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SurVaxM Update

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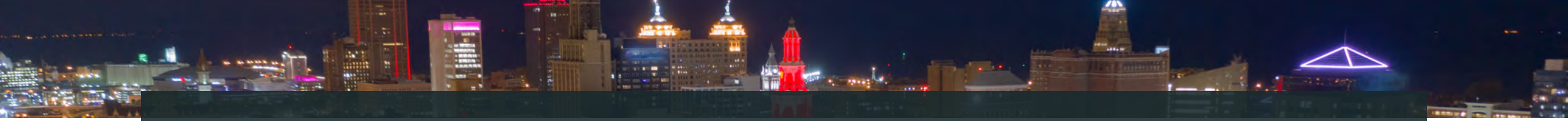

MimiVax History

2006
- National Brain Tumor Foundation "GBM Award"

2012
- MimiVax Formed
- A first-of-its-kind cancer "vaccine" is ready for clinical trials

2013
- Phase 1 in rGBM (ACS Supported)

2015
- Phase 1 data presented at AACR
- Phase 2a in nGBM (Roswell Park Supported)

2016
- Phase 1 in Multiple Myeloma (BMS Collab)

2017
- FDA awards orphan drug status to SurVaxM

2018
- Antibodies to SurVaxM are discovered & developed

2019
- Fosun Pharma Regional Partnership (China)

2020
- Phase 1 for Metastatic Neuro Endocrine Tumors (NET-RF Supported)

2021
- Phase 2a interim data at ASCO

2022
- Randomized Phase 2b in nGBM
- Phase 2a final data at ASCO
- SBIR grant for antibody studies

2023
- Phase 1 in pediatric HGG (PBTC collab.)
- FDA grants SurVaxM a Fast-Track Designation
- Phase 2a published

2024
- Phase 2b fully enrolled
- FDA grants supplemental orphan-drug designation to SurVaxM

2025
- Partnership?
- M&A?
- IPO?

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MimiVax: Pipeline

	Pre-Clinical	Phase 1	Phase 2a	Phase 2b (Randomized)	
SurVaxM (Cancer Vaccine) **FDA Orphan Drug Designation* **FDA Fast-Track Designation*	**SURVIVE** : Newly Diagnosed GBM				NCT02455557 P2a NCT05163080 P2b
	Pediatric High-Grade Glioma		PBTC		NCT04978727
	Multiple Myeloma + lenolidomide				NCT02334865
	Metastatic Endocrine Tumors (NET's)		NEUROENDOCRINE TUMOR RESEARCH FOUNDATION		NCT03879694
MV2C2 Antibody • *Humanized IgG* • *Camelid sdAb*	Cancer				Roswell Park & George Wash. Univ.
	Auto-immune Disease	NIH National Institute of Neurological Disorders and Stroke			
MV209 Survivin CAR-T	Cancer				

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Survivin as a target

- **Survivin is:**

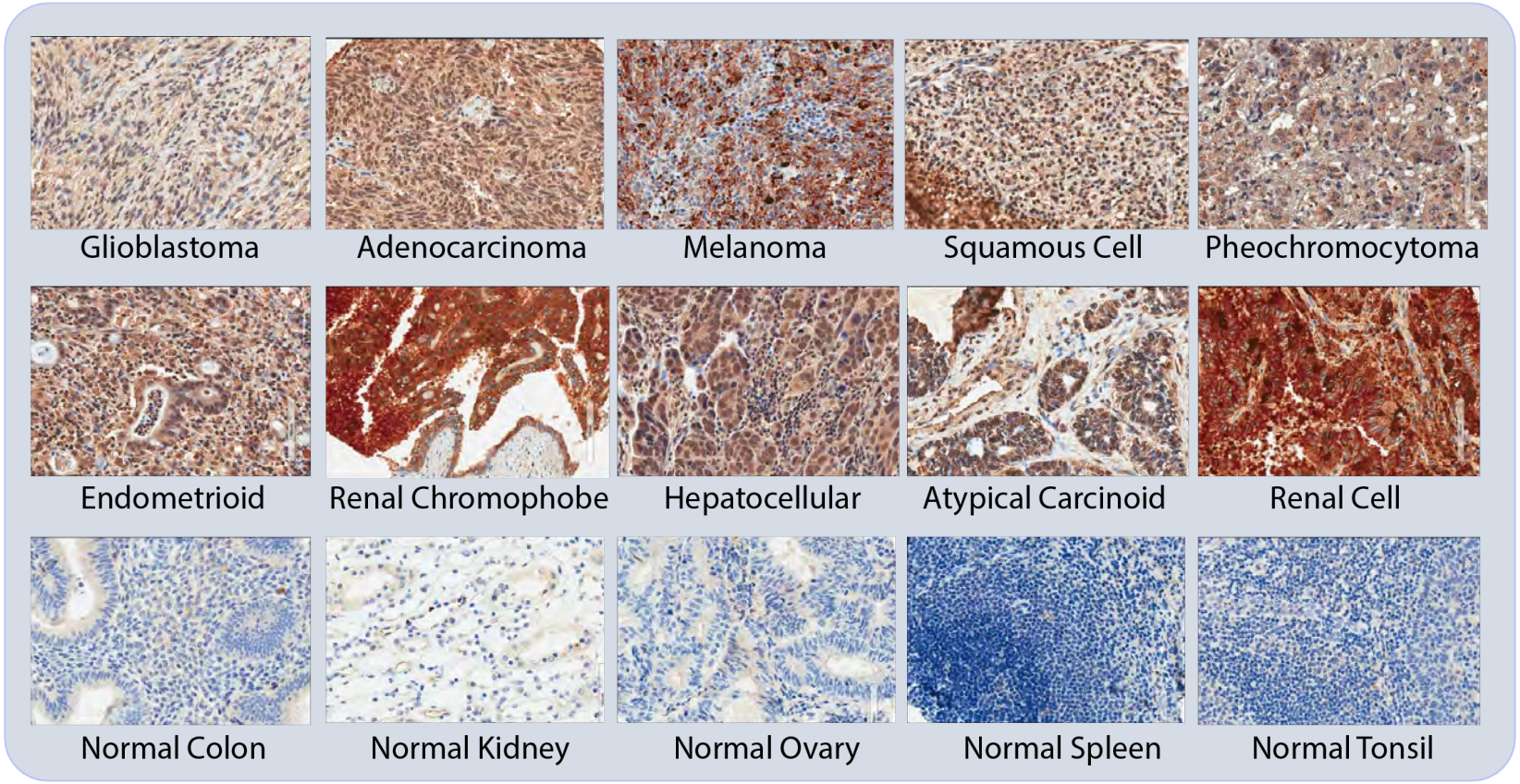
  An over-expressed **Pan-Cancer** target

  An Onco-fetal protein, typically turned on during fetal development

  Rarely expressed in adult tissues

  7 distinct protein isoforms

  Cytoplasmic, Nuclear, Mitochondrial & Cell-Surface expression patterns



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SurVaxM Vaccine

SurVaxM is:

An off-the-shelf immunotherapeutic

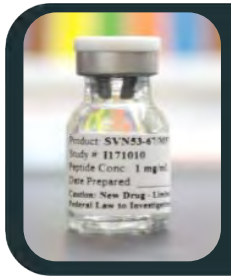
Targeted to a key structural epitope of survivin

Modified to enhance its immunogenicity

SurVaxM's MOA is:

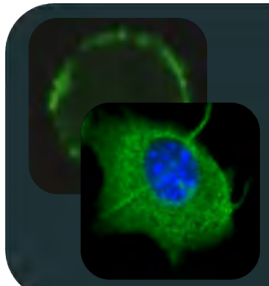
Both IgG & T-Cell immune-mediated attack

Potential for biological interference by IgG



- 15 AA Structurally-Altered Synthetic Long Peptide (SLP)
- Conjugated to highly immunogenic Keyhole Limpet Hemocyanin (KLH)
- Adjuvanted with Montanide & Local GM-CSF (sargramostim)

- Dosage: 500µg SurVaxM in Montanide ISA51 VG + 100µg GM-CSF
- Delivered as a Subcutaneous Injection
- 4 initial biweekly doses (q2week x 4)
- Ongoing maintenance dosage once every 2 months (q2month)



- Produces high affinity antibodies (IgG) that target cell-surface survivin
- $CD4^+$ & $CD8^+$ T-Cells target intra-cellular survivin via MHC-associated epitope presentation

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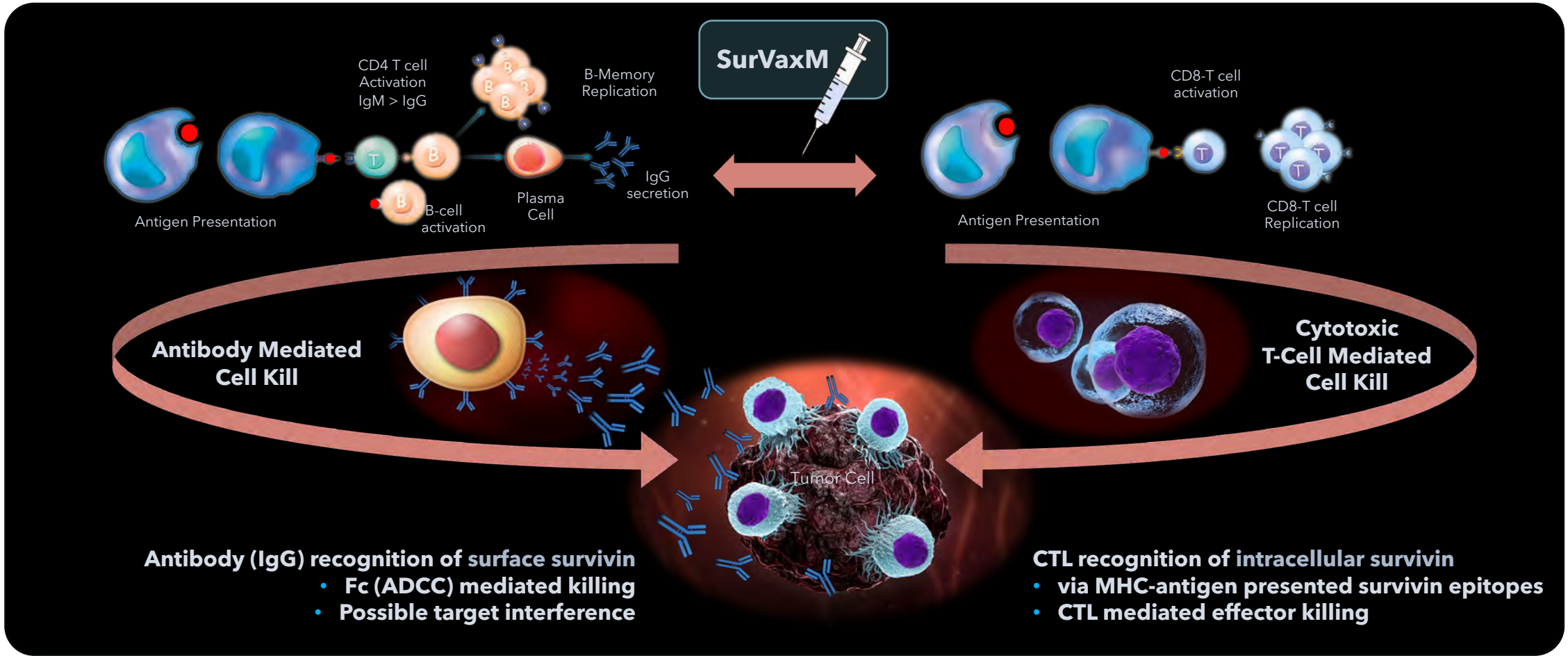
Immune Response



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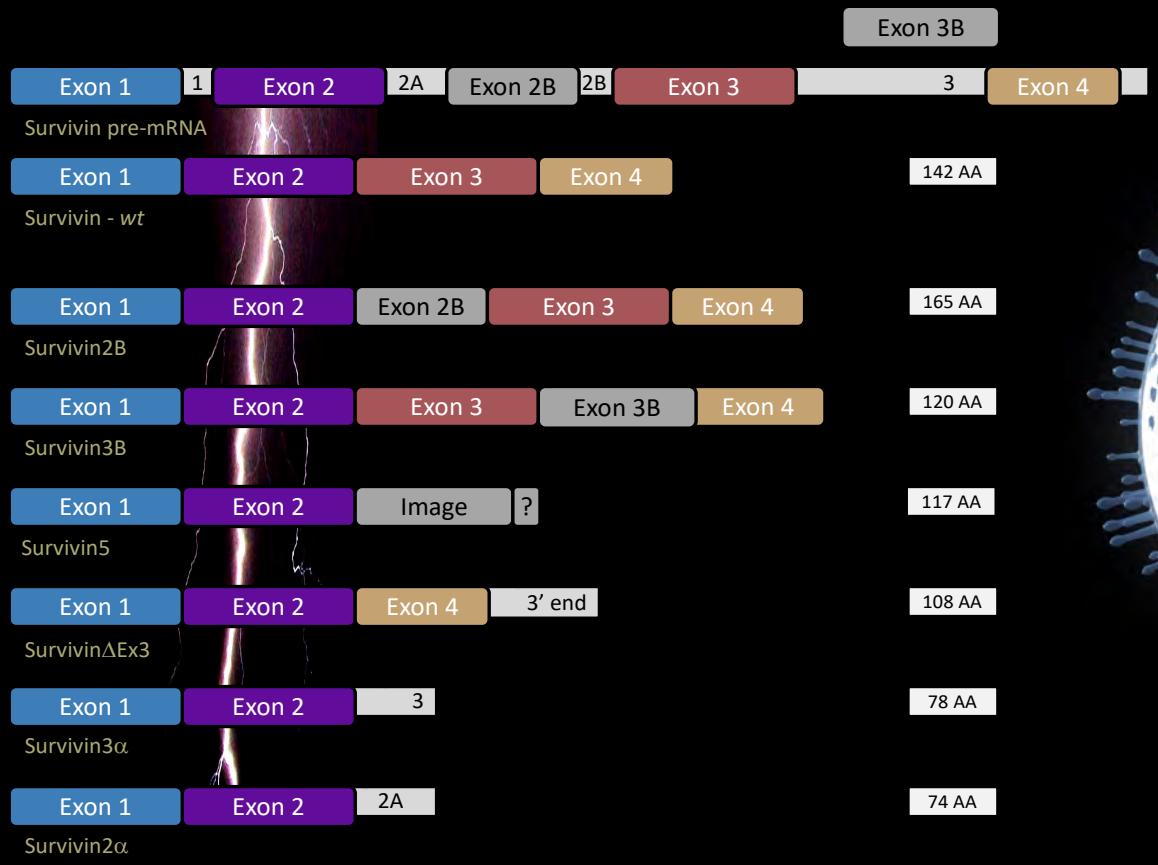
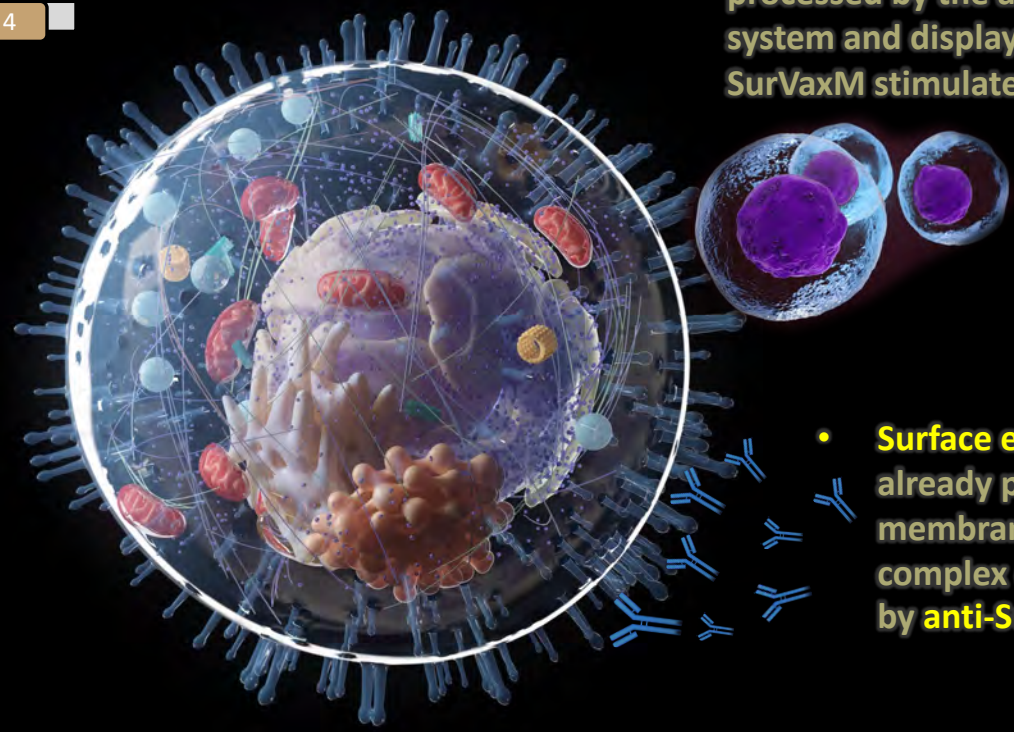
SurVaxM targets a conserved region of survivin present in several survivin-family isoforms

- **Survivin has several isoforms, with different functions & cellular localization.**





- **Nuclear & Cytoplasmic Survivin** is processed by the antigen presentation system and displayed via MHC for SurVaxM stimulated **T cells to engage**

- **Surface expressed Survivin** is already present at the plasma membrane in a protein complex directly recognizable by **anti-SurVaxM antibodies**

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Clinical Data

Phase 2a in newly diagnosed GBM
2024 Update

Survival Data – Measured from Diagnosis

SurVaxM: Phase 2a Study of SurVaxM in adult nGBM

(NCT02455557)

PHASE 2a Single Arm DESIGN:

NEWLY DIAGANOSED GLIOBLASTOMA (*n*=63)

Gross total resection (≤ 1cm^3)
& completed initial Standard of Care therapy

Enrolled at:

ROSWELL PARK COMPREHENSIVE CANCER CENTER
DANA-FARBER CANCER INSTITUTE
Beth Israel Lahey Health Beth Israel Deaconess Medical Cent...
MASSACHUSETTS GENERAL HOSPITAL
Cleveland Clinic

SurVaxM (Single Arm)

SurVaxM in emulsion with Montanide Sargramostim (local injection)

Combined with Standard TMZ

- Dosing q2w x 4 doses and then q2m until tumor progression or unacceptable toxicity occurs.

ENDPOINTS:

1º Progression Free Survival (+)
2º Overall Survival (+)
3º Immune Response & Biomarker Analysis (DNA/RNA) (+)

- Enrolled: 2015-2020
- Published: JCO 2023
- *Ongoing Updates…*

ROSWELL PARK COMPREHENSIVE CANCER CENTER
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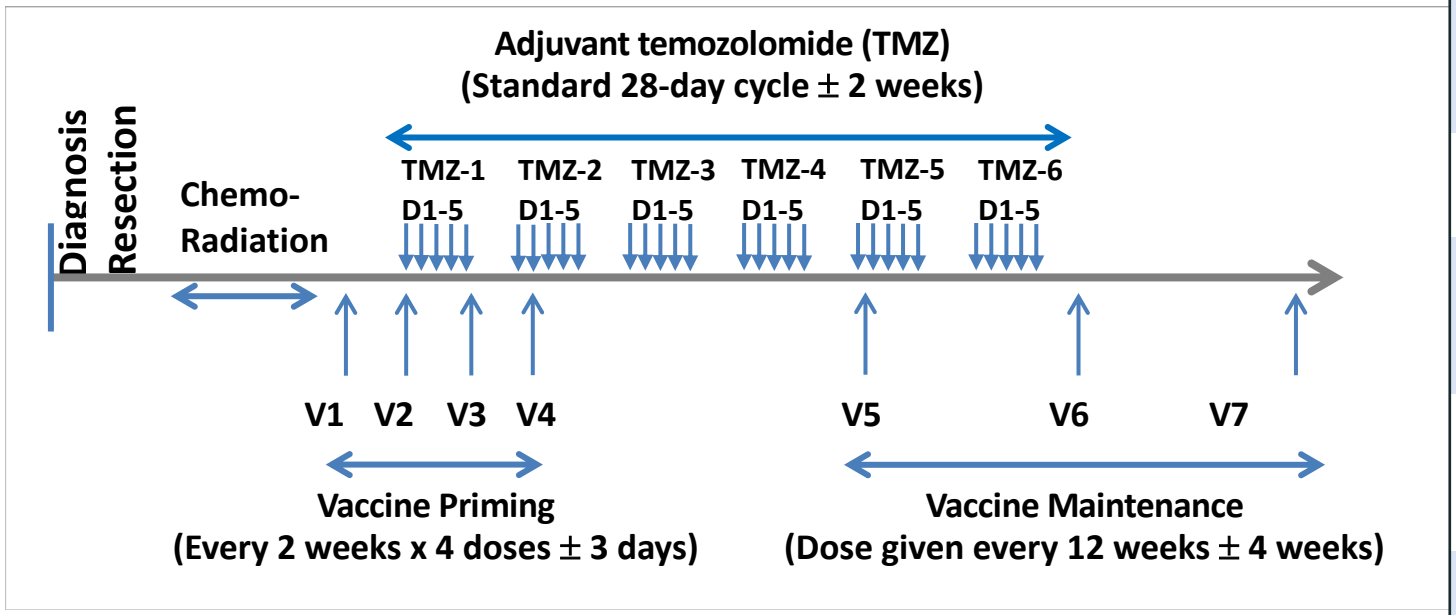
Phase 2a Study of SurVaxM in nGBM: Schedule & Demographics



Total patients (n = 63)		
Gender	Male	38 (60%)
	Female	25 (40%)
Age	Mean	56.5
	Median	60
	Range	20-82
KPS score	Median	90
	Range	70-100
MGMT Status	Unmethylated	29 (46%)
	Methylated	33 (52%)
	Unknown	1
IDH status	wt	53 (84%)
	IDH1-R32h	8 (13%)
	Unknown	2
% SVN (IHC)	1-4%	2 (3.2%)
	5-9%	15 (23.8%)
	10-19%	35 (55.6%)
	≥20%	12 (19.0%)

Ahluwalia, MS, Reardon, DA, Abad, AP et al. Phase 2a Study of SurVaxM Plus Adjuvant Temozolomide for Newly Diagnosed Glioblastoma. *J Clin Oncol* 41(7) 1453-1465 (2023).

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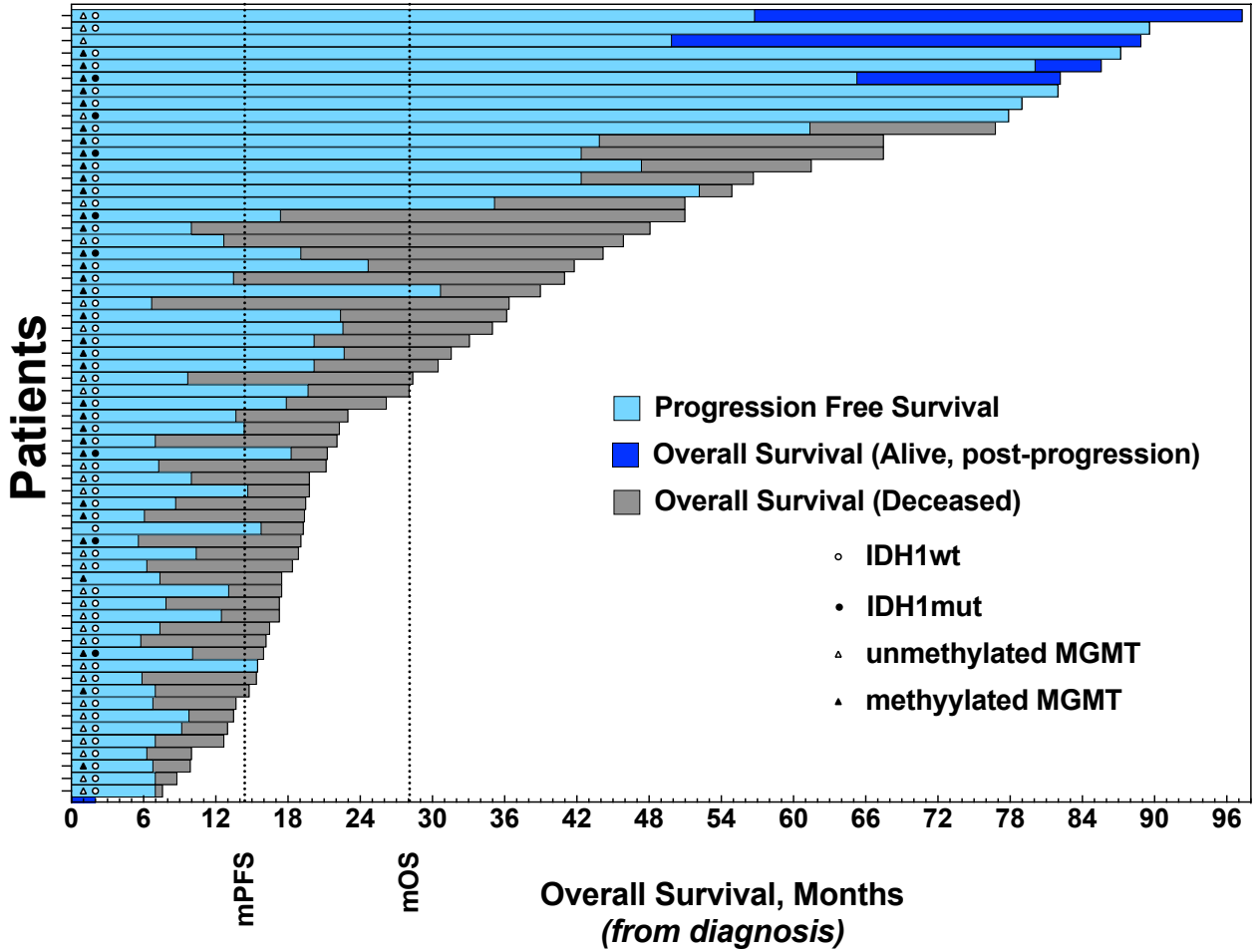
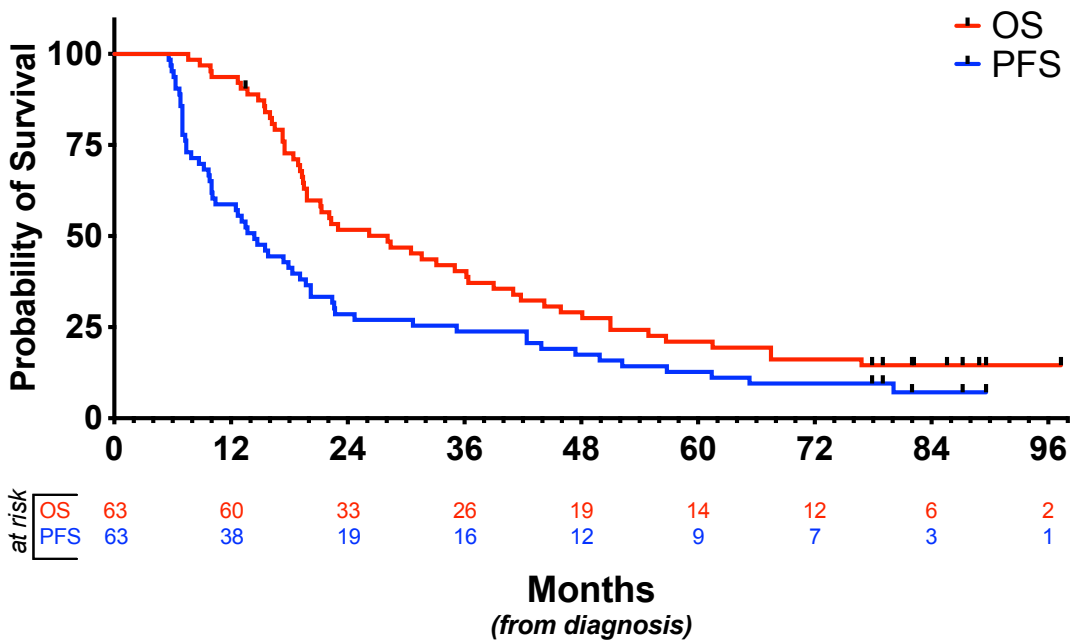
Phase 2a Study of SurVaxM in nGBM (2024)

(All patients, measured from diagnosis, N=63)





Overall Survival	28.1 mos. from Diagnosis (expected is ~15-18 mos.)
Progression Free Survival	14.4 mos. from Diagnosis (expected is ~4-7 mos.)

update to Ahluwalia, MS, Reardon, DA, Abad, AP et al. Phase 2a Study of SurVaxM Plus Adjuvant Temozolomide for Newly Diagnosed Glioblastoma. *J Clin Oncol* 41(7) 1453-1465 (2023).

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Phase 2a Study of SurVaxM in nGBM: Safety

Preferred term	Grade 1	Grade 2	Grade 3	Grade 4
Alopecia	1/1 (1.6%)			
Amnesia	2/2 (3.1%)			
Arthralgia	3/3 (4.7%)			
Asthenia		1/1 (1.6%)		
Back Pain	1/1 (1.6%)			
Chills	1/1 (1.6%)			
Confusion			1/1 (1.6%)	
Decreased appetite	1/1 (1.6%)	1/1 (1.6%)		
Fatigue	12/12 (18.8%)	1/1 (1.6%)		
Hyperhidrosis	1/1 (1.6%)			
Hypersensitivity				
Hypertension - aggravated		1/1 (1.6%)		
Influenza-like illness	7/3 (4.7%)			
Injection site haematoma	5/4 (6.3%)			
Injection site induration	5/3 (4.7%)			
Injection site pain	12/9 (14%)			
Injection site pruritus	2/2 (3.1%)			
Injection site reaction	37/24 (37.5%)	3/3 (4.7%)		
Injection site swelling	2/2 (3.1%)			

Preferred term	Grade 1	Grade 2	Grade 3	Grade 4
Lymphopenia	2/2 (3.1%)	6/6 (9.4%)	1/1 (1.6%)	1/1 (1.6%)
Malaise	2/2 (3.1%)			
Myalgia	4/4 (6.3%)	1/1 (1.6%)		
Nausea	1/1 (1.6%)			
Neutrophil count decreased	2/2 (3.1%)	2/2 (3.1%)		1/1 (1.6%)
Panniculitis		2/2 (3.1%)		
Paresthesia	3/3 (4.7%)			
Platelet count decreased	2/2 (3.1%)			
Pruritus	2/2 (3.1%)	1/1 (1.6%)		
Pyrexia	2/2 (3.1%)			
Rash	2/2 (3.1%)	1/1 (1.6%)	1/1 (1.6%)	
Rash maculo-papular			1/1 (1.6%)	
Skin hypertrophy	1/1 (1.6%)			
Subcutaneous nodule	3/3 (4.7%)			
Transaminases increased		1/1 (1.6%)		
Urticaria	1/1 (1.6%)	1/1 (1.6%)		
Leukopenia	4/4 (6.3%)			

***AE's are inclusive of those attributable to temozolomide

Ahluwalia, MS, Reardon, DA, Abad, AP et al. Phase 2a Study of SurVaxM Plus Adjuvant Temozolomide for Newly Diagnosed Glioblastoma. *J Clin Oncol* 41(7) 1453-1465 (2023).

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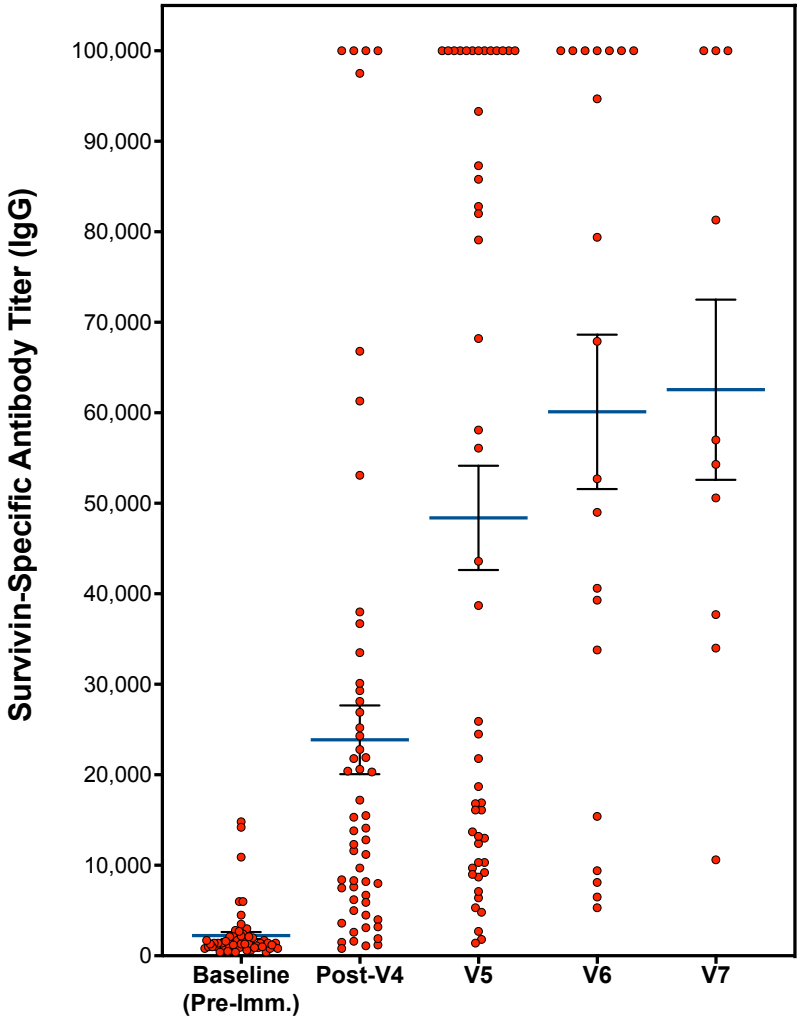
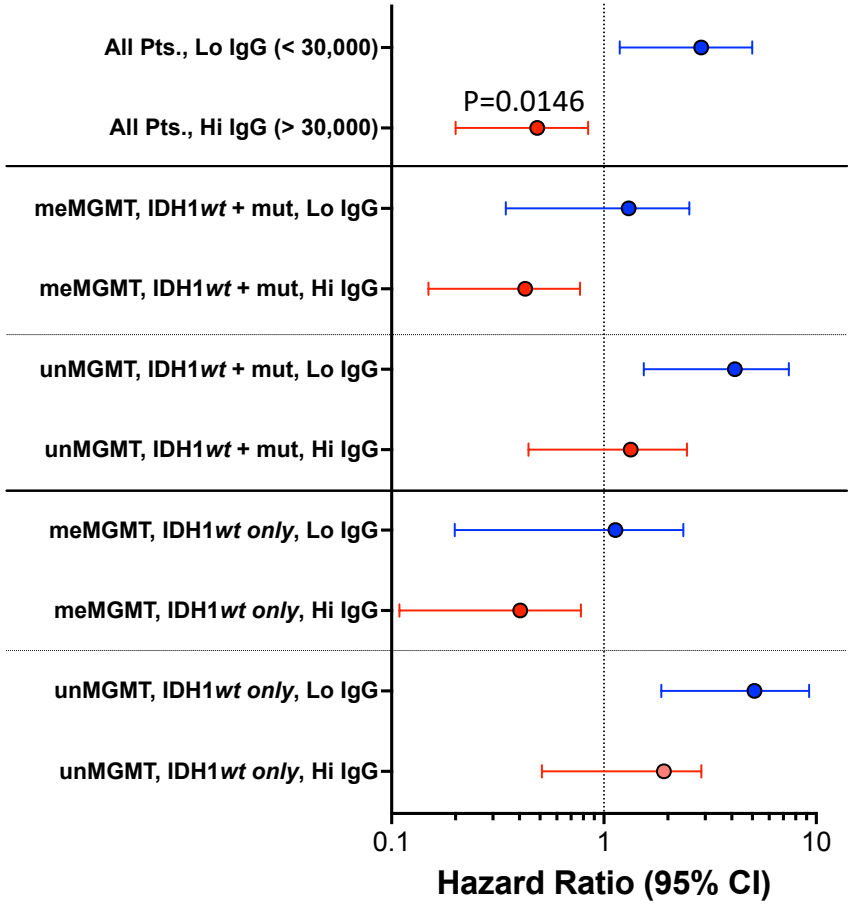
Phase 2a Study of SurVaxM in nGBM: IgG Response Correlates with OS





- Significantly higher OS associated with high titer IgG responses
- Stratification by IDH1 and MGMT all trend to better OS with higher titer IgG

Ahluwalia, MS, Reardon, DA, Abad, AP et al. Phase 2a Study of SurVaxM Plus Adjuvant Temozolomide for Newly Diagnosed Glioblastoma. *J Clin Oncol* 41(7) 1453-1465 (2023).

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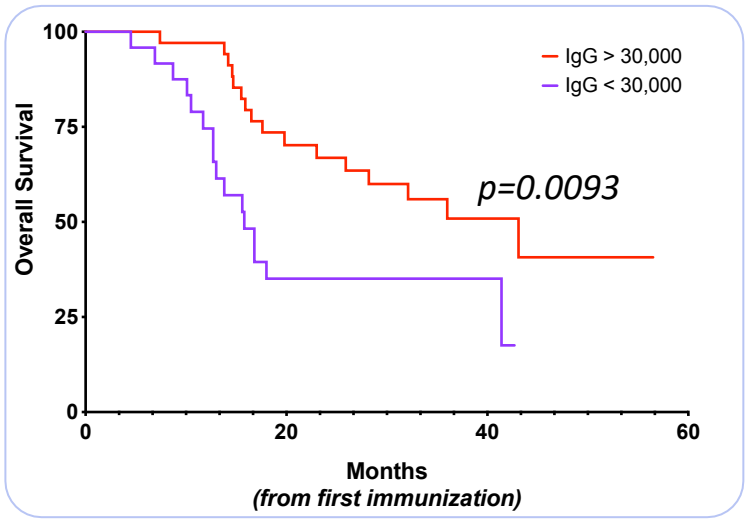
Biomarker Response from Phase 2a Study

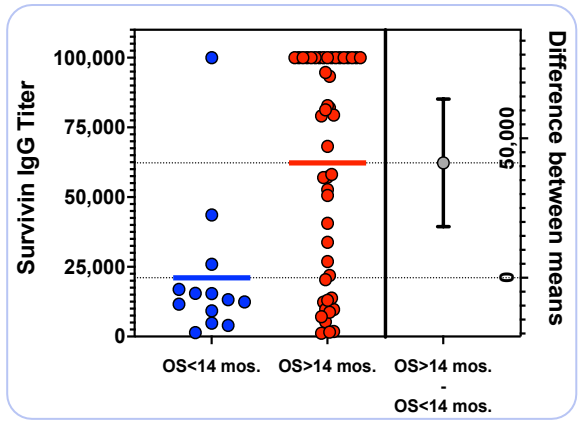
↑ Antibody (IgG) Response = ↑ OS & PFS (P=0.0146)



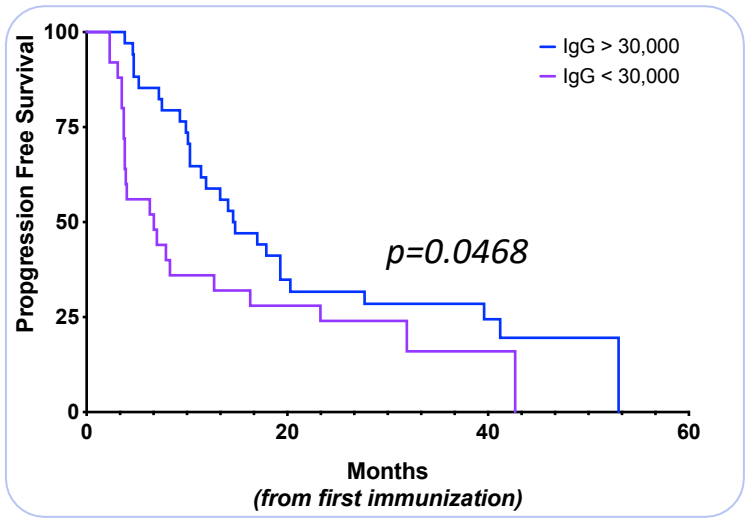
SurVaxM mOS

IgG > 30,000 = 43.1 mos.

IgG < 30,000 = 15.8 mos.



P=0.0146 for patients with IgG responses > 30,000 titer (HR, 0.41; 95% CI, 0.20-0.84)



SurVaxM mPFS

IgG > 30,000 = 14.7 mos.

IgG < 30,000 = 6.7 mos.

76% of patients had IgG > 30,000

Ahluwalia, MS, Reardon, DA, Abad, AP et al. Phase 2a Study of SurVaxM Plus Adjuvant Temozolomide for Newly Diagnosed Glioblastoma. *J Clin Oncol* 41(7) 1453-1465 (2023).

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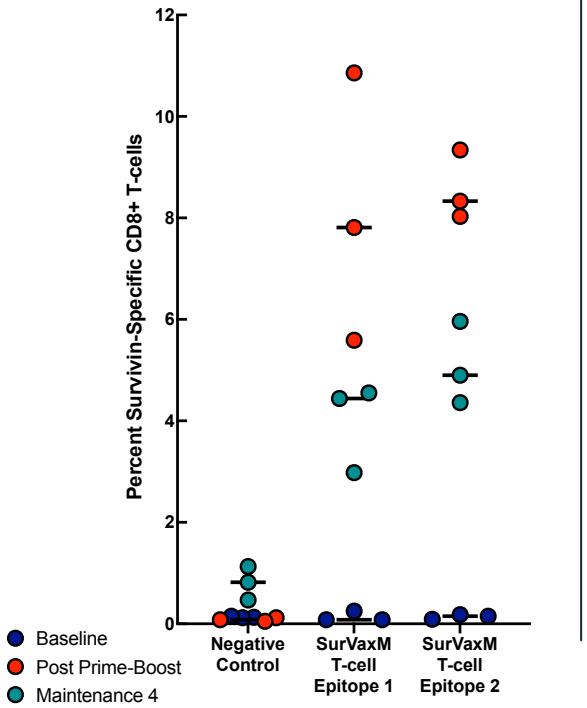
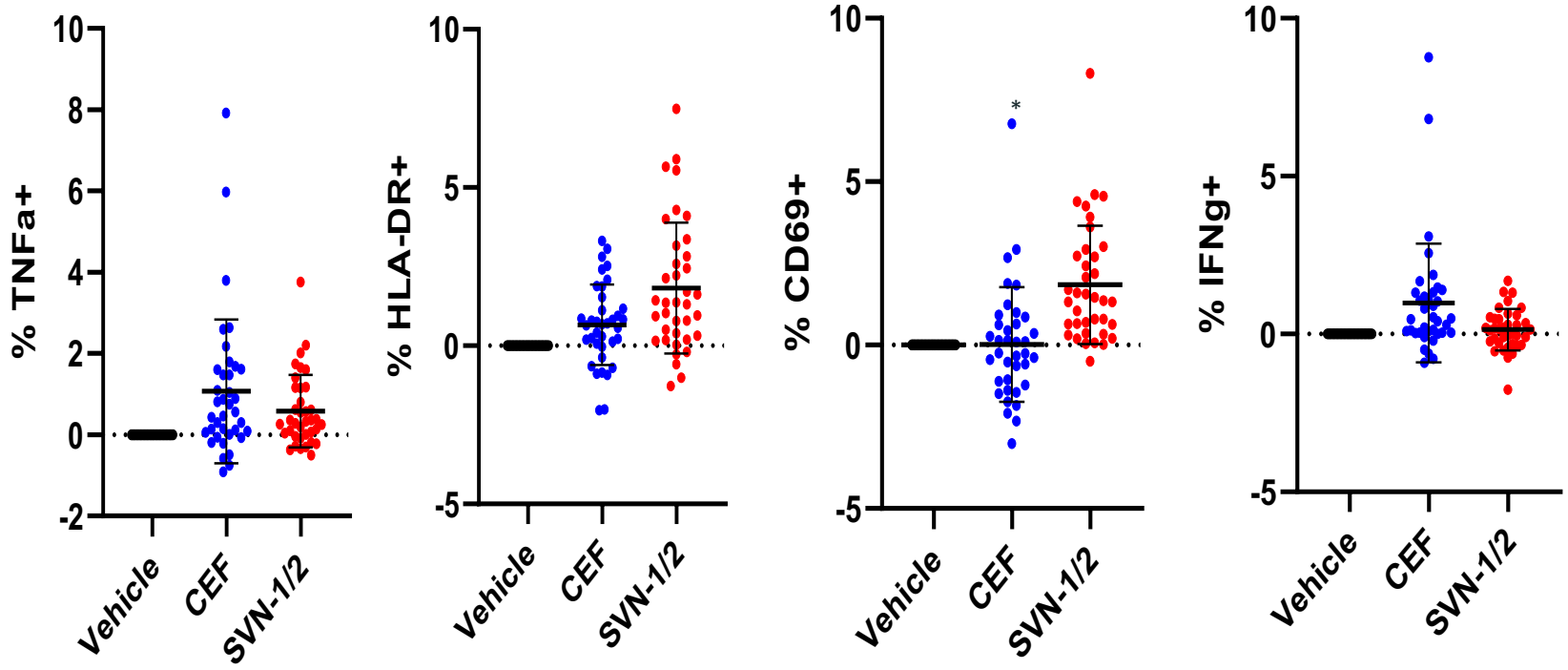
Phase 2a Study of SurVaxM in nGBM: T-Cell Response

CD8+ T cell responses
(MHC-I Dextramers)



CD8+ T Cell responses
(to Survivin peptides)



Ahluwalia, MS, Reardon, DA, Abad, AP et al. Phase 2a Study of SurVaxM Plus Adjuvant Temozolomide for Newly Diagnosed Glioblastoma. *J Clin Oncol* 41(7) 1453-1465 (2023).

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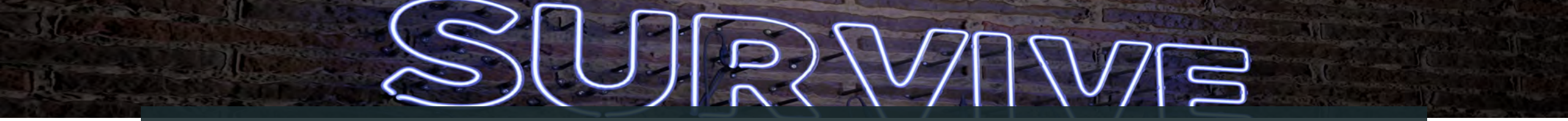

Phase 2b Study of SurVaxM in nGBM (SURVIVE)

Prospective Randomized Placebo-Controlled Trial of SurVaxM for Newly Diagnosed Glioblastoma (NCT0516308)

PHASE 2b RCT DESIGN:

NEWLY DIAGANOSED GLIOBLASTOMA (*n*=270)

Gross total resection (≤ 1cm^3)
& completed initial Standard of Care therapy
(Same as Phase 2a)

Stratified for MGMT methylation & IDH1 status

RANDOMIZED 3:2

SurVaxM (Arm A)
SurVaxM in emulsion with Montanide
Sargramostim (local injection)
Standard-of-care TMZ

Placebo (Arm B)
Saline in emulsion with Montanide
Saline (local injection)
Standard-of-care TMZ

- Dosing q2w x 4 doses and then q2m until tumor progression or unacceptable toxicity occurs.

ENDPOINTS:

1º Overall Survival:
- OS12 (surrogate)
- mOS (confirmatory)

2º Progression Free Survival:
- mPFS
- 1rst per Central Imaging (RANO)
- 2nd per PI

3º Immune Response & Biomarker Analysis (DNA/RNA)

ROSWELL PARK
DANA-FARBER CANCER INSTITUTE
NORTON CANCER INSTITUTE
FRED HUTCH CURES START HERE
Overlook Medical Center ATLANTIC HEALTH SYSTEM
Cleveland Clinic
UCSF Brain Tumor Center
TEXAS ONCOLOGY More breakthroughs. More victories.
NYU Langone Health
Miami Cancer Institute BAPTIST HEALTH SOUTH FLORIDA
Northwell Lenox Hill Hospital

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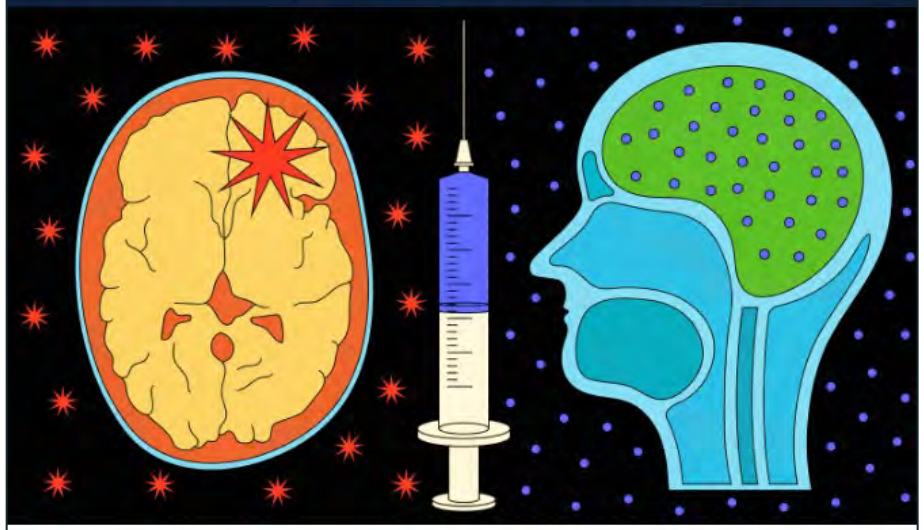
Recently Featured in National Media

NEWS WATCH NOW

Experimental vaccine shows promise in delaying the return of aggressive brain tumor

The vaccine, called SurVaxM, was shown to nearly double the survival time in a trial of 63 patients. Researchers now hope to confirm the findings in a larger trial.



An experimental brain tumor vaccine targets a protein found in tumors called survivin that's thought to play a role in the survival of cancer cells. Allie Sullberg for NBC News

SAVE

June 12, 2023, 5:00 AM EDT

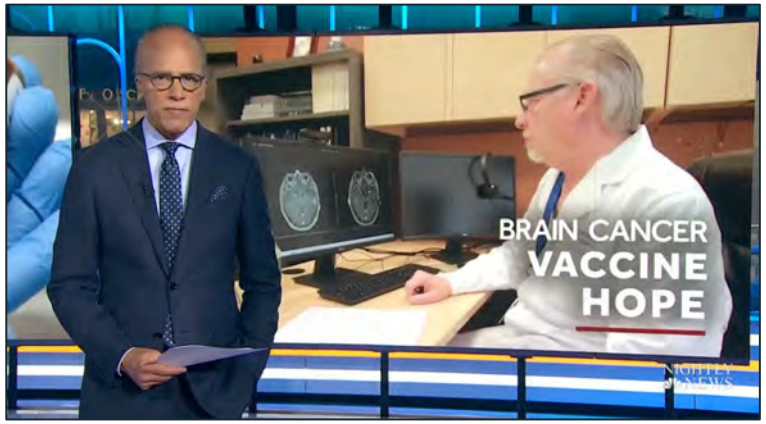
By Berkeley Lovelace Jr.

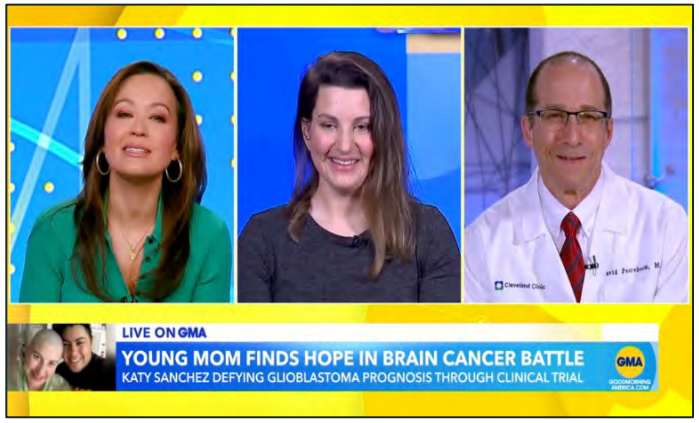
NBC NIGHTLY NEWS with LESTER HOLT

GOOD MORNING AMERICA abc

CNBC

MSNBC





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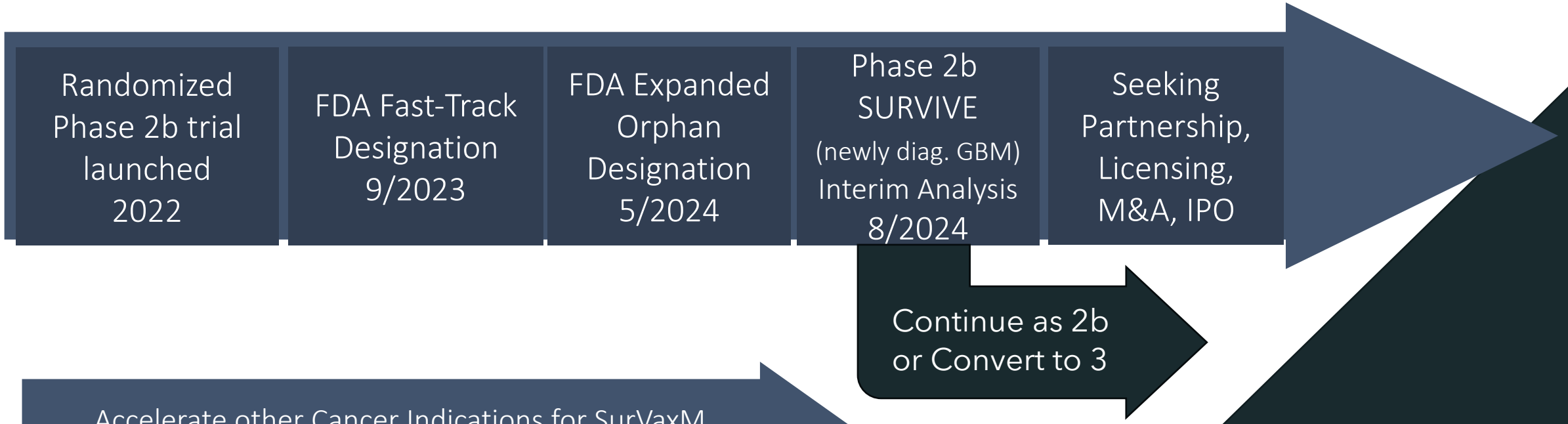
MimiVax: Timeline



Independent US Market Analysis:
SurVaxM ranks #2 for a predicted $254M US market share

Parameters	Efficacy	Safety	Entry Order	Return on Asset	Weighted Score	Rank	Phase	Company	Mkt Cap	Share	Market Share Prediction
Scores											
1st Line Drug											$2.8B Total
DCVax	9	9	10	7.5	8.9	1	phase 3 (single arm)	**Northwest Bio**	$648M	$0.60	$271.1
SurVaxM	**9**	**9**	**7**	**9**	**8.7**	**2**	**phase 2b RCT**	**MimiVax**	**$120M Private**		**$254.7**
INO-5401	8.5	8.5	7	8	8.2	3	phase 1/2	**Inovio**	$116M	$0.45	$152.5
VAL-083	8	8	8	8	8.0	4	phase 1	**Kintara**	$5.4M	$3.23	$157
Enzastaurin	8	8	7	8	7.9	5	phase 1/2	**Denovo**	$45M Private		$133.7
Paxalisib	7.5	8	8	8	7.8	6	phase 2 (single arm)	**Kazia**	$28M	$1.23	$152.2
Temferon	7.5	8	6	8.5	7.6	7	phase 1/2	**Genenta**	$108M	$5.97	$123.4
AV-GBM-1	7	8	6	8.5	7.4	8	phase 2 (single arm)	**Avita**	$610M	$4.65	$103.2
TV1-Brain-1	6	6	7	8.5	6.5	9	phase 1	**TVAX**	$50M Private		$66.9
LAM561 (2-OHOA)	5	5	9	8	6.1	10	phase 1/2	**Laminar**	$5M Private		$176.5
ITI-1000 (pp65 DC Vaccine)	5	5	7	7.5	5.7	11	phase 1	**Immunomics**	$64M Private		$88.6

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Glioblastoma Markets: SurVaxM could have a $2.5B global market for GBM alone

Market Capture Per Year			
Glioblastoma	**Cases/yr**	**24% (Low)**	**40% (Average)**
USA	13,000	**$0.31**	**$0.52**
China	70,000	$1.68	$2.80
Japan	2,700	$0.06	$0.11
Korea	627	$0.02	$0.03
France	3,200	$0.08	$0.13
Germany	4,700	$0.11	$0.19
Italy	4,300	$0.10	$0.17
Spain	2,600	$0.06	$0.10
UK	2,800	$0.07	$0.11
	Billions	$2.49	$4.16

- With low market penetrance (24%) SurVaxM is $310.0M GBM market per year in the US alone
- COGS SurVaxM
  expected to be $300/single dose base manufacture cost
- Estimated Pricing
  potentially $100,000/8 dose regimen/yr.
- Comparatively a course of temozolomide chemotherapy currently used for all GBM patients (SOC) is $120,000/yr. and represents a $600M GBM market/yr.
- In contrast to cellular-based immune therapies (DC, CART) which average >$200,000/dose and are close to $1M per course/per patient. Cellular immunotherapy is very difficult for insurance reimbursement and market sustainability.

Sources:
1. Annual Report to the Nation on the Status of Cancer, 1999–2015 JNCI: Journal of the National Cancer Institute, 2019
2. Chin Med J (Engl). 2011 124(17):2578-83., Datamonitor Healthcare
3. Global, regional, and national burden of brain and other CNS cancer, 1990–2016: a systematic analysis for the Global Burden of Disease Study 2016
4. Brain Tumor Res Treat. 2017 5(1):16-23.

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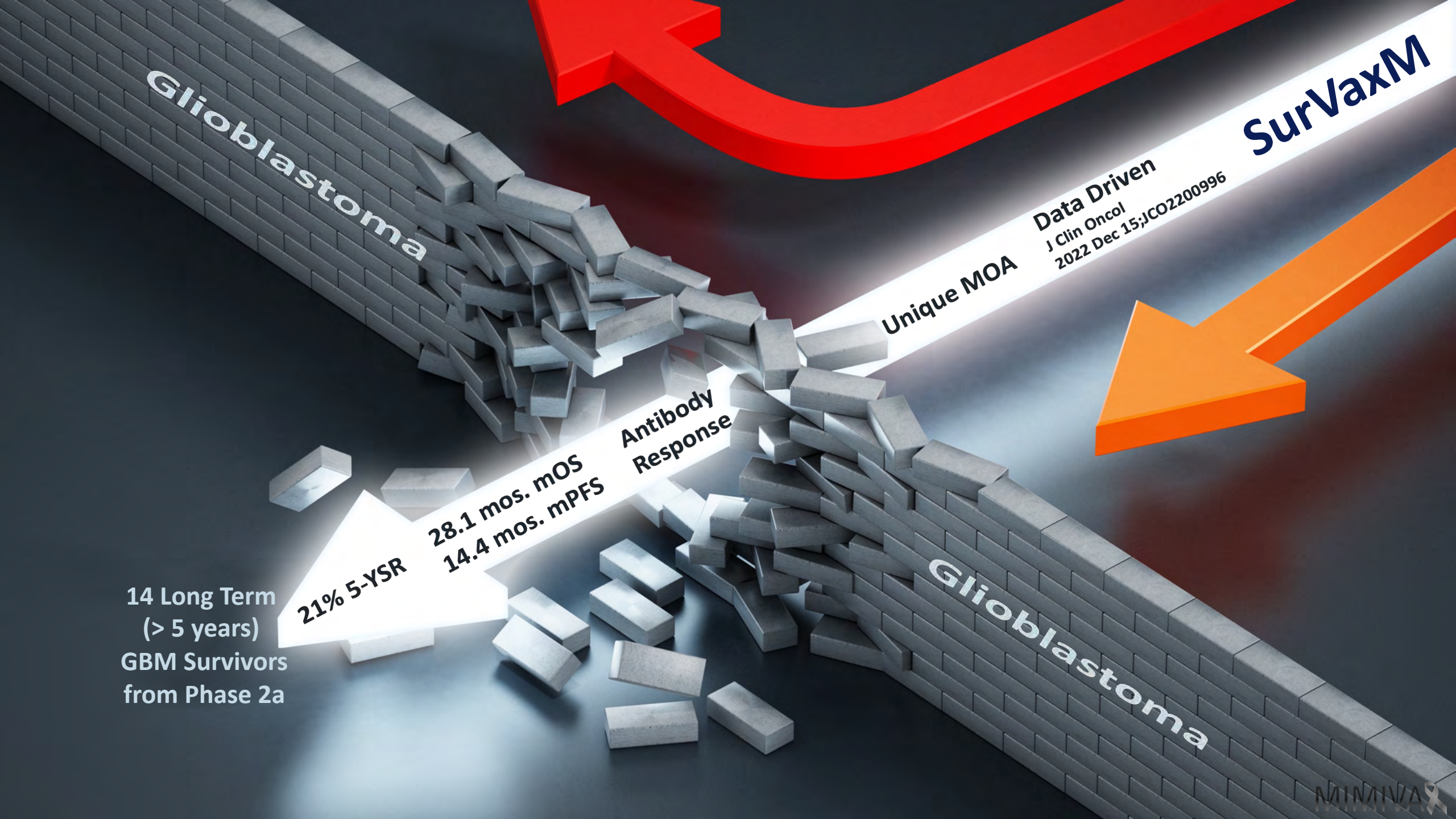
Glioblastoma
SurVaxM
Unique MOA
Data Driven
J Clin Oncol
2022 Dec 15;JCO2200996
Antibody Response
28.1 mos. mOS
14.4 mos. mPFS
21% 5-YSR
14 Long Term (> 5 years) GBM Survivors from Phase 2a
Glioblastoma

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MICHAEL CIESIELSKI, PHD

CEO & co-founder

ROBERT FENSTERMAKER, MD

CMO & co-founder

DANIELLE CASUCCI, BA, BS, GN, CCRP, CCIP

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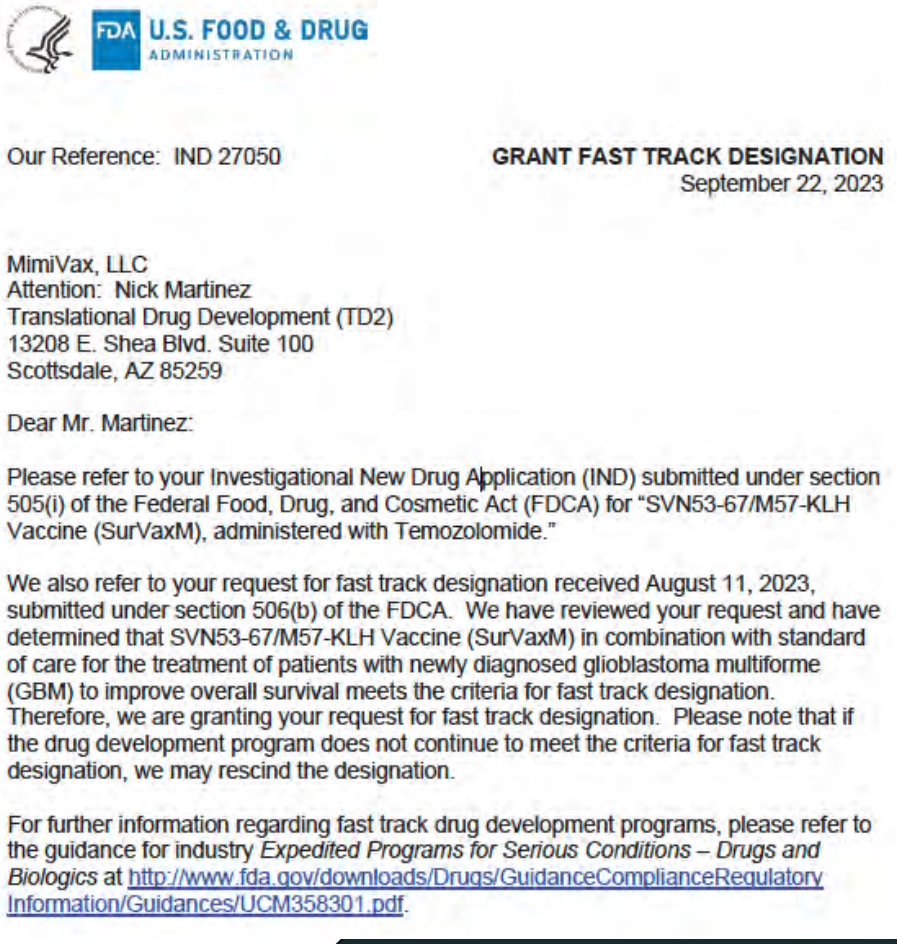
WORKING TOGETHER WITH EXPERIENCED CRO'S

PROUDLY SUPPORTED BY PRIVATE INVESTORS, VENTURE PHILANTHROPY, DONATIONS & THE BUFFALO, NY COMMUNITY

MimiVax:Updates

MimiVax was granted Fast-Track Designation Approval by US FDA for SurVaxM on 9/22/2023



U.S. FOOD & DRUG ADMINISTRATION

Our Reference: IND 27050

GRANT FAST TRACK DESIGNATION
September 22, 2023

MimiVax, LLC
Attention: Nick Martinez
Translational Drug Development (TD2)
13208 E. Shea Blvd. Suite 100
Scottsdale, AZ 85259

Dear Mr. Martinez:

Please refer to your Investigational New Drug Application (IND) submitted under section 505(i) of the Federal Food, Drug, and Cosmetic Act (FDCA) for "SVN53-67/M57-KLH Vaccine (SurVaxM), administered with Temozolomide."

We also refer to your request for fast track designation received August 11, 2023, submitted under section 506(b) of the FDCA. We have reviewed your request and have determined that SVN53-67/M57-KLH Vaccine (SurVaxM) in combination with standard of care for the treatment of patients with newly diagnosed glioblastoma multiforme (GBM) to improve overall survival meets the criteria for fast track designation. Therefore, we are granting your request for fast track designation. Please note that if the drug development program does not continue to meet the criteria for fast track designation, we may rescind the designation.

For further information regarding fast track drug development programs, please refer to the guidance for industry *Expedited Programs for Serious Conditions – Drugs and Biologics* at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM358301.pdf.

Additional Data

MV2C2 Antibody Program

Myasthenia Gravis

This project was made possible by funding from the National Institute of Neurologic Disorders and Stroke Small Business Research Programs (SBIR/STTR)

SCAN ME

Humanized MV2C2 Program

Murine MV2C2-IgG2b (prototype)

Humanized MV2C2-IgG1 (Lead candidate)

NIH-NINDS-SBIR Supported

- Lead human antibody slated for Ph 2 SBIR application, IND enabling for auto-immune disease (Myasthenia Gravis)
- sdAb second generation survivin targeting binders/SurVaxM agents in oncology (tissue penetrating & ADC options)
- Seeking development and/or acquisition partners for antibody platform program

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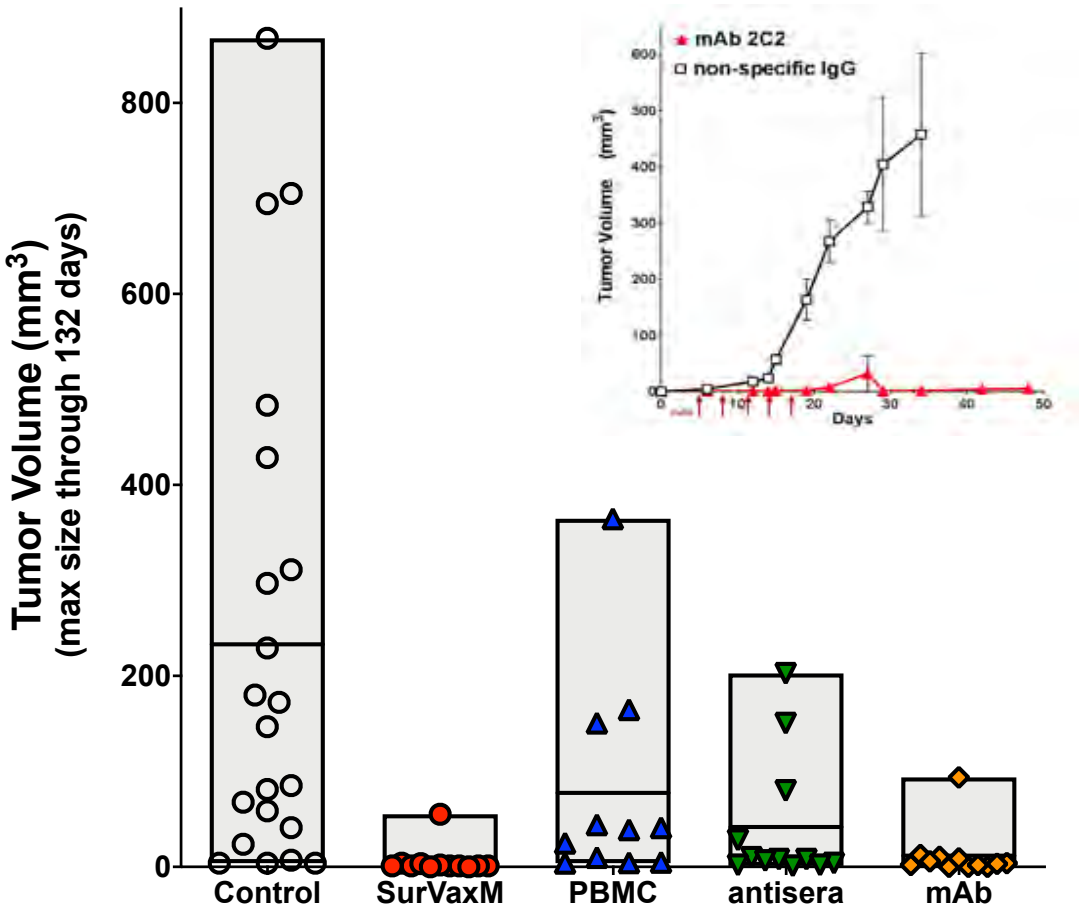
SurVaxM anti-tumor humoral and cellular response

- **The anti-survivin antibody (MV2C2) used SurVaxM as the antigen to recapitulate what we see in patients for further study**
- **GL261 glioma cell model growing SQ in C57Bl/6 mice**
- **Adoptively transferred PBMC from SurVaxM immunized to naïve mice retains some anti-tumor activity**
- **Transferred SurVaxM antisera also retains some anti-tumor activity in naïve mice**
- **Purified murine mAb IgG exhibits potent anti-tumor activity by itself without any T cells**
  - **Survivin isoforms are present at the cell surface, accessible to antibody-mediated immune mechanisms**



Fenstermaker, RA et al. Survivin Monoclonal Antibodies Detect Cell Surface Expression and Inhibit Tumor Growth in vivo. Clin. Cancer Res., (2018)

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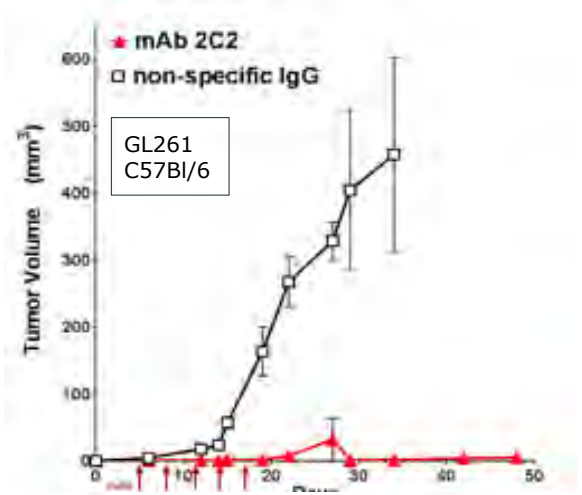
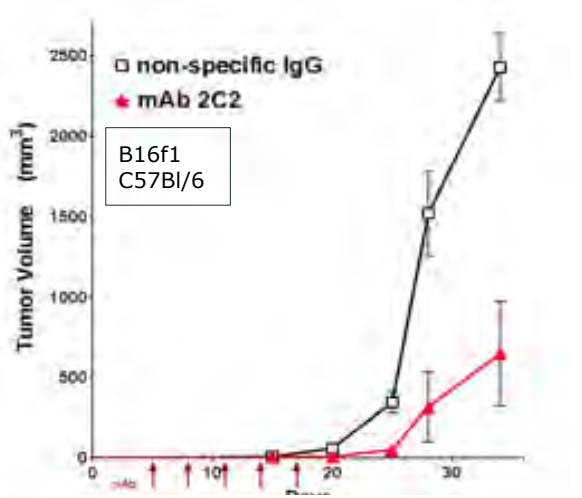
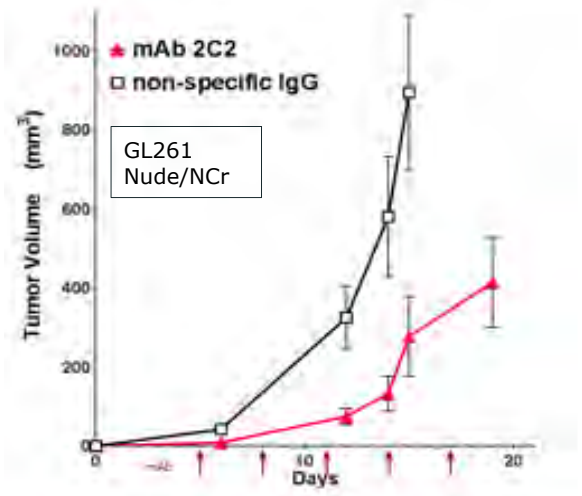
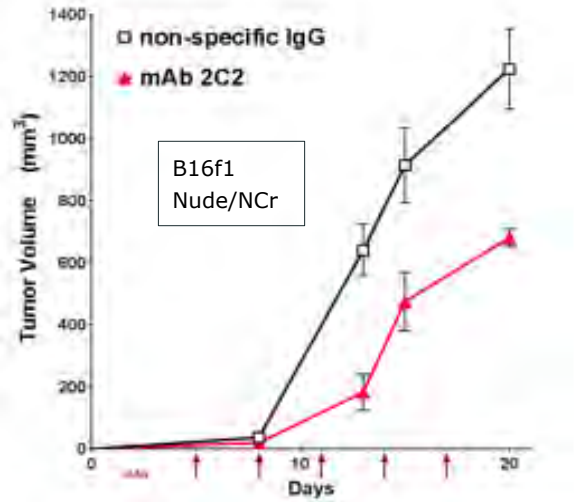
Anti-SurVaxM derived mAb IgG: KT0A0
Pre-clinical studies: Melanoma & Glioma

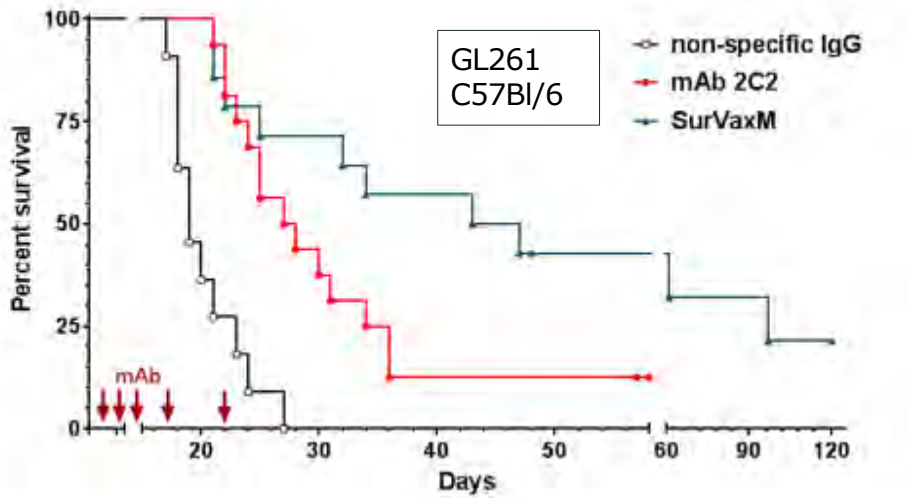








- Cloned anti-SurVaxM antibodies control tumor growth in SQ models of glioma(GL261) & melanoma (B16)



- Also effective treating GL261 growing intracranially

*Fenstermaker, RA et al. Survivin Monoclonal Antibodies Detect Cell Surface Expression and Inhibit Tumor Growth in vivo. Clin. Cancer Res., March 14 2018

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Total Survivin Expression MG Thymus

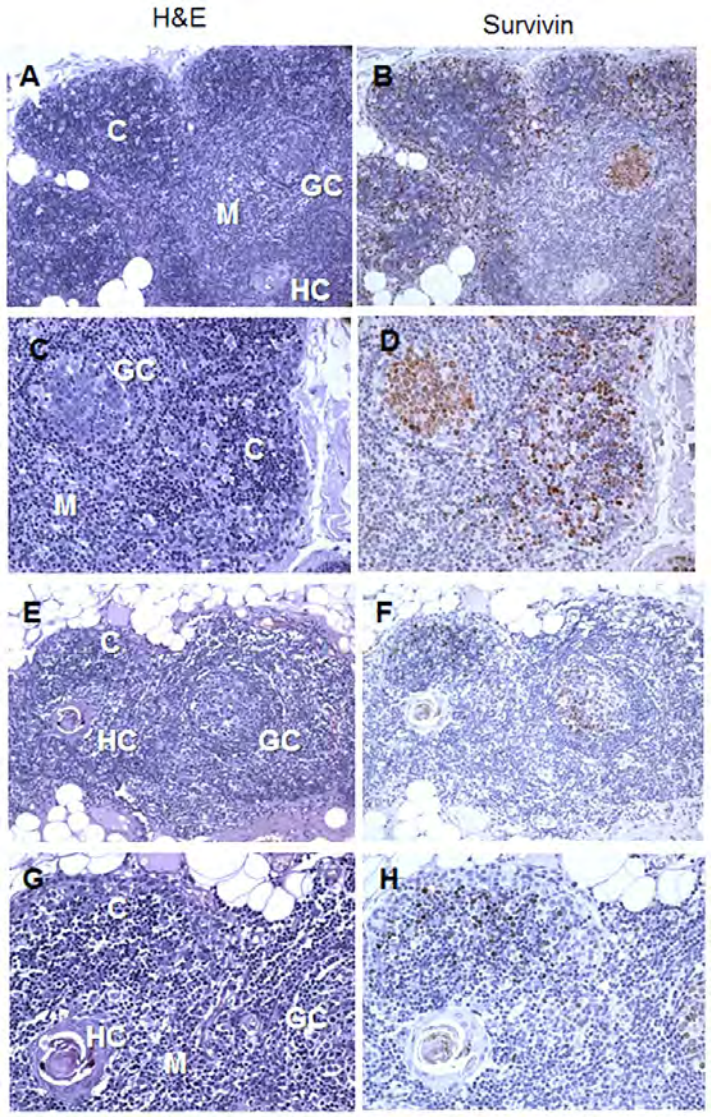


Figure 3. Survivin expression in the thymus. Representative images from an analysis of eleven thymuses from MG patients were analyzed for survivin expression (immunosuppression treated, n=7; immnosuppression naïve, n = 4).

A–D) MG thymus from a 24-year-old woman who had clinical symptoms for 2 years and an AChR antibody level of 19.3 nmol and had never received immunosuppression or prednisone showed a well developed cortex (C) and medulla (M), lymphofollicular hyperplasia with a germinal center (GC) close to Hassall's corpuscle (HC).

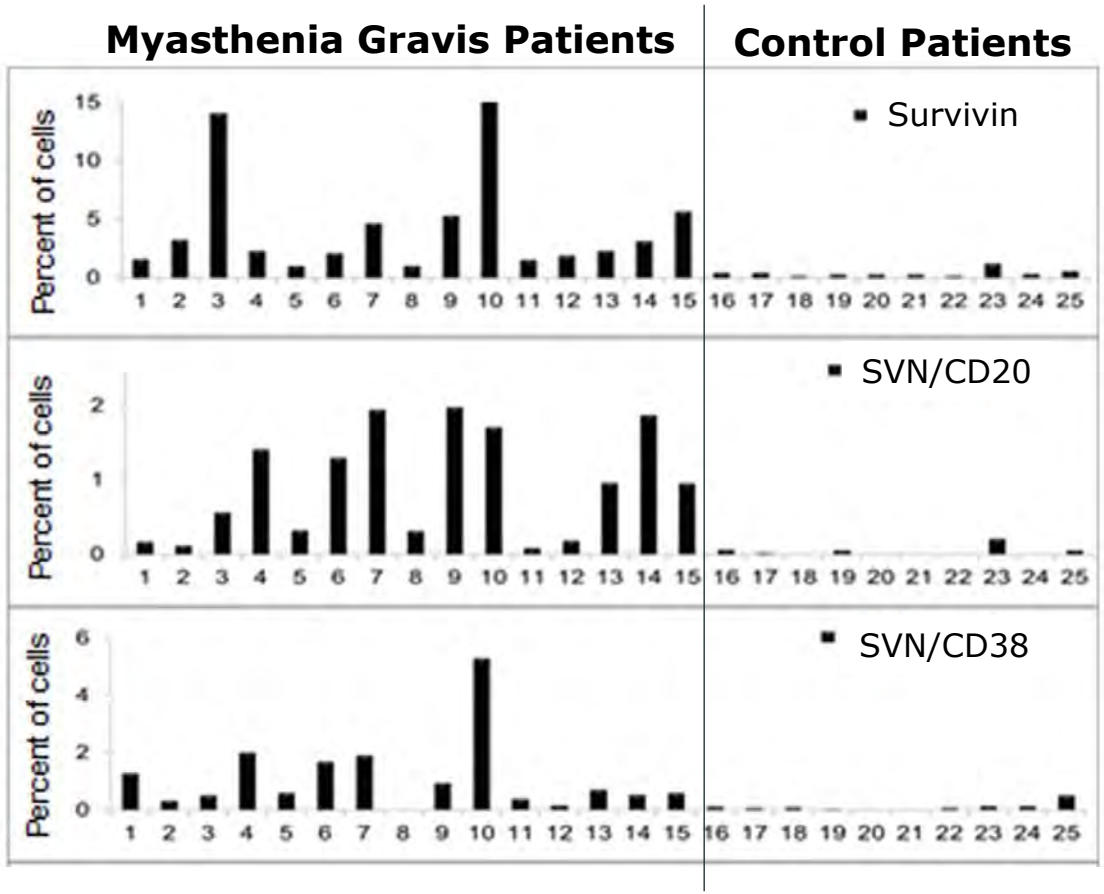
B,D) High number of survivin positive cells in the cortex (C), cortico-medullary junction and the GC.

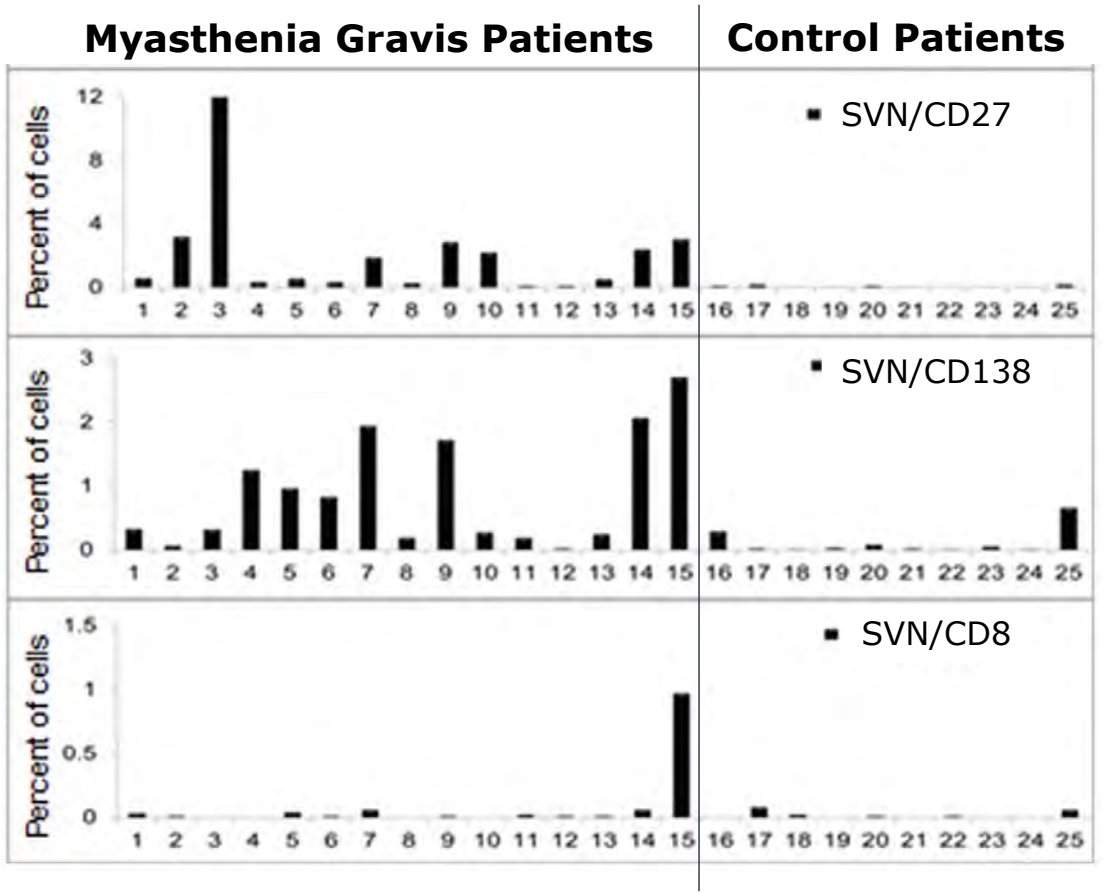
E–H) EOMG thymus from a AChR antibody positive 21-year-old female with lymphofollicular hyperplasia after long-term immunosuppression showing cortical atrophy and a slightly regressive germinal center (GC) close to a Hassall's corpuscle (HC).

F,H) Low number of survivin positive lymphocytes in the remnant cortical area (C), and the germinal center (GC) (A,B,E,F,6100; C,D,G,H6200).

doi:10.1371/journal.pone.0102231.g003

Survivin expression of B-cells (plasma lineage) in myasthenia gravis patients





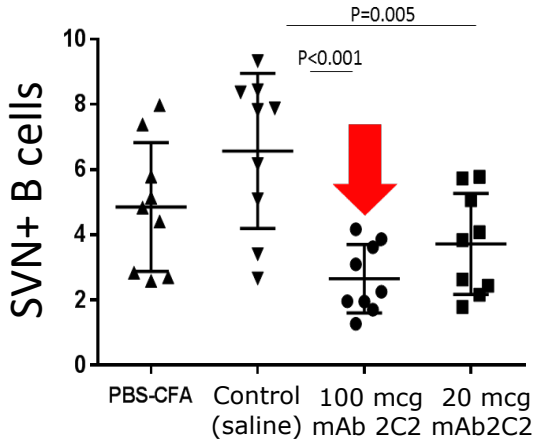
Survivin expression in myasthenia gravis patients (1–15) and control (16–25) PBMCs. FACS analysis of total survivin expression of PBMC stained with antibodies to indicated markers. Data reflect the percentage of total cells staining positive.

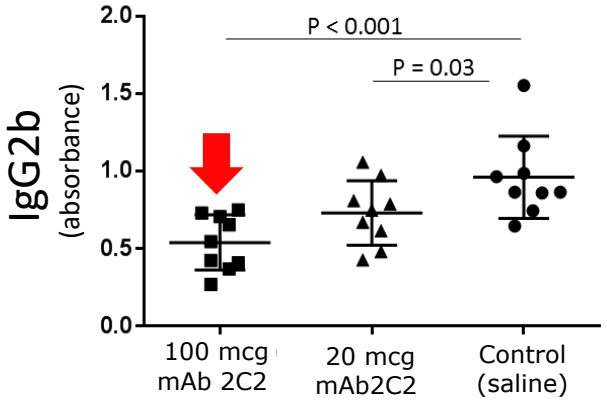
Kusner L. L., Ciesielski M. J., Marx A., Kaminski H. J., Fenstermaker R. A. PLoS One 9: e102231. (2014)

MIMIVA

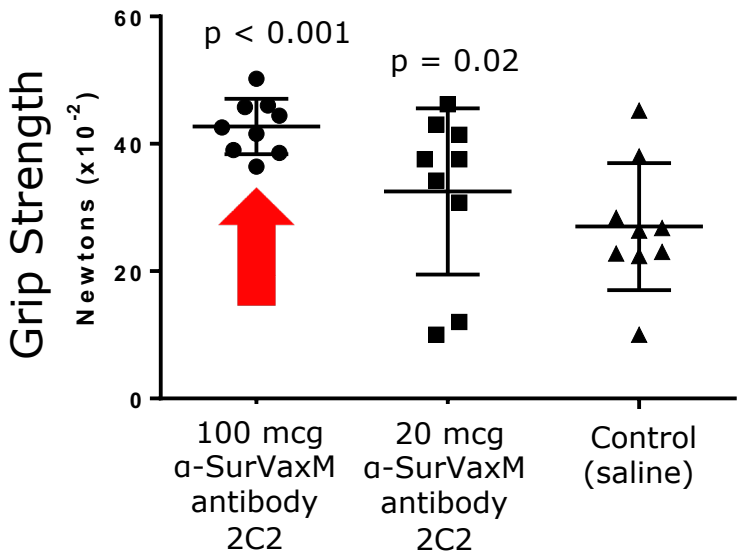
Significance: mAb 2C2 reduces severity of Myasthenia Gravis in animal models

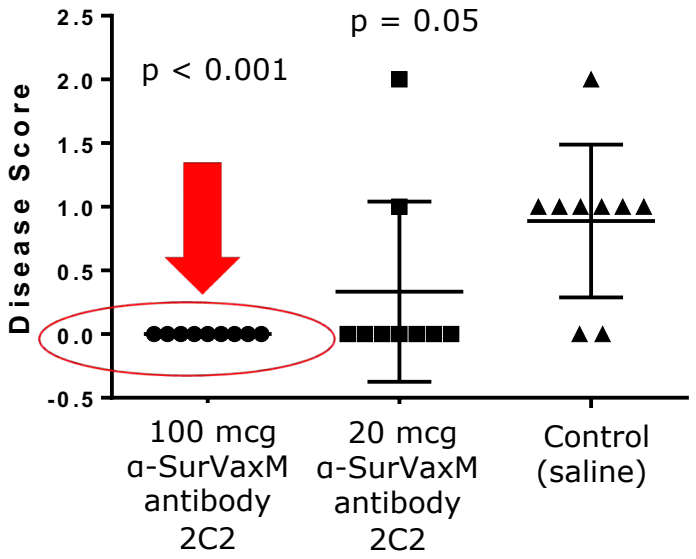
Experimental Autoimmune Myasthenia Gravis (EAMG) preclinical mouse model





- **After 14 days of every other day MV2C2 injection (20-100ug/i.p.)**
  - **SVN(+) B-cells <u>reduce</u> numbers**
    - **IgG2b levels <u>decline</u>**
      - **Strength <u>increases</u>**
        - **<u>Overall disease score decreases</u>**





Zhang, X; Ciesielski, M; Fenstermaker, R; Kaminski, H; Kusner, L. J Immunol. Oct 1; 205(7): 1743–1751 (2020)

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