



MimiVax is a privately held, clinical-translational biotech based in Buffalo, NY, developing immunotherapy for survivin-expressing cancers and autoimmune diseases. Our mission is to disrupt cancer and provide hope for patients.

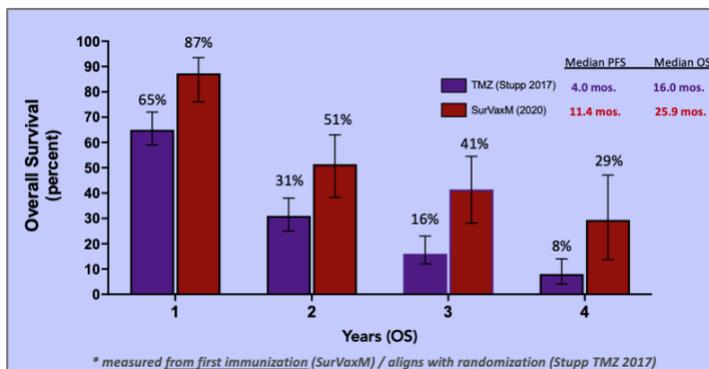
Our lead agent, **SurVaxM** is a novel immunotherapeutic cancer vaccine (peptide mimic-conjugate) designed to stimulate a multi-focal immune response to the tumor specific protein “survivin”. While vaccines are typically thought of as ways to prevent disease, cancer vaccines represent an immunostimulant to prevent tumor progression. SurVaxM is delivered through (cell-free) subcutaneous injection to stimulate both antibody & T-cell based immunity.

MimiVax holds an exclusive license to the SurVaxM platform patent portfolio for worldwide development & commercialization. MimiVax is led by a [globally recognized team and board](#) with extensive Neuro-Oncology, Immunology, Business, and Industry experience.

MimiVax Pipeline:

Product Candidate	Indication	Combo	Pre-Clinical	Phase 1	Phase 2a	Randomized Phase 2b	clinicaltrials.gov
SurVaxM [®]	Newly Diagnosed Glioblastoma nGBM	Temodar Standard of Care		Phase 2a Completed	Phase 2b New Recruiting		Phase 2a NCT02455557 Phase 2b NCT05163080
	Recurrent Glioblastoma rGBM	KEYTRUDA MERCCK		Fully Enrolled (n=40)			NCT04013672
	Multiple Myeloma	Revlimid Strat. Myers Sqzab		Fully Enrolled (n=18)			NCT02334865
	Pediatric Relapsed/Progressive Medulloblastoma, High-Grade Glioma, Ependymoma & Newly Diagnosed DIPG	PBTC		Not yet recruiting Opening Q3-2022			NCT04978727
*FDA Orphan Drug Designation	Metastatic Neuroendocrine Tumors NET's	NET		Recruiting			NCT03879694
MV2C2 mAb	Survivin Expressing Cancers & Myasthenia Gravis (Autoimmune Disease)						• Roswell Park • George Wash. Univ.
MV209 CAR-T	Survivin Expressing Cancers						• Roswell Park

Phase 2a clinical trial data:



SurVaxM Clinical Trials:

Phase 1 (recurrent glioma). Completed; SurVaxM demonstrated to be safe and tolerable in 8 patients with recurrent glioma. SurVaxM also showed efficacy signals in these patients that had been failed by all standard therapies. Having expectations of only a few months survival, SurVaxM treated patients survived 1-6 years.

Phase 2a (newly diagnosed glioblastoma). Completed; 63 newly diagnosed glioblastoma patients (at five cancer centers) were enrolled to receive SurVaxM. In this single arm study, median time to tumor progression was 11.4 months (vs. 4 mos. for historical control). Overall survival was 25.5 months (vs. 16 mos. historical control).

Pediatric High Grade Glioma (HGG), Recurrent Medulloblastoma & Diffuse Intrinsic Pontine Glioma (DIPG): With no effective salvage regimens almost all children with progressive or relapsed malignant brain tumors succumb to their disease. Survivin is highly expressed in a variety of pediatric cancers. [A collaborative multi-center pilot study of SurVaxM in children](#) with progressive or relapsed medulloblastoma, HGG, ependymoma & newly diagnosed DIPG is planned for Q2-2022

Our goals are:

- To enroll first 100 patients to our newly opened SurVaxM phase 2b study in newly diagnosed glioblastoma
 - Complete interim analysis; perform sample size power adjustments and/or conversion to a pivotal study
- Complete CMC scaling to supply sufficient SurVaxM for potential commercial use
- Develop pre-clinical assets, MV2C2 monoclonal antibody for autoimmune disease (see page 2)
- Secure necessary funding; bridge to IPO and/or pharma partnerships for SurVaxM commercialization



About SurVaxM (Lead agent):

- Synthetic peptide conjugate designed to stimulate both an antibody and T-cell response in patients
- Biweekly subcutaneous injection x 4 doses; boosted every 2 mos. thereafter
- Its target, “survivin” family members, are present in >90% all forms of cancer and not just brain tumors
- FDA orphan disease designation (awarded 2017)
- Phase 2b multi-center randomized study is now open and enrolling patients

About MV2C2 antibody (Secondary Pipeline agent):

- Murine mAb (IgG) derived from SurVaxM immunization (Isolates the humoral component of SurVaxM MOA)
- MV2C2 binding affinity of 9.9×10^{-10} KD, with conformational specificity for survivin
- Efficacy in pre-clinical cancer models of glioma and melanoma
- Efficacy in pre-clinical autoimmune disease models of Myasthenia Gravis (autoreactive neuro-muscular response)
 - Survivin-expressing B cells may be targeted by MV2C2 as an effective therapeutic approach
 - Survivin is present in other autoimmune conditions, greatly expanding the utility of the SurVaxM platform

Highlights and Recent News

Roswell Park Opens Phase 2b Randomized Clinical Trial of Promising Brain Cancer Immunotherapy (2/4/2022). [Roswell Park](#) is the first center to treat patients in the advanced-stage clinical trial utilizing the brain cancer vaccine SurVaxM, offering a new treatment option for patients who are dealing with newly diagnosed glioblastoma. The multicenter randomized trial ([SURVIVE](#)) is sponsored by MimiVax LLC, a company spun off from Roswell Park in 2012. [more info](#)

MimiVax, LLC Receives FDA Approval to Initiate a New Phase 2b Clinical Study for the Treatment of Newly Diagnosed Glioblastoma (11/12/2021). [MimiVax](#) has received a “Study May Proceed” notification from the US FDA to initiate the Phase 2b trial of [SurVaxM](#) in newly diagnosed glioblastoma. The phase 2b “[SURVIVE](#)” trial will evaluate SurVaxM in a randomized, blinded, placebo-controlled, multi-center study to enroll at 15 U.S. and China sites. [more info](#)

MimiVax closes on \$5M (12/10/2021). MimiVax closed recently on a \$5 million round of funding that will support its Phase 2b trials, which opened at Roswell Park Comprehensive Cancer Center earlier this month and will eventually span about 15 cancer centers in the U.S. and China. [more info](#)

MimiVax LLC and Shanghai Fosun Pharmaceutical Co. Ltd. announce exclusive licensing agreement on SurVaxM for glioblastoma treatment in China (11/18/2019). Under terms of the agreement, Fosun Pharma and MimiVax will seek to clinically develop and commercialize SurVaxM to make it available for patients in China. Deal represents the largest Phase 2 asset license between the US and China in 2019. [more info](#)

MimiVax presents results of SurVaxM in glioblastoma at ASCO 2019 Meeting. Completed Phase 2a clinical studies confirm [SurVaxM's](#) strong proof of concept efficacy and safety profile to address newly diagnosed glioblastoma, which is currently a severe unmet medical need. Updated median progression free survival (mPFS) is 15.5 months from diagnosis. Median overall survival (OS) is at 28.5 months from diagnosis. SurVaxM immunotherapy generated encouraging efficacy and immunogenicity in glioblastoma with minimal toxicity. [more info](#)

MimiVax looks for game-changer in GBM as SurVaxM shows signal at interim look. In the ongoing study, survival trends strengthened as the data have matured. With the phase 2a in nGBM so far achieving a survival rate that exceeds the historical standard of care by 40 percent, the study already met its six-month PFS endpoint. [more info](#)

MimiVax is assessing investment & pharma partnering opportunities to achieve its goals

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