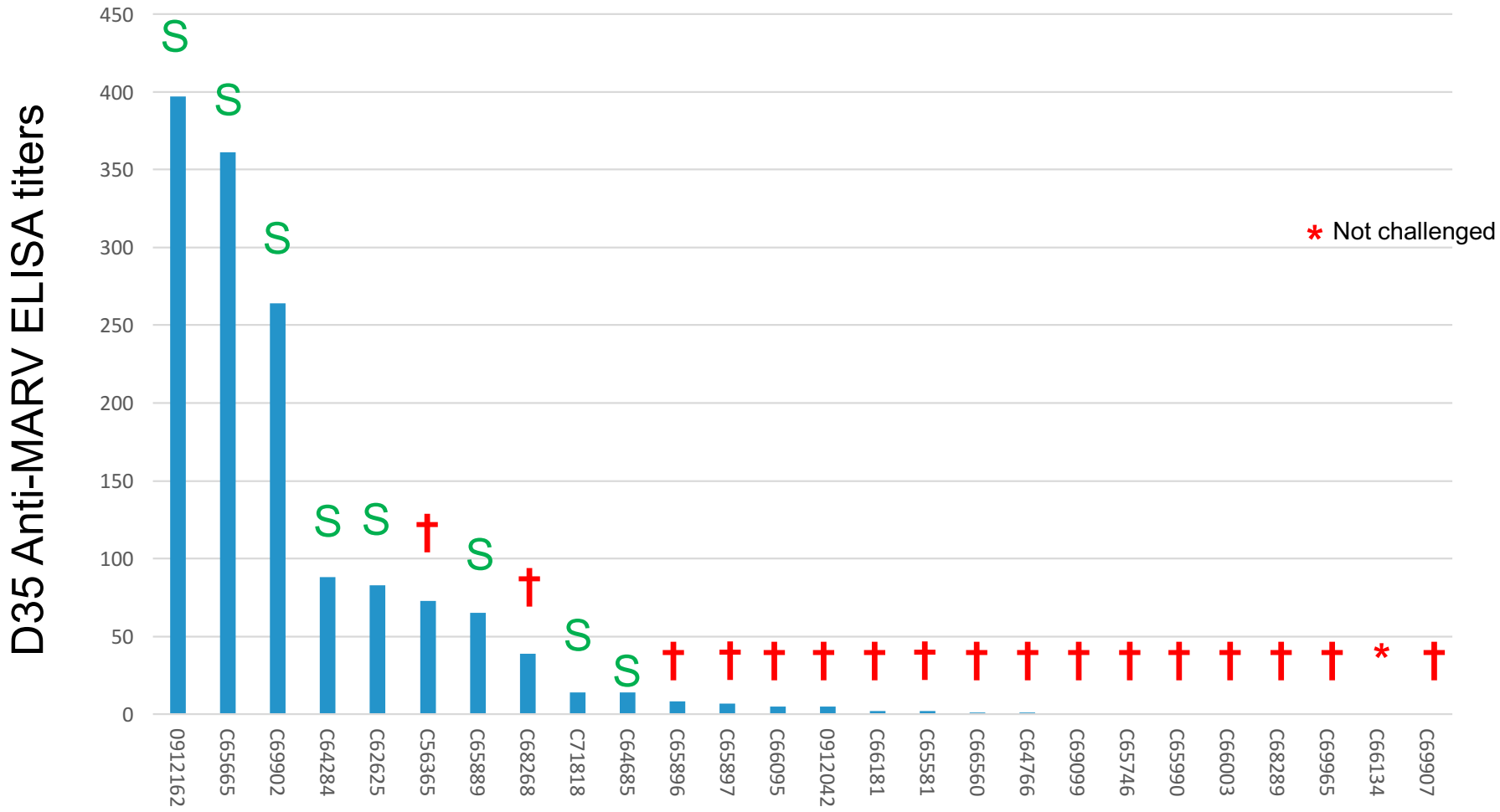
Relationship between D35 anti-MARV ELISpot response and post challenge outcome



Relationship between D35 anti-MARV Neut Ab titer and post challenge outcome



Relationship between D35 anti-MARV ELISA titer and post challenge outcome

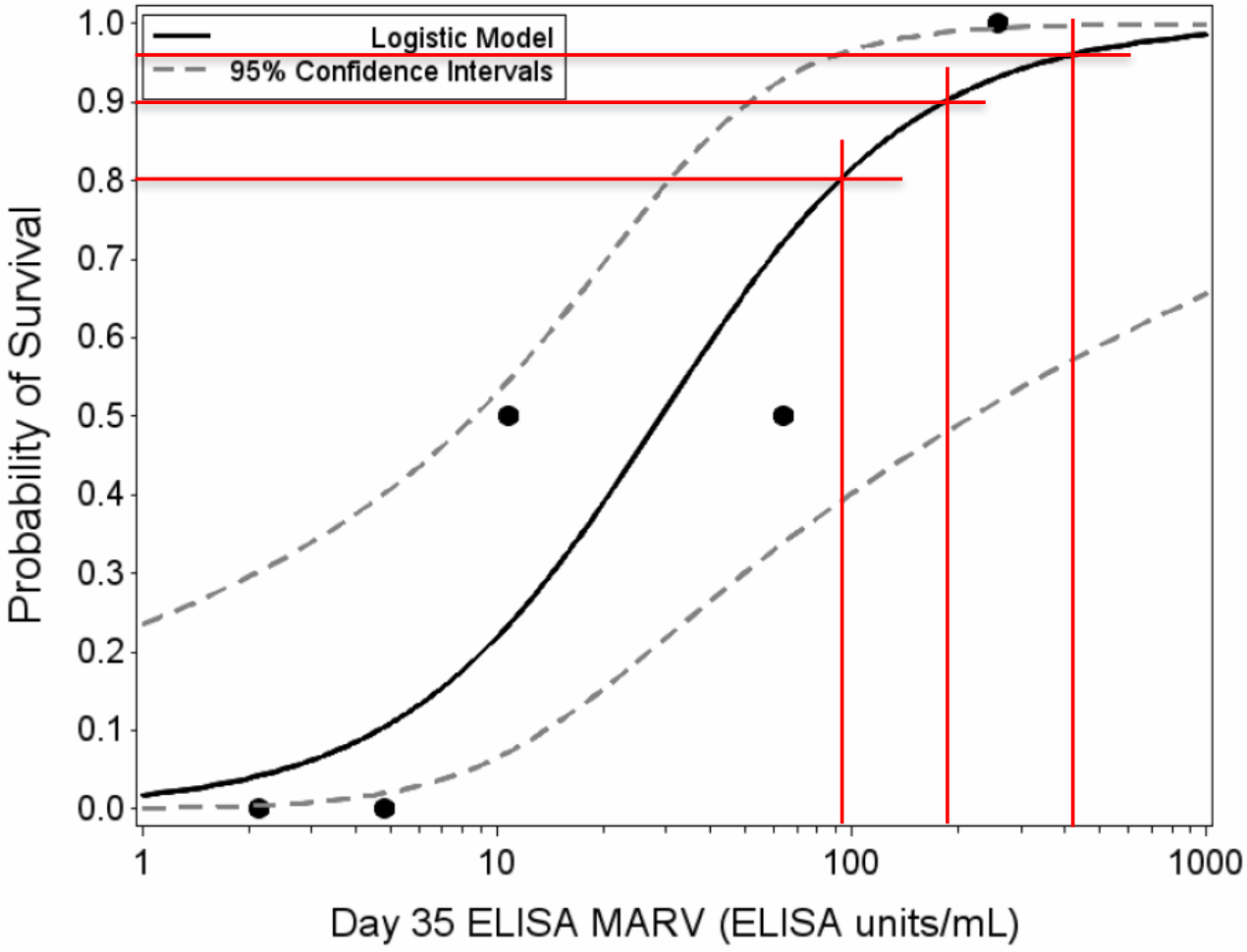


Univariate Logistic Regression Models Fitted to Immune Response Data

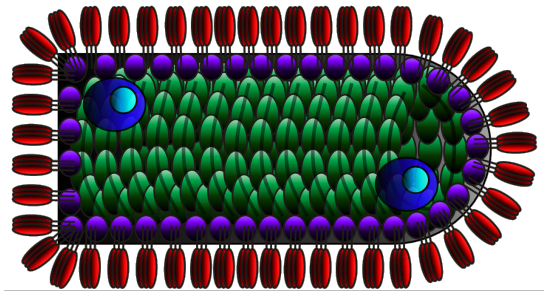
			Slope			Area Under Curve	
Assay	Virus	Study Day	Estimate	P-Value	False Discovery Rate Benjamini-Hochberg P-Value	Model	Cross-Validated
ELISA	MARV	7	-0.7858	0.8256	0.9256	0.5313	0.0625
		14	1.1315	0.0847	0.2541	0.7227	0.5391
		28	2.1322	0.0078*	0.0351*	0.9219	0.8750
		35	2.7562	0.0061*	0.0351*	0.9688	0.9453
ELISPOT	MARV	14	2.8808	0.2862	0.4293	0.6250	0.1250
		28	5.2777	0.1416	0.2657	0.6875	0.3750
		35	3.0389	0.1476	0.2657	0.6602	0.3594
Neutralization	MARV	28	-0.1142	0.9256	0.9256	0.5273	NA
		35	1.1052	0.4713	0.6060	0.5547	0.1016

Only MARV GP-specific ELISA responses at study days 28 and 35 (p-values = 0.0078 and 0.0061, respectively) were shown to be significantly associated with survival

Using an Immune Correlate to Gauge *Potential* Protective Efficacy of a Vaccine in Ph I/II Clinical samples



- Extrapolate an "threshold" MARV GP-specific ELISA response associated with 80%, 90% or 95% probability of survival
- Experimental vaccines capable of eliciting and / or maintaining an immune response above a pre-defined "protective" level might be expected to be efficacious and would warrant additional development



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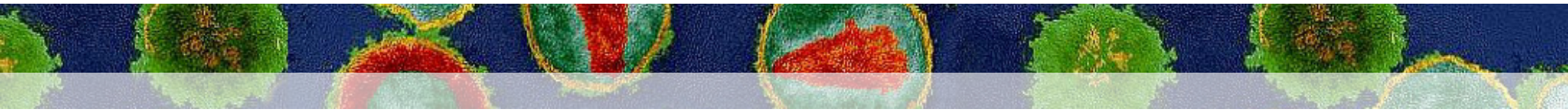

rVSV-MARV-01: Marburg Vaccine Phase I Study

Phase 1 Dose Escalation and Vaccination Schedule in Months (Days)					
Study Arm	**N**	**Total Dose**	**Month 0 (Day 0)**	**Month 1 (Day 28)**	**Month 1 (Day 56)**
Cohort 1	10	2.5×10^4 PFU	rVSVN4CT1-MARVGP1	—	rVSVN4CT1-MARVGP1
	3	—	control (saline)	—	control (saline)
Cohort 2	10	2.5×10^5 PFU	rVSVN4CT1-MARVGP1	—	rVSVN4CT1-MARVGP1
	3	—	control (saline)	—	control (saline)
Cohort 3	10	2.0×10^6 PFU	rVSVN4CT1-MARVGP1	—	rVSVN4CT1-MARVGP1
	3	—	control (saline)	—	control (saline)
Cohort 4	10	2.0×10^6 PFU	rVSVN4CT1-MARVGP1	rVSVN4CT1-MARVGP1	—
	3	—	control (saline)	control (saline)	—
Total	52 (40 vaccine/12 placebo)				
PFU = plaques forming units.					

Work in-progress:

- **Development of a VesiculoVax™ Vaccine with >2 yr shelf life at room temperature**
  - rVSV-EBOV and rVSV-MARV lyophilized with ~75% retention of potency
  - rVSV-SUDV lyophilization development in progress

- **Development of a Quadra-valent VesiculoVax™ panFilo/Lassa Vaccine**
  - rVSVN4CT1-EBOV/SUDV/MARV/LASV has entered animal testing

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