StemVax
THERAPEUTICS

STEMVAX, LLC

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StemVax Therapeutics
Los Angeles, California,
A NovAccess Global Company (XSNX)

Overview

- Investment Highlights
- Program Overview
- Technology
- Phase I Trial (Intro)
- Investor Opportunity
- Summary

Investment Highlights

Clinical and Pre-Clinical stage biopharmaceutical company developing next-generation immunotherapy products to treat Brain Cancer.

- Personalized Immunotherapy
- Dendritic cell-based approach to promote anti-tumor immunity
- Enhanced dendritic cell maturation and functionality over first-generation vaccine

Lead Candidate, TLR-AD1, dendritic cell-based vaccine for the treatment of glioblastoma multiforme (“GBM”)

- Particularly lethal form of cancer with minimal improvements in standard of care.
- Orphan Drug designation
- Preclinical data shows significant increase in survival over parent “first generation” vaccine.

IP estate of 2 issued patents additional patent development

Program Overview

Immunotherapy in Development: TLR-AD1

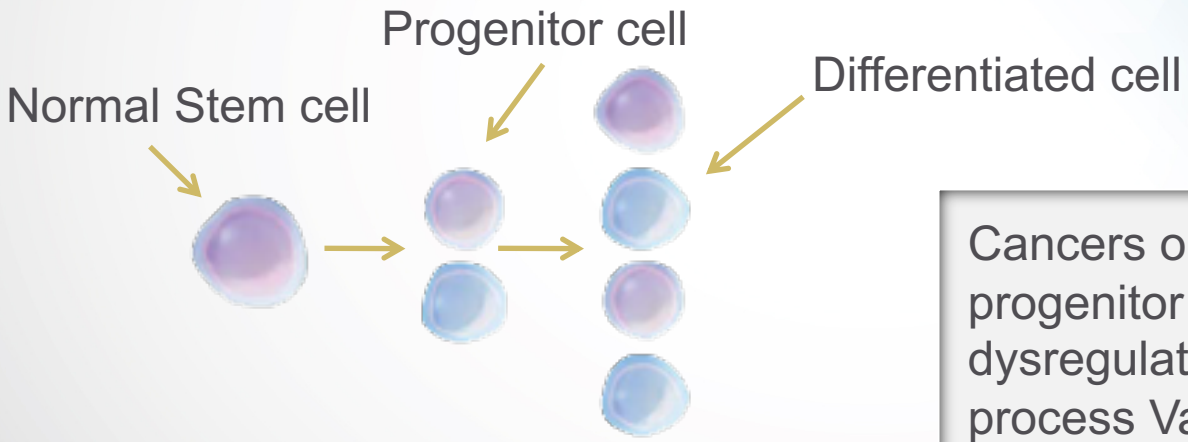
- Preclinical development demonstrated efficacy over leading dendritic cell immunotherapy approach currently in Phase II clinical trials (“ICT”)
- Can be combined with various antigens, including cancer stem cell antigens
- Preparing IND to be filed by end Q1 2021; Phase I clinical trial to start by end Q2 2023 or in Q3 2023
- With filing of IND will also file for Orphan Drug Designation

Program Overview

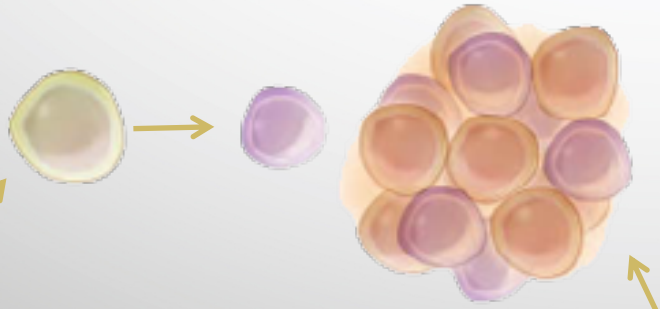
StemVax, LLC Company Development:

- Seeking initial funding through NIH SBIR and Investors
- Business Plan development
- Executive Board Development
- Scientific Advisory Board

Targeting Tumor



Cancers originate in tissue progenitor or stem cells through dysregulation of the self-renewal process Various antigens produce varying level of immunogenicity



Various antigens produce varying level of immunogenicity

Cancer Stem/progenitor

Heterogenous tumor

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Glioblastoma Multiforme (GBM)

- More than 18,000 brain tumors are diagnosed each year in the United States.
- GBM is the most common primary brain tumor in adults.
- Five-year survival rates are less than 5% for GBM.

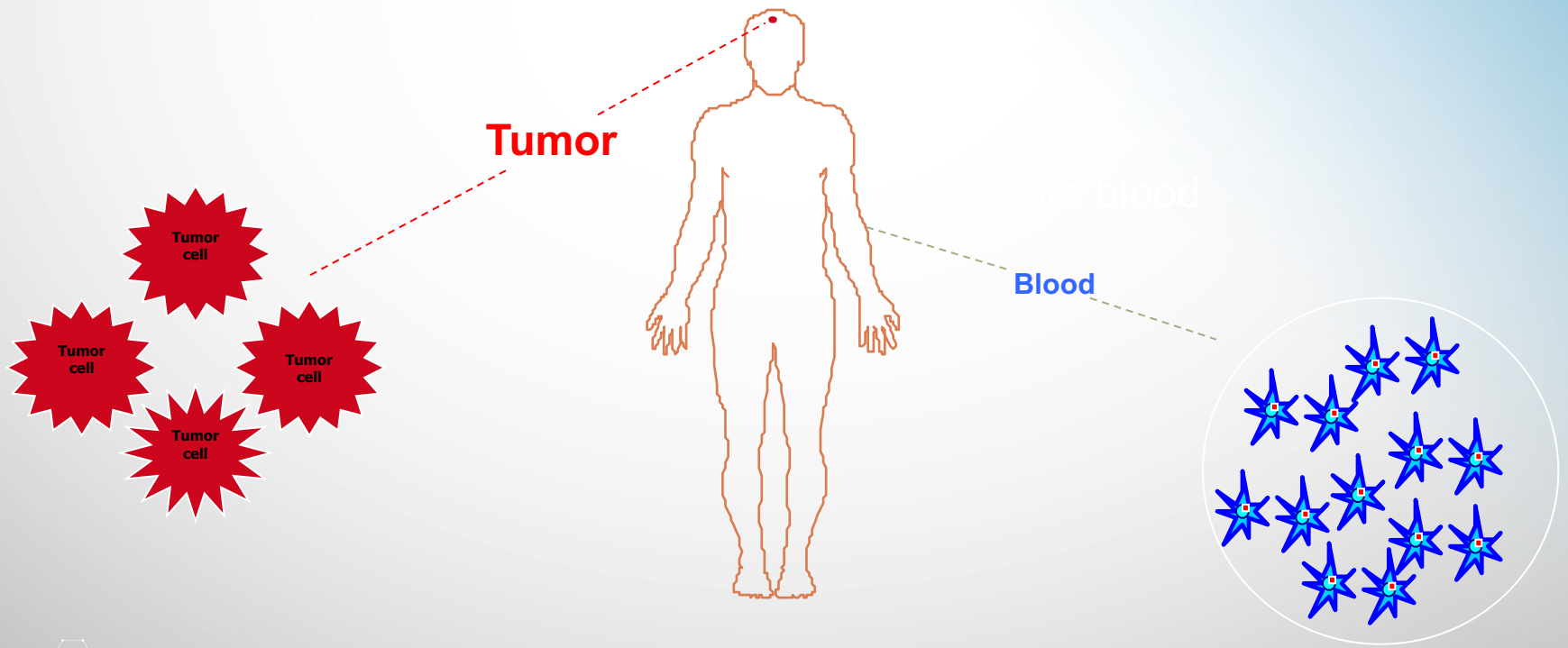
Glioblastoma Multiforme (GBM)

- Standard of Care: Surgical resection followed by radiation and temozolamide chemotherapy remains the most effective treatment.
- 15-month median survival.
- Additional GBM therapies needed - Immunotherapy?
  - Vaccination with cytokine-transfected tumor cells
  - Adoptive transfer of tumor-activated T cells
  - **Administration of antigen-pulsed dendritic cell (DC) vaccines - why?**
- All have been associated with enhanced immunity and/or favorable clinical outcomes

Dendritic Cell Vaccine (1st Generation)

- Improves survival in responders (Phase I and II)
- Not a cure
- Needs improvement-survival rates, outcomes

Brain Tumor Vaccine



Antigen Presenting Cells
(Dendritic cells)

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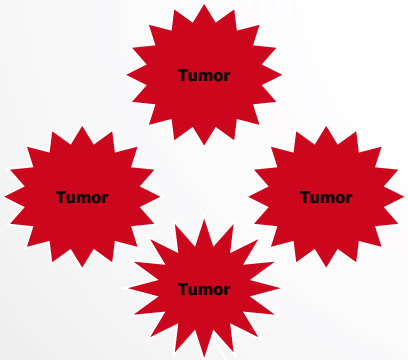
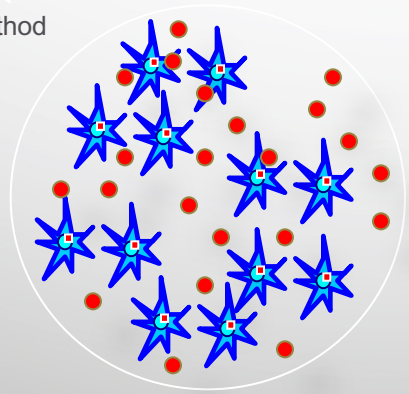
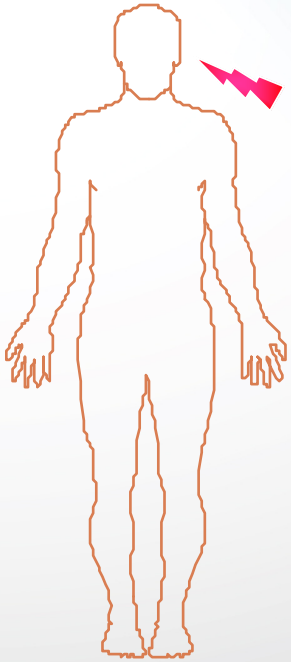
Brain Tumor Vaccine



Glioma cell lysate

Freeze-thaw method





Anti-tumor immune response

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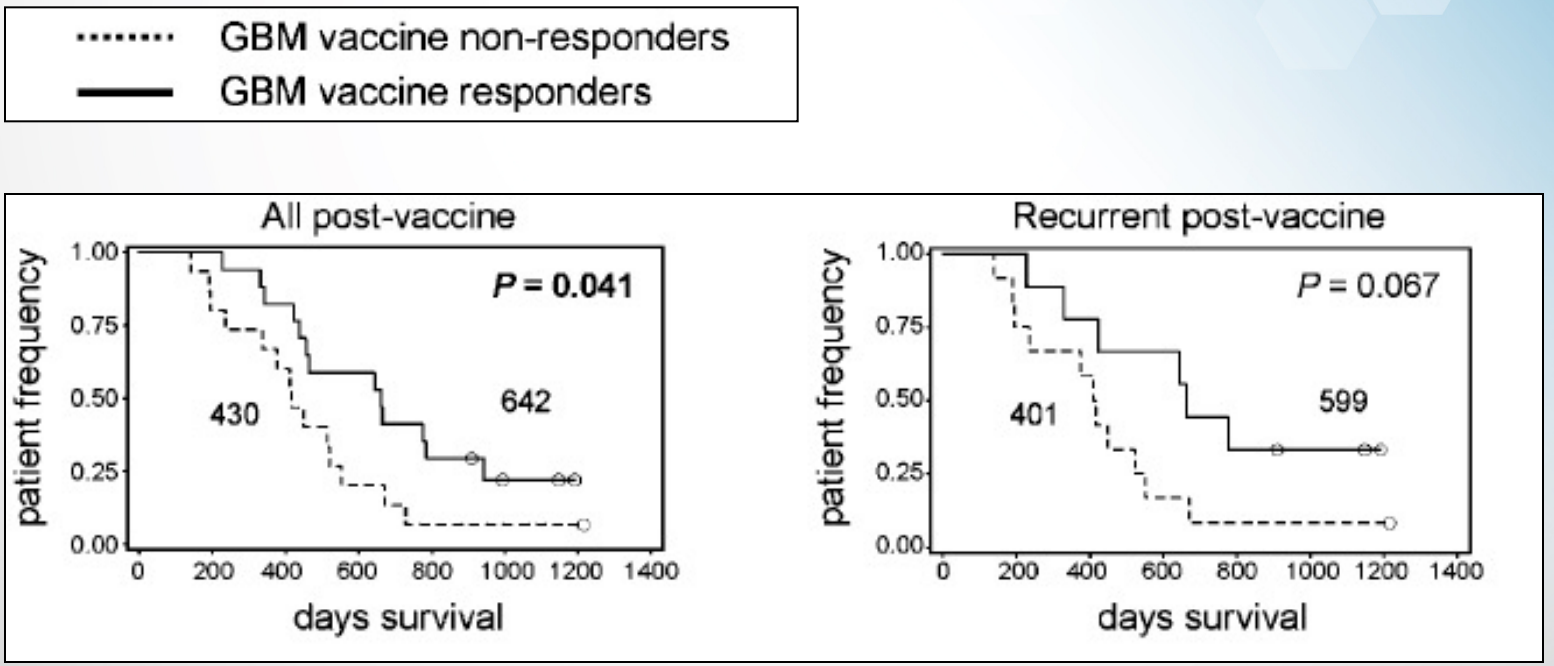
1st Generation Vaccine-Bulk Tumor Lysate



TTS (time from surgical resection immediately preceding vaccination to time of death)

(Wheeler et al, 2008, Cancer Research)

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How do we improve DC vaccine?

- Toll-like receptor (TLR) adjuvants

2nd Generation Vaccine - 6 Common Antigens (ICT-107)

ICT-107 - Targets Cancer Stem Cells Lead Indication in GBM

- PII data not encouraging and why we overcome the issues with ICT-107
- Why we are better and will succeed?

Antigen	Treats
gp100	melanoma, brain
MAGE-1	melanoma, brain, ovarian
IL-13Ra2	brain, ovarian
Her-2/neu	breast, ovarian
AIM-2	breast, colon, brain
Trp-2	melanoma, brain

Phase I Trial Results for ICT-107

Significant increase in median Progression Free Survival (PFS)
- 16.9 months for ICT-107
- 6.9 months for historical SOC*

Significant increase in 3-year PFS
- 38% for ICT-107
- 6% for historical SOC*

Significant increase in median Overall Survival (OS)
- 38.4 months for ICT-107
- 14.6 months for historical SOC*

Significant increase in 3-year OS
- 55% for ICT-107
- 16% for historical SOC*

Cancer Immunol Immunother. 2013 Jan;62(1):125-35

*Surgery followed by radiation and temozolomide (TMZ).
Stupp et al. N Engl J Med. 2005 Mar 10;352(10):987-96.

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3rd Generation Vaccine-TLR-AD-1

- Antigen specific or antigens derived from bulk lysate combined with Toll-like receptor (TLR) adjuvants

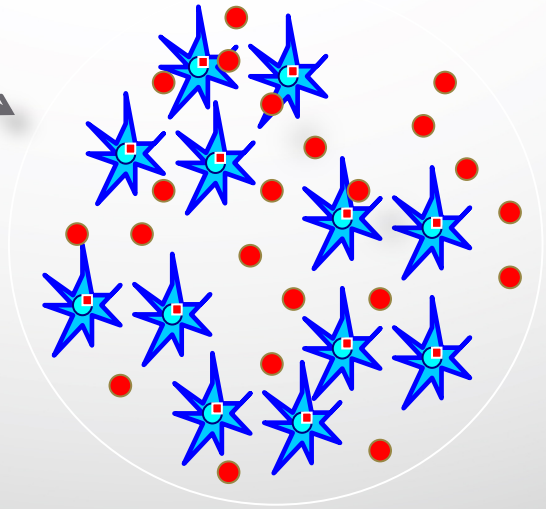
- Pre-clinical mouse model data show significant improvements in survival and dendritic cell activation and function

Dendritic Cell Assay

Glioma Antigens-Specificity

2.- Current
Toll-like receptor (TLR)
Adjuvants-Activate

TLR2, TLR4, TLR9



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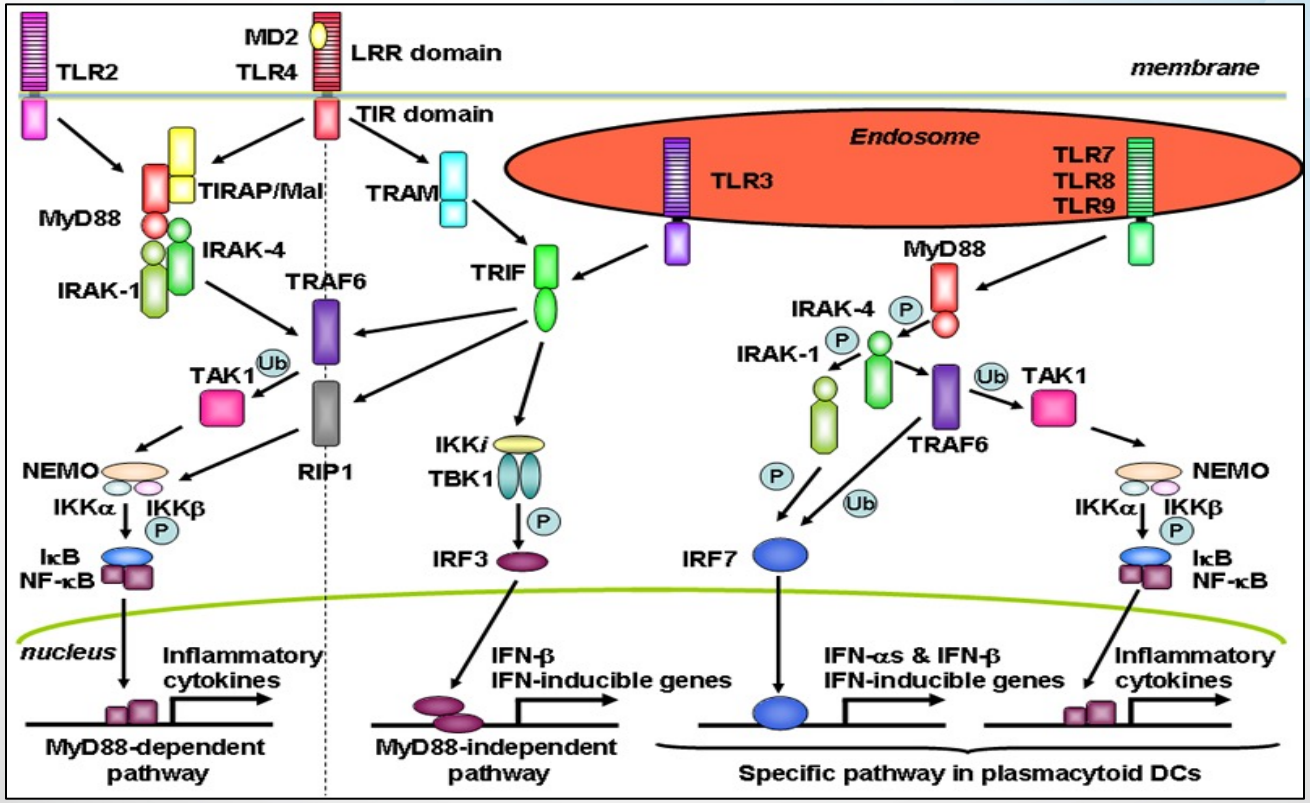
TLR Signaling Pathway



- Each TLR family member has its specific signaling pathway.
- TLR signaling is a common pathway to induce inflammatory cytokines.

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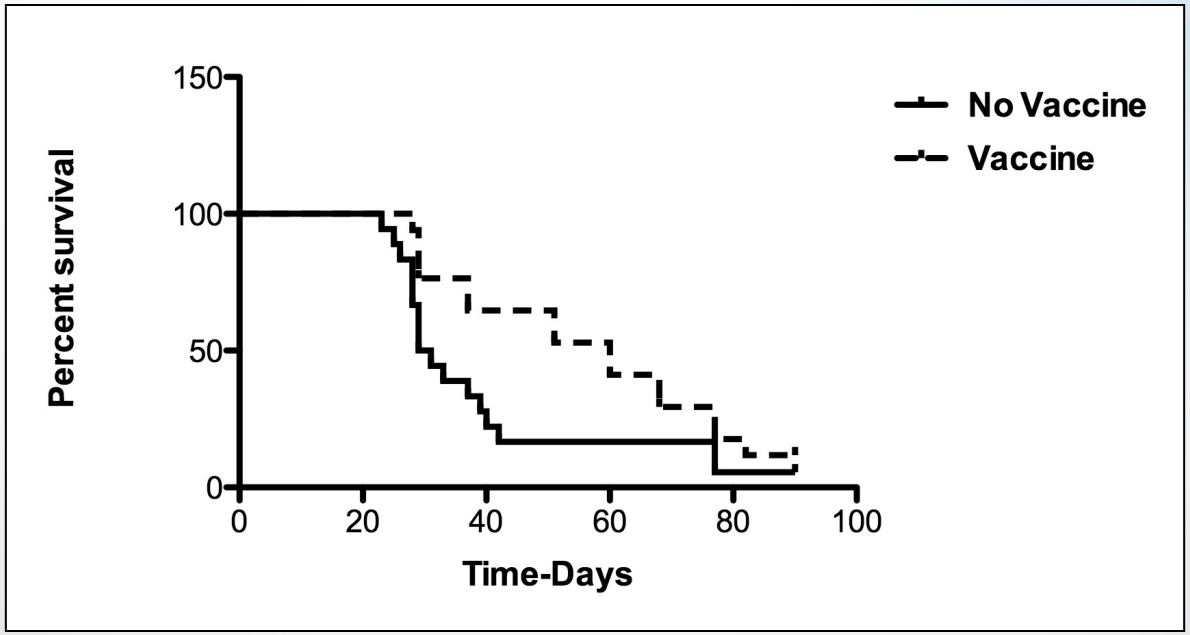
Pre-Clinical Kaplan-Mier Survival Analysis of Vaccinated Glioma Bearing Mice (Controls)



Median Survival

No Vaccine: 30 days **Vaccine:** 60 days

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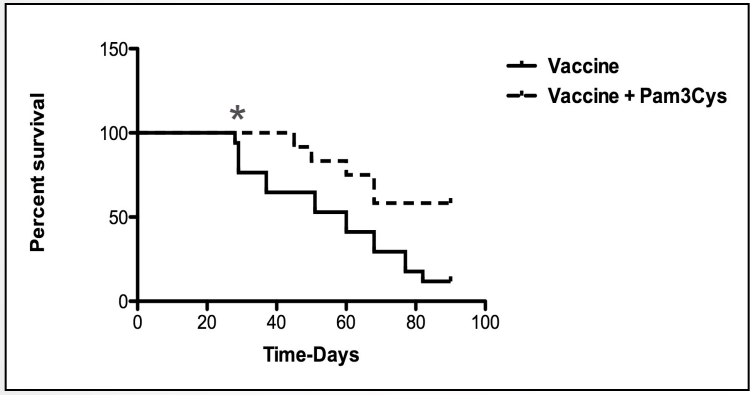
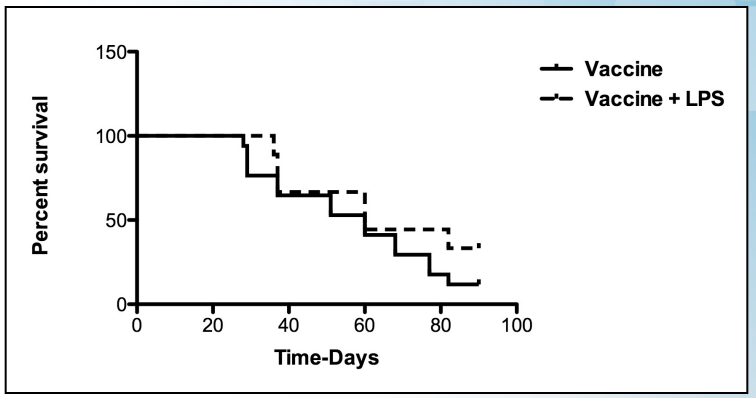
Pre-Clinical Kaplan-Mier Survival Analysis of Vaccinated Glioma Bearing Mice (Vaccine vs. TLR adjuvants)



Median Survival

Vaccine: 60 days

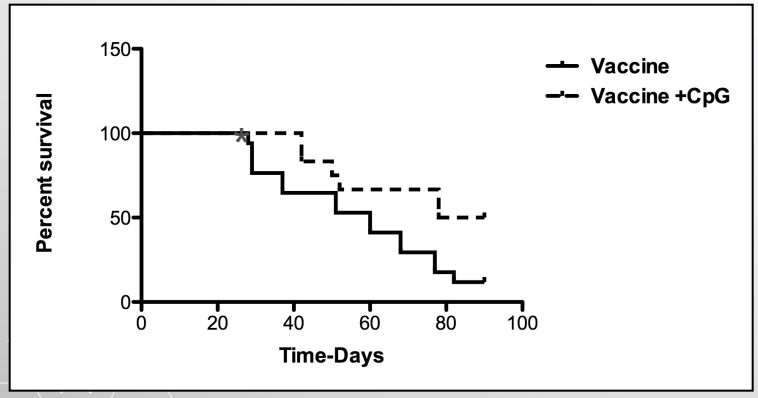
Vaccine + Pam3Cys: <90 days



Median Survival

Vaccine: 60 days

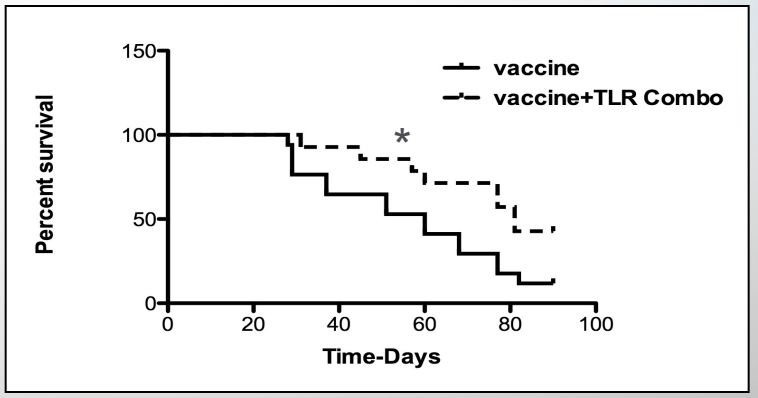
Vaccine + LPS: 60 days



Median Survival

Vaccine: 60 days

Vaccine + CpG: 84 days



Median Survival

Vaccine: 60 days

Vaccine + TLR Combos: 81 days

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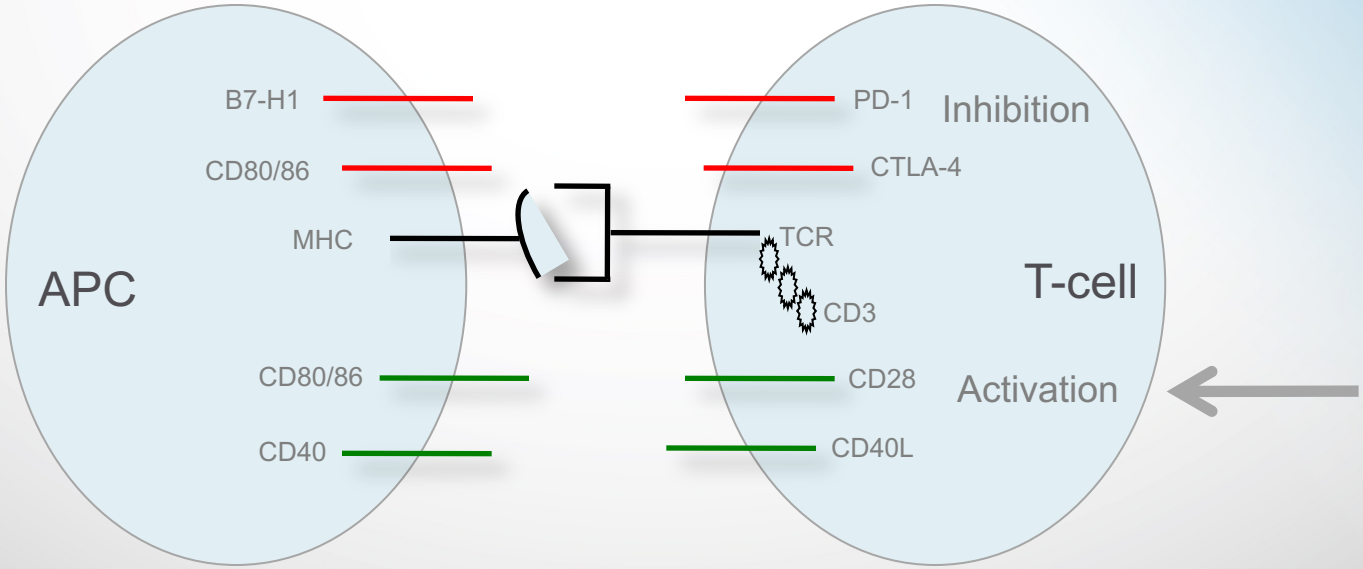
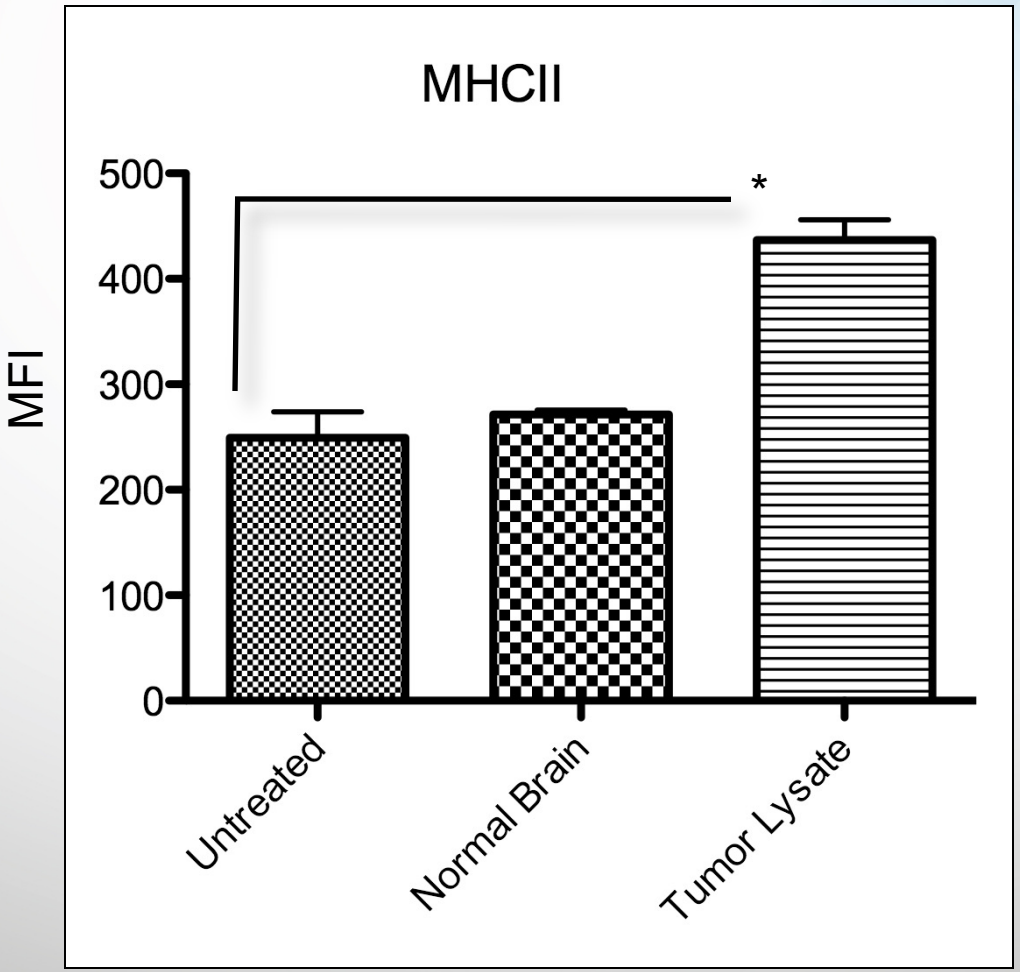
DC Activation Molecules

- Co-stimulatory:
  - CD80 (B7-1)
  - CD86 (B7-2)
  - CD40
- MHC II (Major histocompatability complex for antigen presentation to T cells)
- Pro-inflammatory cytokines (IL-12, TNF-α, IL-6)

Co-Signaling Molecules



Glioma Lysate Activates vs. Normal Brain Control (Flow Cyotmetry Assay)



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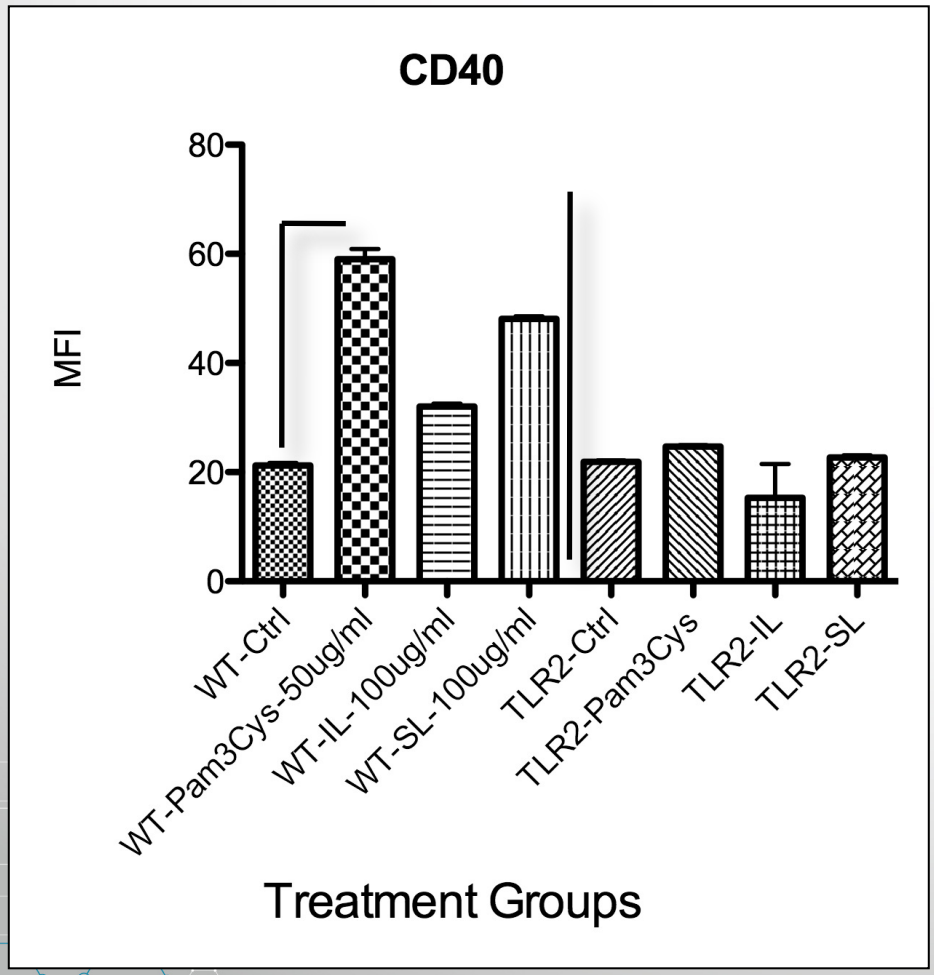
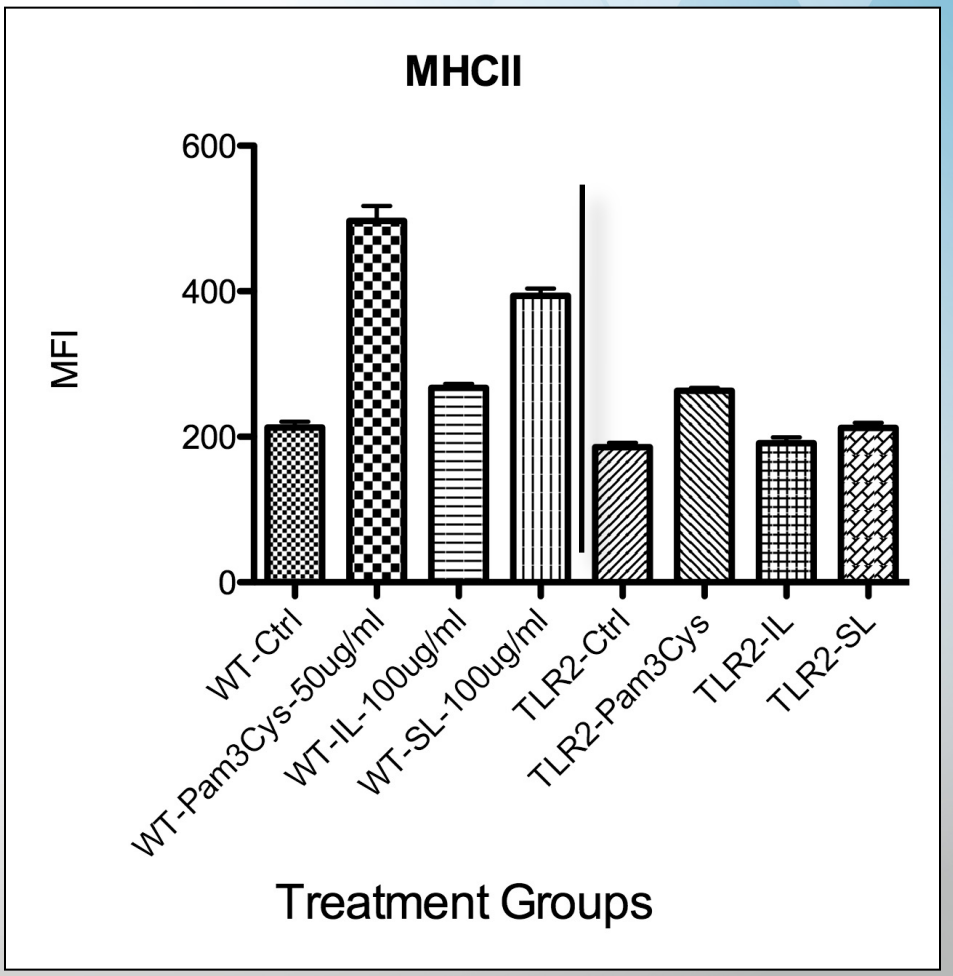
Glioma Lysate Activates DC Through TLRs TLR2 (Flow Cytometry Assay)





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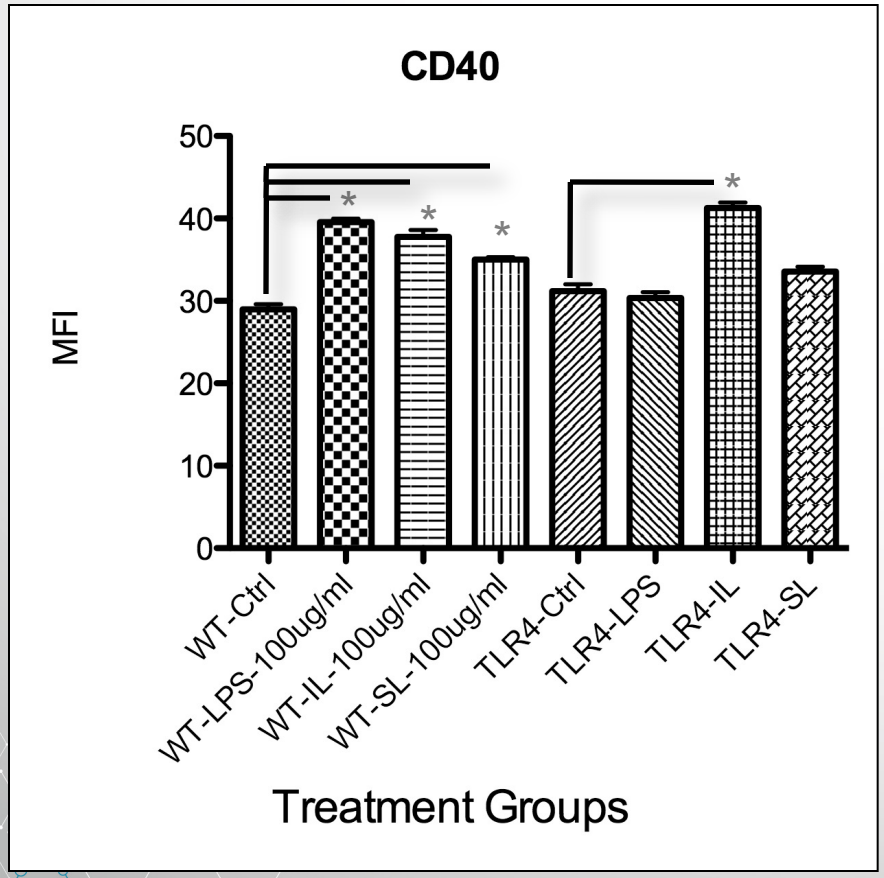
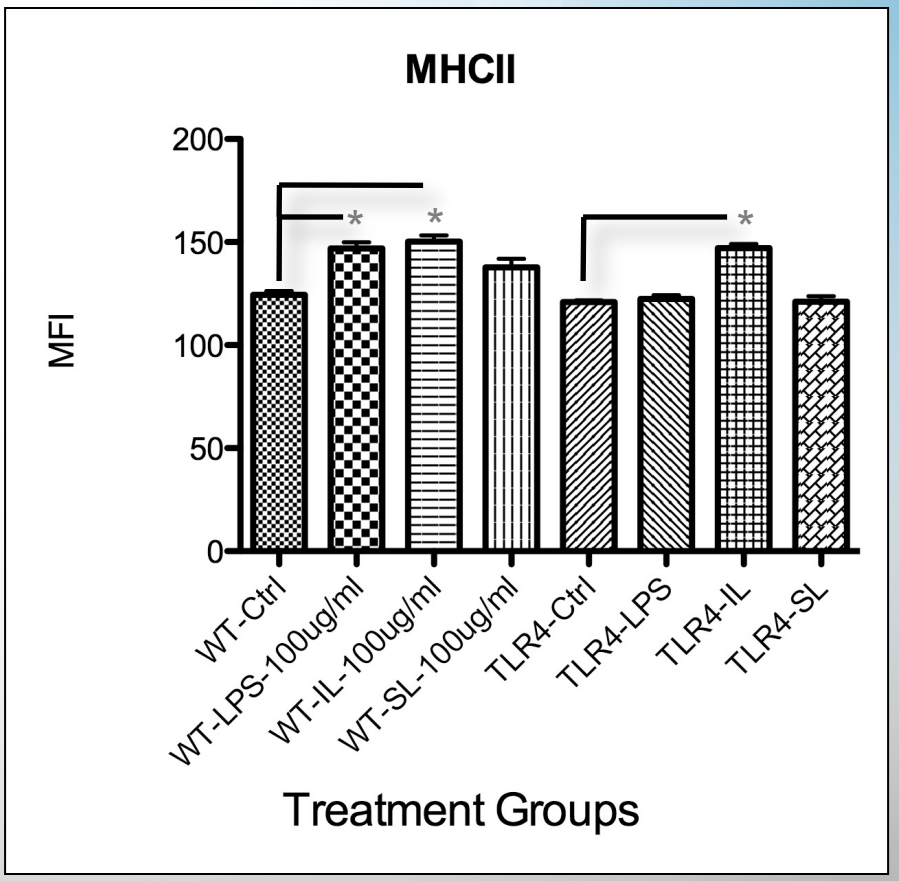
Glioma Lysate Activates DC Through TLRs TLR4 (Flow Cytometry Assay)





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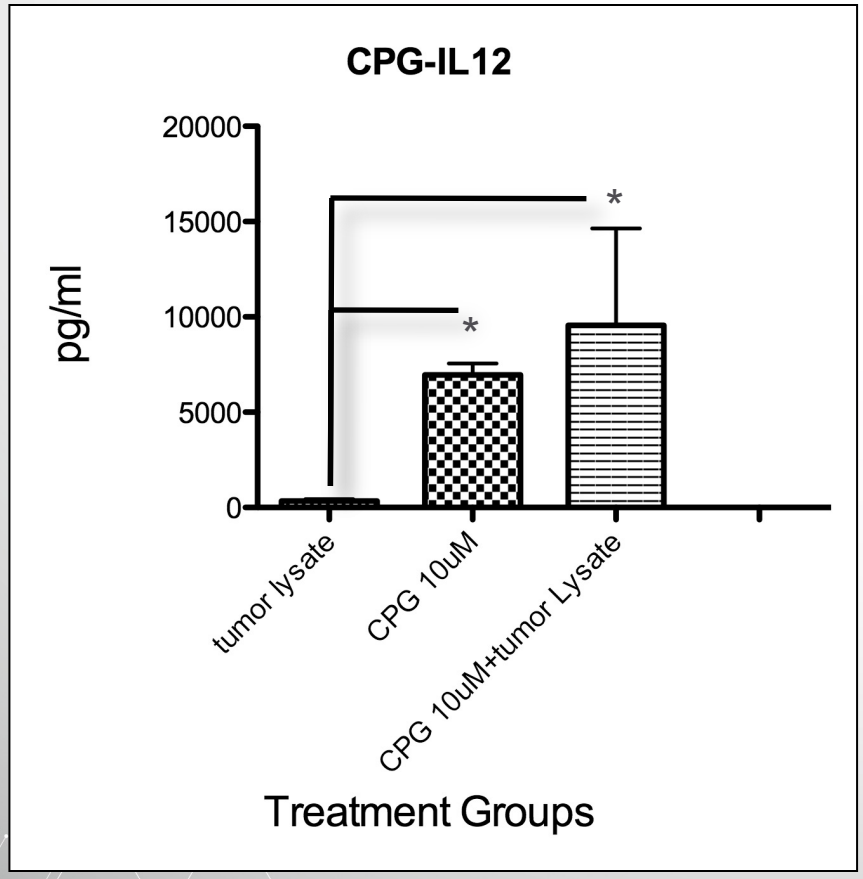
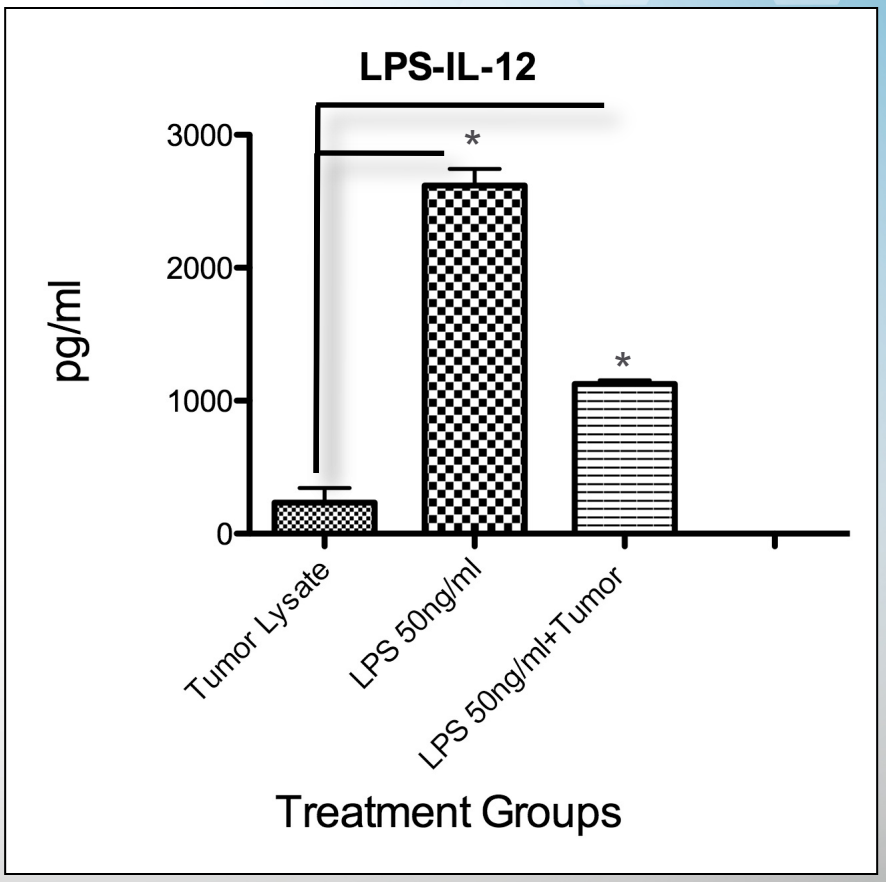
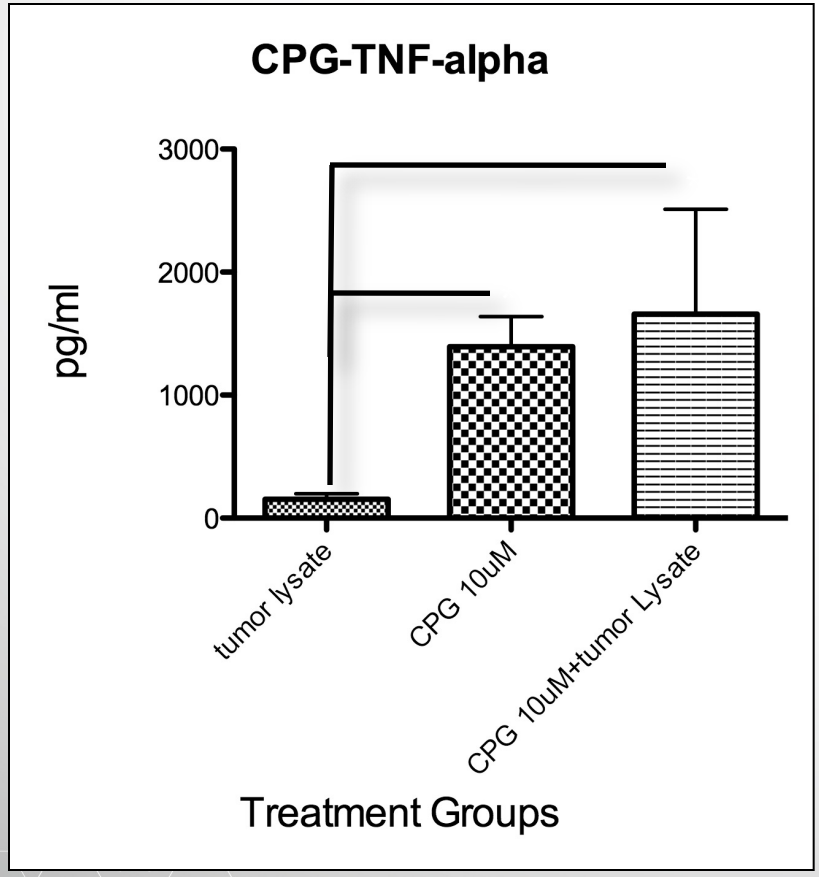
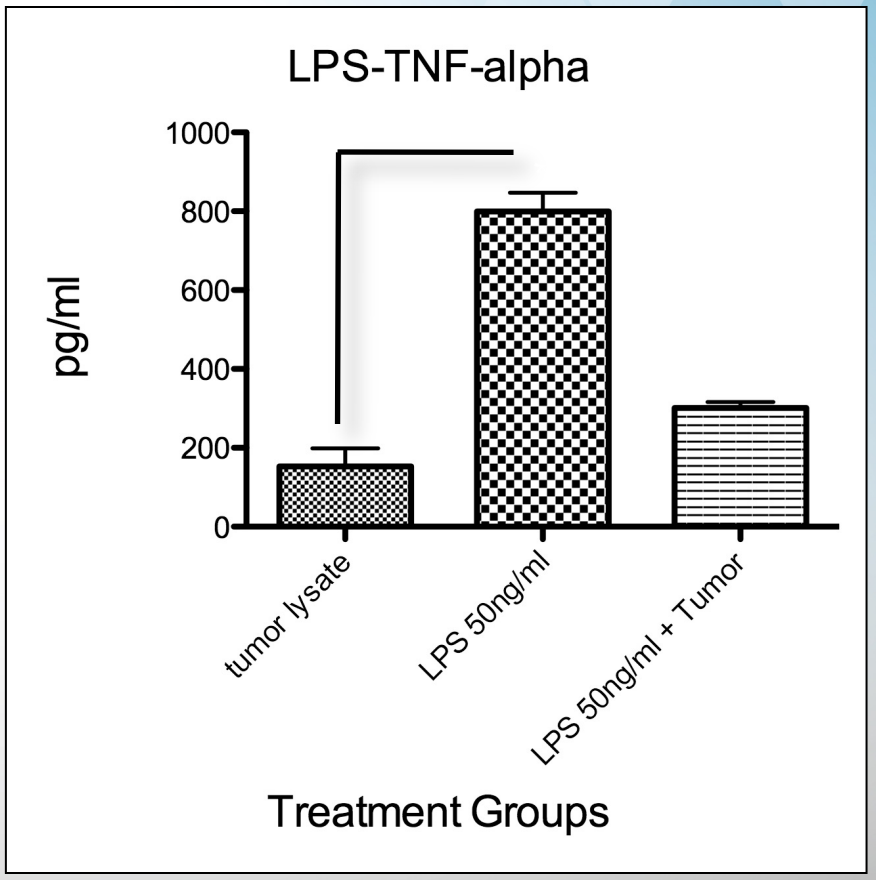
DC Cytokine Expression (IL-12) After Glioma Lysate and TLR Ligands (ELISA Based Assay)



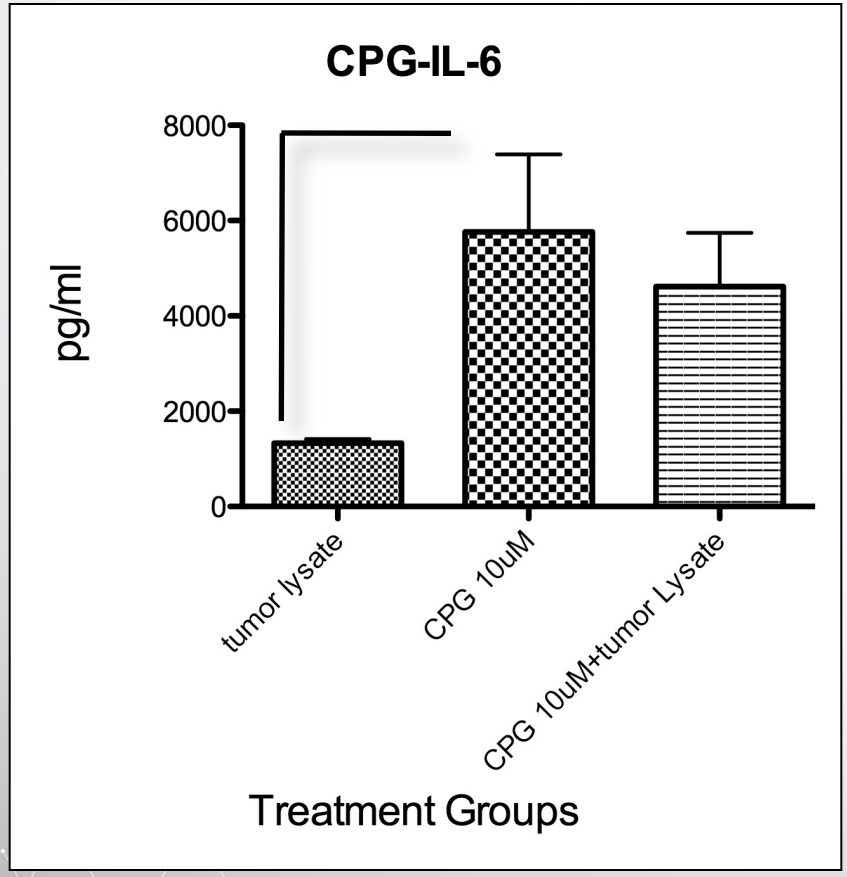


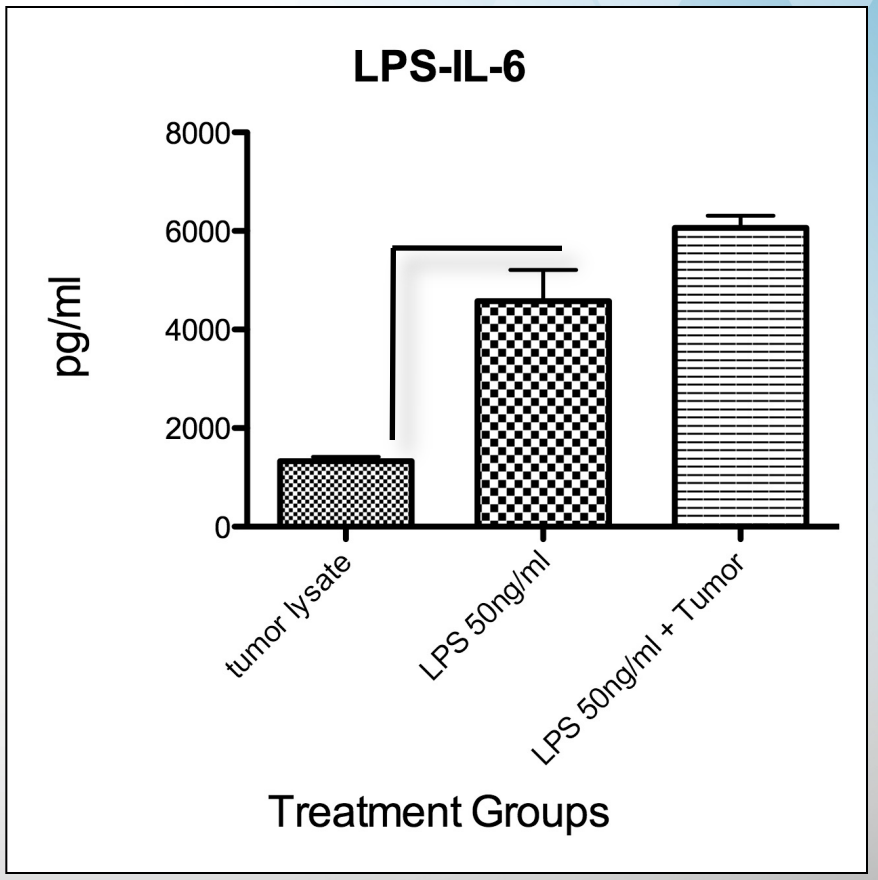
DC Cytokine Expression (TNF-α) After Glioma Lysate and TLR Ligands (ELISA Based Assay)





PBMDC Cytokine Expression (IL-6) After Glioma Lysate and TLR Ligands (ELISA Based Assay)





Summary

- Glioma lysate activation of DCs is at least partially regulated through TLR signaling and is MyD88 dependent.
- TLR2 signaling in DCs may be one the predominant receptors for glioma lysate signaling.
- Glioma lysate and TLR ligands may work together to maximize an anti-tumor immune response.

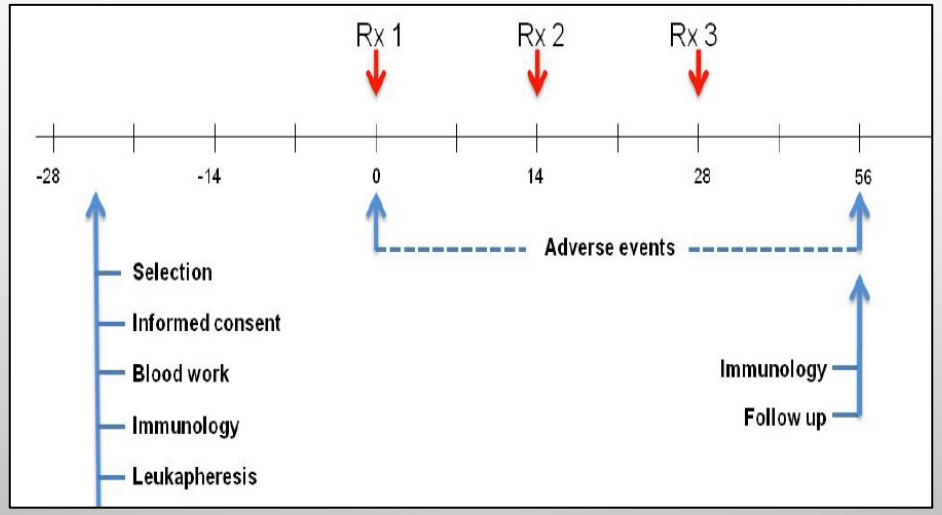
Highlights

- Can be combined with any antigen specific technology
- Proven mechanism of dendritic cell maturation and function
- Essential for patient-based (personalized) immunotherapy

Phase I Trial with TLR-AD1

Nonrandomized, single-center study

- Cedars-Sinai Medical Center, Department of Neurosurgery
- Twenty GBM patients, newly diagnosed
- Patients will receive Standard of Care (surgery and chemo-radiation) followed by three vaccinations of TLR-AD1 every 2 weeks



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Milestones Over Next 18 Months

- File for IND for Orphan Drug Designation; Initiate Phase I or II Clinical Trial
- Apply for NIH SBIR grant
- Complete Seed/Series A rounds for a total investment of 5 million

Current Management Team

- Dwain Morris-Irvin, PhD, MPH
  Founder, Chief Scientific Officer
- Christopher Wheeler, PhD
  President
- Peter Weinstein, PhD, JD
  Legal Council
- XSNX Biotech Advisory Board