



## Disrupting Cancer Through SurVaxM Immunotherapy

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[#disruptingcancer](#)

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# MimiVax History & Progress



2012

- Spin-out of Roswell Park Cancer Institute
- Founded in Buffalo, NY



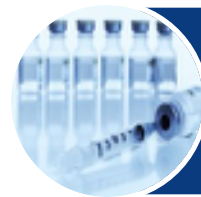
2015

- Series A; Buffalo Capital Partners
- SurVaxM Phase 1 recurrent glioma completed; mOS = 18.3 mos.



2016

- SurVaxM Phase 2 for newly diagnosed glioblastoma (Buffalo-Cleveland-Boston)
- SurVaxM Phase 1 + Revlimid for Multiple Myeloma



2017

- Orphan Designation Awarded by FDA



2018

- Landmark discovery of survivin on the cell surface (Fenstermaker & Ciesielski, Clin Cancer Res. 24:2642-2652)



2019

- SurVaxM Phase 2 Completed (n = 63)  
PFS6 = 97% OS12 = 94%  
mPFS = 15.5 mos. mOS > 30.5 mos.














- SurVaxM Phase 1 in Neuro-Endocrine Tumors (NET)
- SurVaxM Phase 1 in Pediatric Medulloblastoma & HGG
- SurVaxM Phase 1/2 + Keytruda for recurrent glioblastoma
- SurVaxM entering pivotal trial, newly diagnosed glioblastoma

## RECOGNITION AND PEER REVIEWED GRANT SUPPORT



# Multiple Asset Pipeline – Expanding Indications

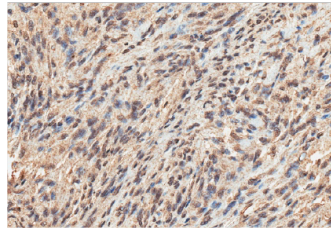
Product Candidate	Indication	Combo	Pre-Clinical	Phase 1	Phase 2	Pivotal/ RCT	Pharma Collaborators & Clinical Centers
SurVaxM®	Newly Diagnosed Glioblastoma (nGBM) NCT02455557	 Standard of Care (SOC)	FDA Orphan Drug Designated Accelerated Approval Path Phase 2 completed Q4 2018			RCT Initiating 2019	<ul style="list-style-type: none"><li>Manmeet Ahluwalia, Cleveland Clinic</li><li>David Reardon, Dana Farber</li><li>William Curry, MGH</li><li>Eric Wong, Beth Israel Med. Ctr.</li><li>Robert Fenstermaker, Roswell Park</li></ul>
	Recurrent Glioblastoma (rGBM)						<ul style="list-style-type: none"><li>Manmeet Ahluwalia, Cleveland Clinic</li><li>Merck &amp; Co.</li></ul>
	Multiple Myeloma NCT02334865						<ul style="list-style-type: none"><li>Kelvin Lee, Roswell Park</li><li>Celgene</li></ul>
	Pediatric Relapsed/Refractory Medulloblastoma & High-Grade Glioma (HGG)						<ul style="list-style-type: none"><li>Laura Wiltsie, Roswell Park</li></ul>
	Metastatic Neuroendocrine Tumors (NET) NCT03879694						<ul style="list-style-type: none"><li>Renuka Iyer, Roswell Park</li></ul>
MV209 CAR-T	Solid Tumors	TBD	   Novel cell-surface target To Be Progressed With Partners				<ul style="list-style-type: none"><li>Human CAR-T in vitro/in vivo data</li></ul>
MV2C2 mAb	Cancer / Autoimmune Disease	TBD					<ul style="list-style-type: none"><li>IND enabling studies</li></ul>
Exo-Dx	Liquid Diagnostic	-					<ul style="list-style-type: none"><li>Pre/post-surgery study ongoing</li></ul>



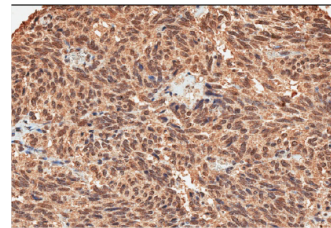
# What is Survivin?

"Survivin" is present in >90% of Cancers, an onco-fetal protein, rare in adult tissues.

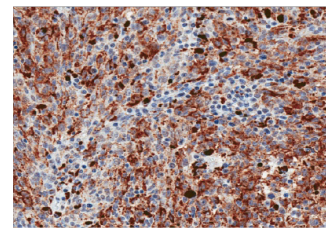
"Survivin" is a poor prognosis indicator & provides tumors the ability to grow and resist other forms of therapy



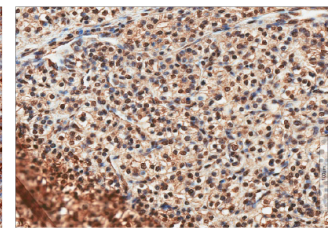
Glioblastoma



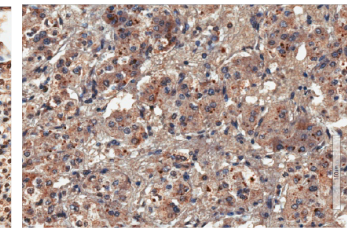
Adenocarcinoma



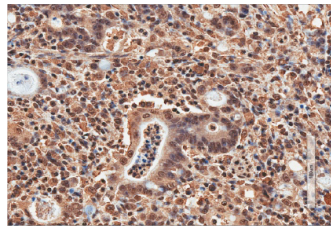
Melanoma



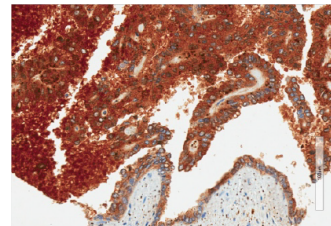
Squamous Cell



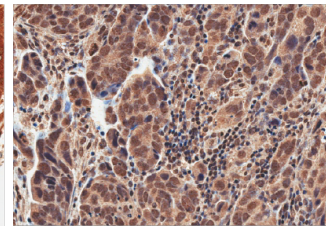
Pheochromocytoma



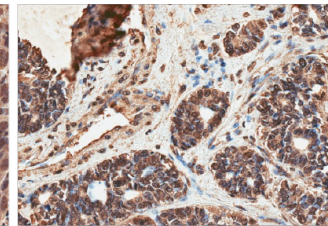
Endometrioid



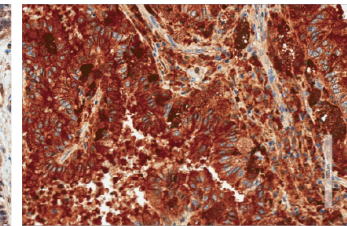
Renal Chromophobe



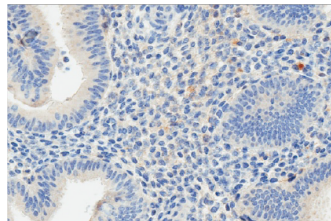
Hepatocellular



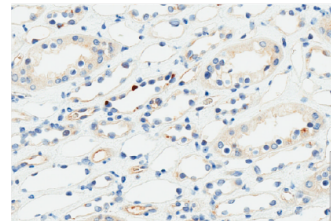
Atypical Carcinoid



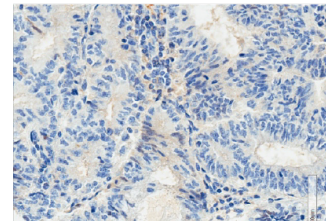
Renal Cell



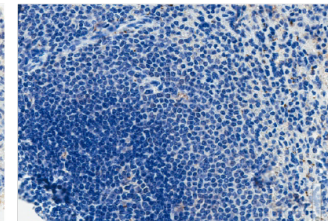
Normal Colon



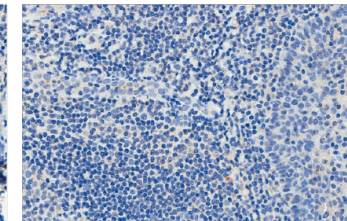
Normal Kidney



Normal Ovary



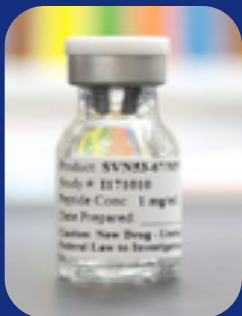
Normal Spleen



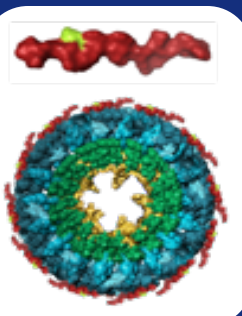
Normal Tonsil

# What is SurVaxM?

An immunotherapeutic vaccine, SurVaxM, utilizes molecular mimicry to circumvent immune tolerance and educate the immune system to target survivin-expressing tumors



- 15 Amino Acid Synthetic long peptide (SLP)
- Enhanced Antigen Presentation Engineering

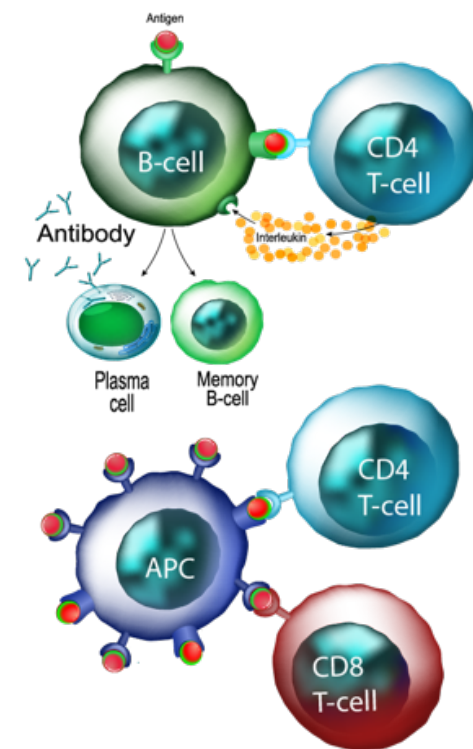


- HMW-Keyhole Limpet Hemocyanin (KLH) conjugate
- High-Density >250 peptide:1 KLH molecule delivery to provoke a robust immune response

SurVaxM is **cell-free** and administered as a subcutaneous injection.

- 500µg SurVaxM in Montanide ISA 51 VG + 100µg GM-CSF,
- 1<sup>st</sup> dose after resection & chemoradiation, before adjuvant temozolomide
- 4 Biweekly doses; followed by every 12 week maintenance dosing

The immune response specifically activates mid-affinity multi-clonal **CD8 T cells**, **CD4 T cells** & **Antibodies** which attack and kill the tumor through **multiple-mechanisms of action**.





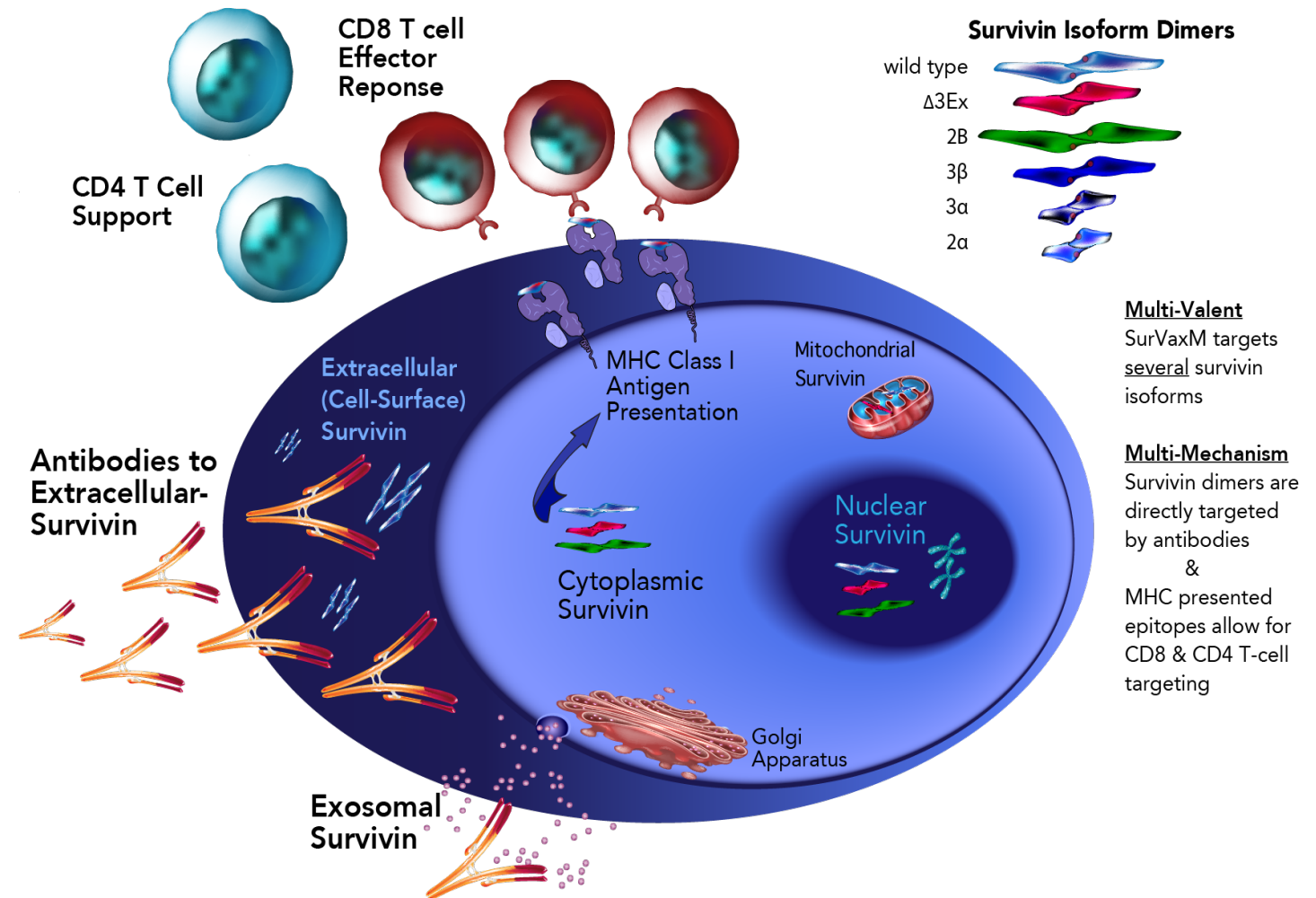
# How does SurVaxM Target Survivin?

“Survivin” exists as several isoforms located in different cellular compartments

- The SurVaxM response targets each isoform through **multiple mechanisms** resulting in **multi-valent immunity** to the many survivin molecular targets

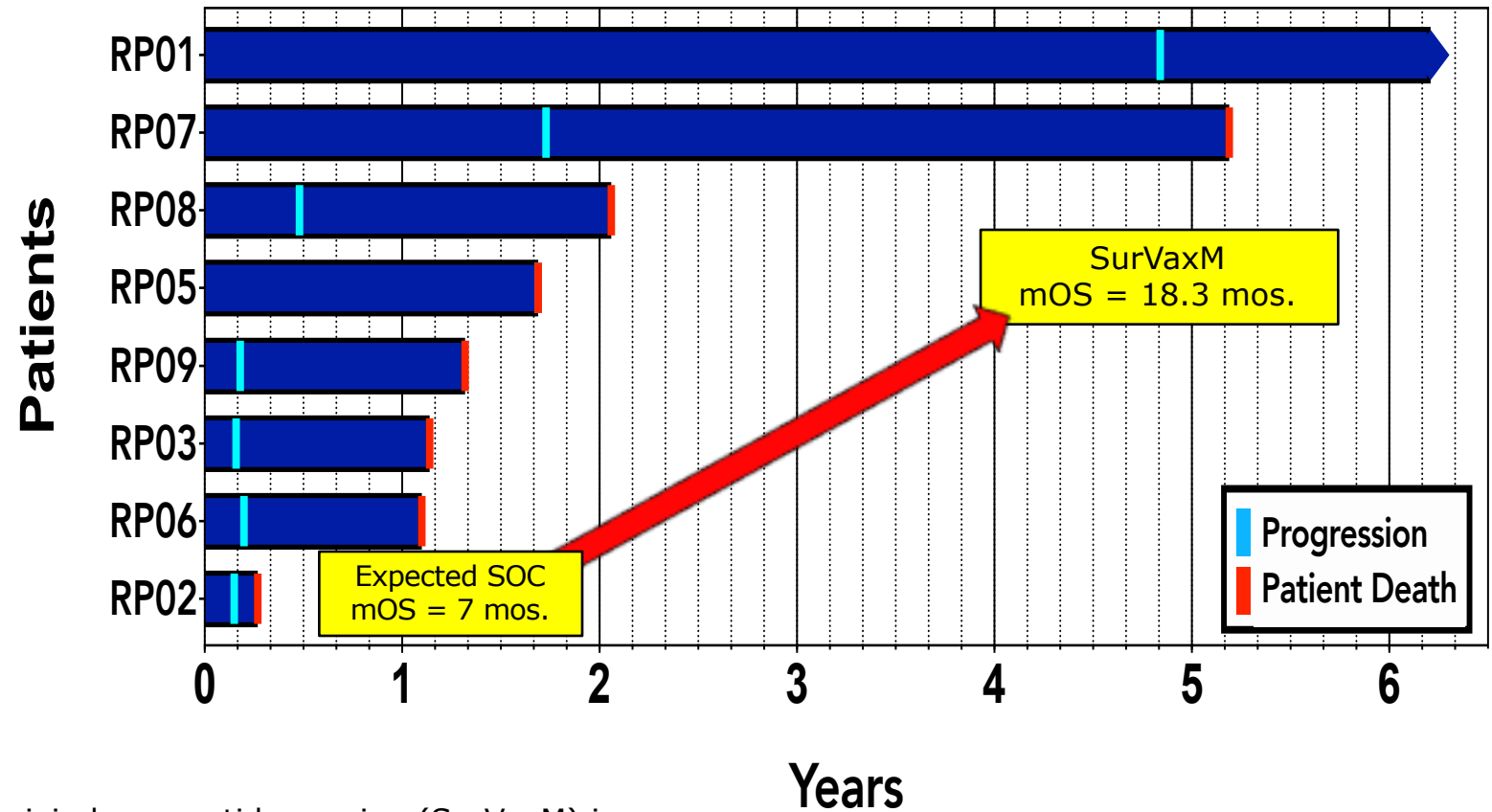
## Primary Actions

- Multi-epitope CD8 T cells via MHC Class I based cytotoxic effector responses
- Unique IgG recognition of cell surface survivin



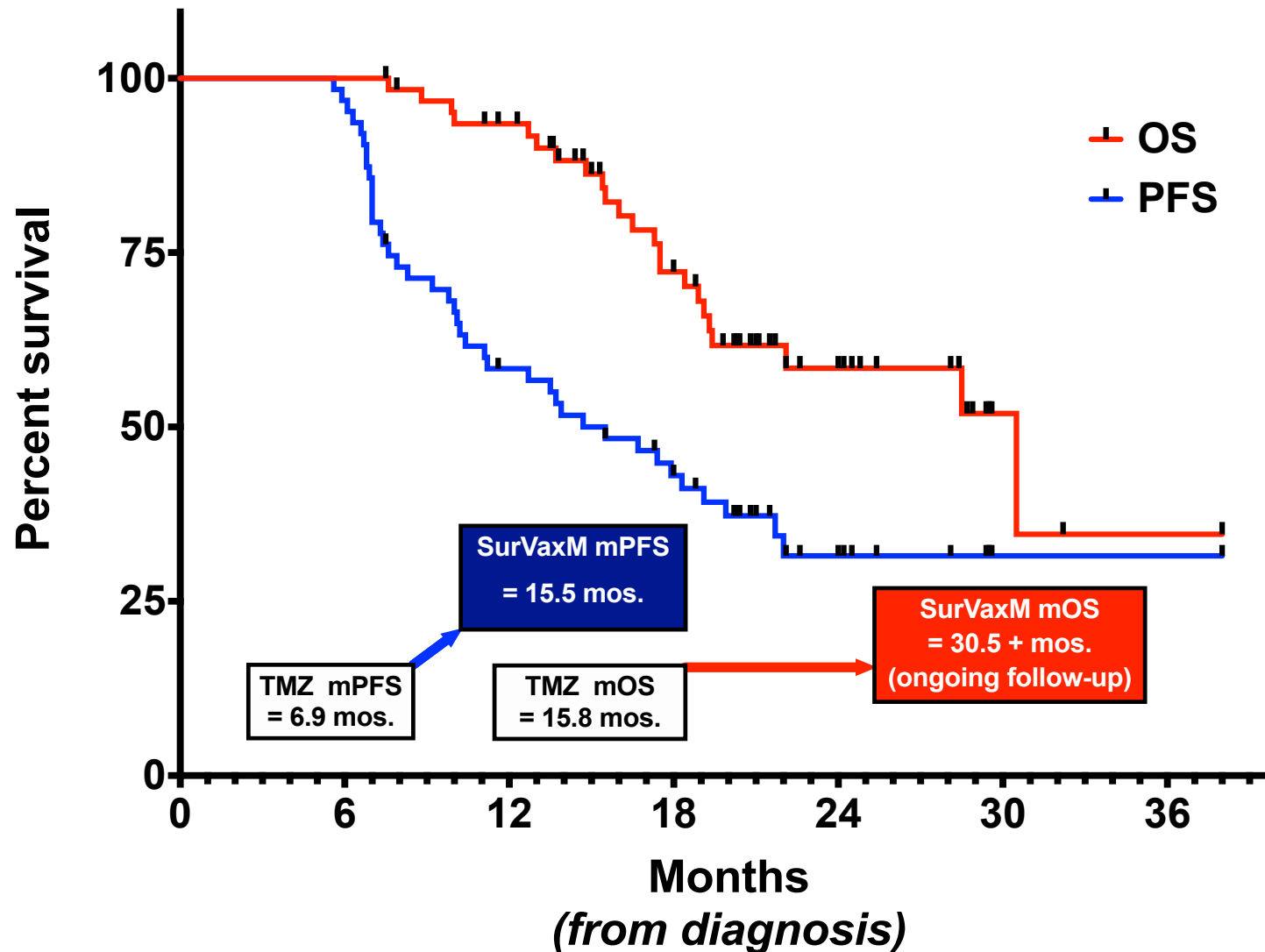
# SurVaxM Phase 1 study: Increased Overall Survival (OS) in Recurrent Glioma

Phase 1 Endpoints	Results in Recurrent glioblastoma <sup>#</sup>
Safety	Safe and tolerable Grade 1 injection site reactions
Immune response	7/8 (+) T cells 7/8 (+) antibodies
Efficacy	7/8 Patients increased OS 1 Complete response (CR)



<sup>#</sup>Fenstermaker RA, et al., Clinical study of a survivin long peptide vaccine (SurVaxM) in patients with recurrent malignant glioma. Cancer Immunol. Immunother. (2016)

# SurVaxM Phase 2 study: Increased Survival (PFS & OS) in Newly Diagnosed Glioblastoma



## Trial Design

- Newly diagnosed GBM (63 Patients)
- Multi-center
- Single arm SurVaxM®
- Comparable/historical SOC data

## Dosing/Schedule

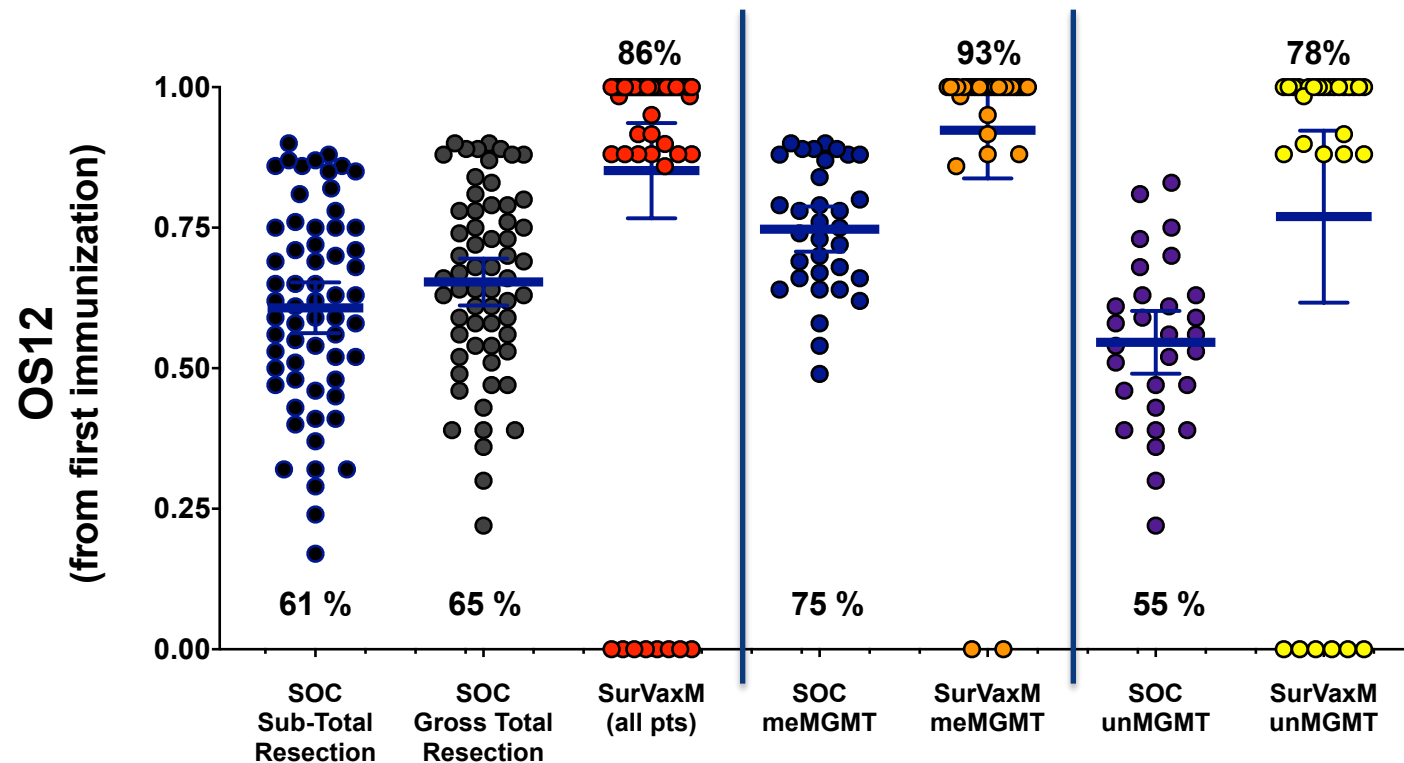
- 1<sup>st</sup> dose post resection/radiation & before adjuvant temozolomide
- 4 biweekly priming doses followed with every 12 week maintenance dosing

## Primary Endpoint Achieved (PFS)

- Data update released at ASCO 2019



# Predicted **OS15** for Standard of Care, Stratified by MGMT Status vs. SurVaxM Data



- **Prediction of SOC OS15** - based upon historical data nomogram\* incorporating patient characteristics of age, sex, KPS, extent of resection & MGMT status derived from larger phase 3 studies.
- SurVaxM Phase 2 OS12 is measured *from diagnosis*, to better align with nomogram data measured *from randomization* (+3 mos. from diagnosis) the SurVaxM OS15 is used.
- The predicted **SOC OS15** of each patient is compared to their actual **SurVaxM OS15**.

\*Neuro-Oncology 2017, 19:669-677

# Overall Survival & Progression Free Survival

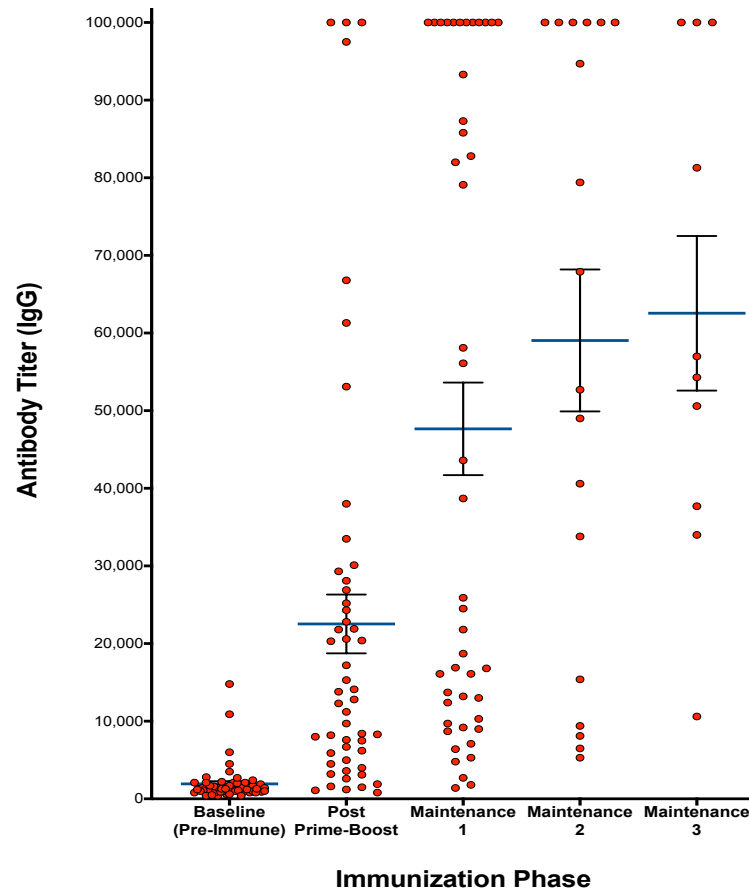
<i>Measured from Diagnosis</i>	OS12	OS24
<b>SurVaxM</b>	<b>93.5%</b>	<b>58.4%</b>
<b>Standard of Care</b>	<b>61-65%</b>	<b>27%</b>

PFS6	PFS12
<b>96.8%</b>	<b>58.4%</b>
<b>54%</b>	<b>27%</b>

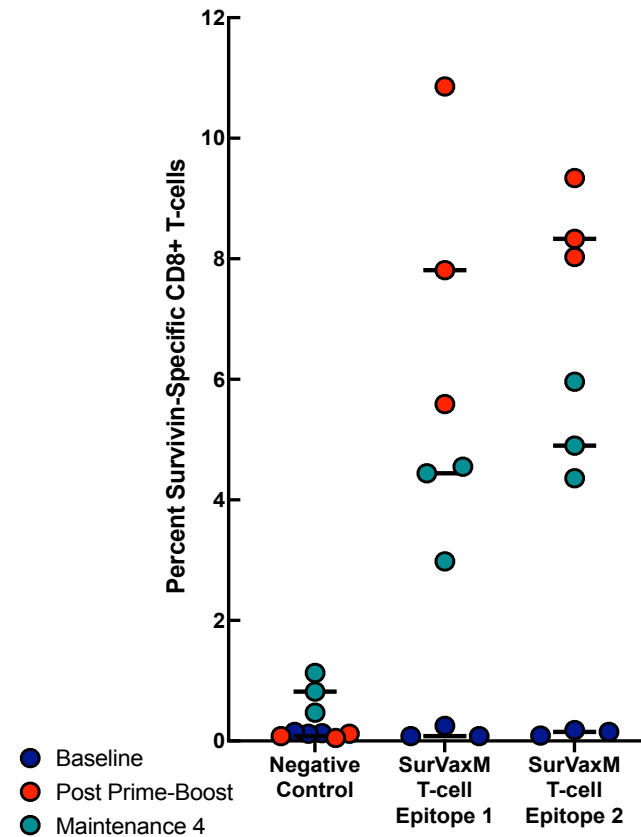
mOS	mPFS
<b>30.5</b>	<b>15.5</b>
<b>15.8</b>	<b>6.9</b>

# IgG & T cell Immune Responses

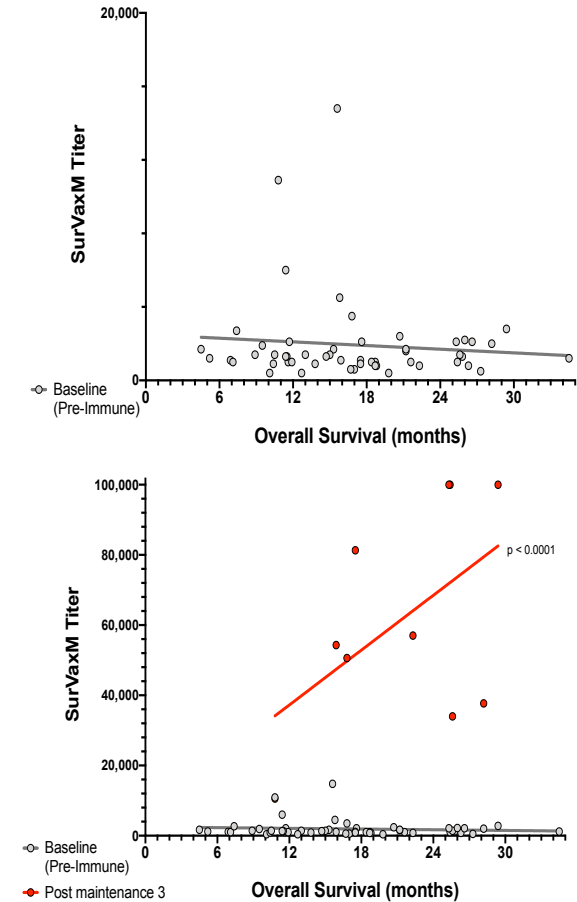
## Survivin-specific IgG



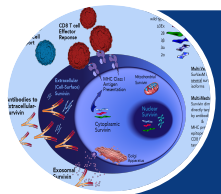
## CD8+ T cell responses



## Anti-survivin IgG correlated with OS



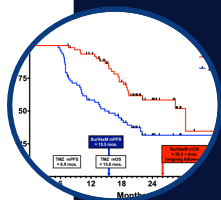
# How is MimiVax Disrupting Cancer with SurVaxM?



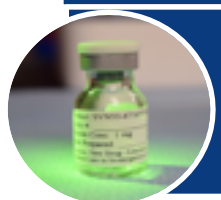
Exceptional therapeutic activity through  
MULTIPLE MOA's and UNIQUE targeting

Low Cost of Goods, Transportable, Stable

- Encouraging efficacy & immunogenicity in nGBM
- **93% of SurVaxM patients are alive at 1 yr**
  - Compared to 61% historical SOC
- **SurVaxM mPFS = 15.5 mos from diagnosis**
  - Compared to 6.9 months historical SOC
- Less risk with higher margin of POC data over SOC



Enhanced QOL, Ease of administration & Safety



Market Exclusivity

- Worldwide patent life beyond 2033+
- FDA Orphan Drug Designation
- Potential for Accelerated Approval Track





# MimiVax Present & Future Development



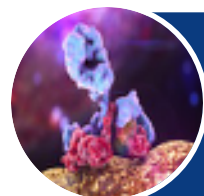
- Current combination studies using SurVaxM
- Phase 1 Multiple Myeloma / Revlimid (Celgene)
  - Phase 2 Recurrent Glioblastoma / Keytruda (Merck)



- Expanding SurVaxM to other cancer indications
- Phase 1 for NeuroEndocrine Tumors (NET)
  - Phase 1 Pediatric Medulloblastoma & HGG



- Entering Pivotal Randomized Controlled Trial (RCT)
- FDA orphan disease designation awarded 2017
  - Pursuing FDA accelerated approval track



- Developing MV2C2 mAb for Oncology & Autoimmune
- MV2C2 pre-clinical activity in melanoma and glioma
  - MV2C2 pre-clinical activity in Myasthenia Gravis



- Developing manufacture of SurVaxM
- USA & Worldwide Pharma Partners



MimiVax is assessing partnering opportunities & fund-raising to accomplish these goals



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