
Pioneering
vaccines that
transform
lives.
IMMUNOMIC
THERAPEUTICS

Immunomic Therapeutics, Inc.

LAMP-Vax for Glioblastoma: CMV-LAMP-Vax™

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Executive Summary

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pp65-LAMP-Vax First Line Therapy for Glioblastoma Multiforme

- **Immunomic Therapeutics is developing novel immunotherapy therapeutics to treat immunology and oncology diseases based on LAMP technology**
- **Potential for LAMP vaccines:**
  - Create polyfunctional immune response
  - Induce antigen-specific Th1-biased TILs at tumor site and activate CD8 T-cells
  - Th1 CD4+ T-cell activity is part of effective immune response to cancer
- **ITI is developing pp65-LAMP-DC vaccine**
  - Currently in a Phase II proof of concept study in newly diagnosed glioblastoma
  - Priming injection site with Td toxin prior to ID administration of dendritic cells loaded with mRNA encoding pp65
    - pp65 is a major CMV protein, providing exceptional tumor specificity
  - Phase I study showed median OS of 35 months and PFS of 31 months
  - Original product concept developed by labs of Drs. Mitchell and Sampson at Duke

Disease Background

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Stage IV Brain Cancer is Glioblastoma Multiforme

Grade IV glioblastoma has the poorest prognosis of all primary brain tumors with 1 and 5 year overall survival of 35% and 4.7% respectively[3]

Brain and GBM Cancer Incidence, 2014[1]			
New Cases	EU	US	JP
Brain Cancer	27,187	22,621	5,276
Glioblastoma (GBM)	14,126	10,225	1,873

GBM Survival & Cases by Age Group[2]			
Age Group (yrs)	Est. Cases (US)	1-Year Survival, %	5-Year Survival, %
0-19	1,336	57.2	19.2
20-44	2,017	66.5	16.9
45-54	1,735	52.7	5.9
55-64	2,772	40.7	3.8
65-74	2,630	23.7	1.7
75+	2,150	9.2	0.8

- Glioblastoma
  - Is cytologically malignant
  - Has rapid pre- and postoperative disease evolution
  - Is highly diverse and heterogeneous disease with variable impacts on prognosis
- IV Brain Cancer – Glioblastoma Multiforme

1. GlobalData, EpiCast Brain Cancer Mdoel, December 2015
2. Cancer Epidemiol. 2014 Oct;38(5):490-5. doi: 10.1016/j.canep.2014.07.014.
3. Neuro Oncol. 2013 Nov; 15(Suppl 2): ii1–ii56. doi: 10.1093/neuonc/not151

Disease Background

Disease Presentation, Diagnosis and SOC Treatment in GBM

Glioblastoma presenting symptoms

General Symptoms

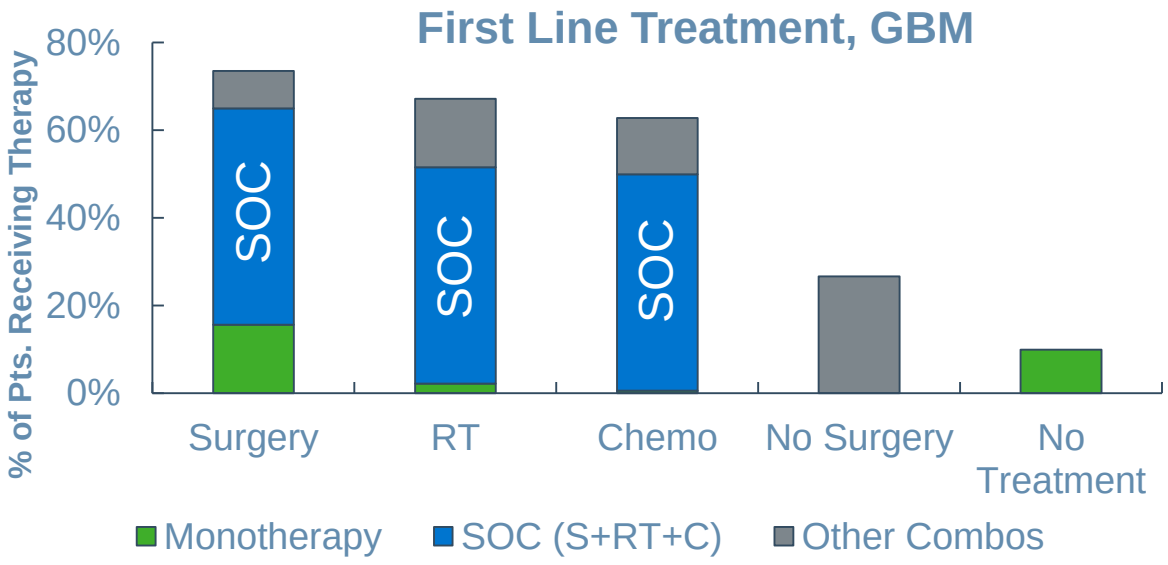
- Headaches
- Seizures
- Nausea/vomiting
- Personality changes
- Aphasia
- Hemiparesis
- Sensory/visual loss

Diagnosis

- MRI to determine high grade vs. low grade gliomas
- Tissue diagnosis necessary for confirmation of GBM

Standard of Care Therapy (NCCN Guidelines)

Surgery	Radiotherapy	Chemotherapy
• Pathological diagnosis • Alleviate mass effect • Increases survival • Not feasible (~10%)	• Increase survival after surgery in newly diagnosed patients	• Temozolomide (TMZ) • Extend survival • Potentially increase therapeutic effect of RT



Immune Cycle in Glioblastoma

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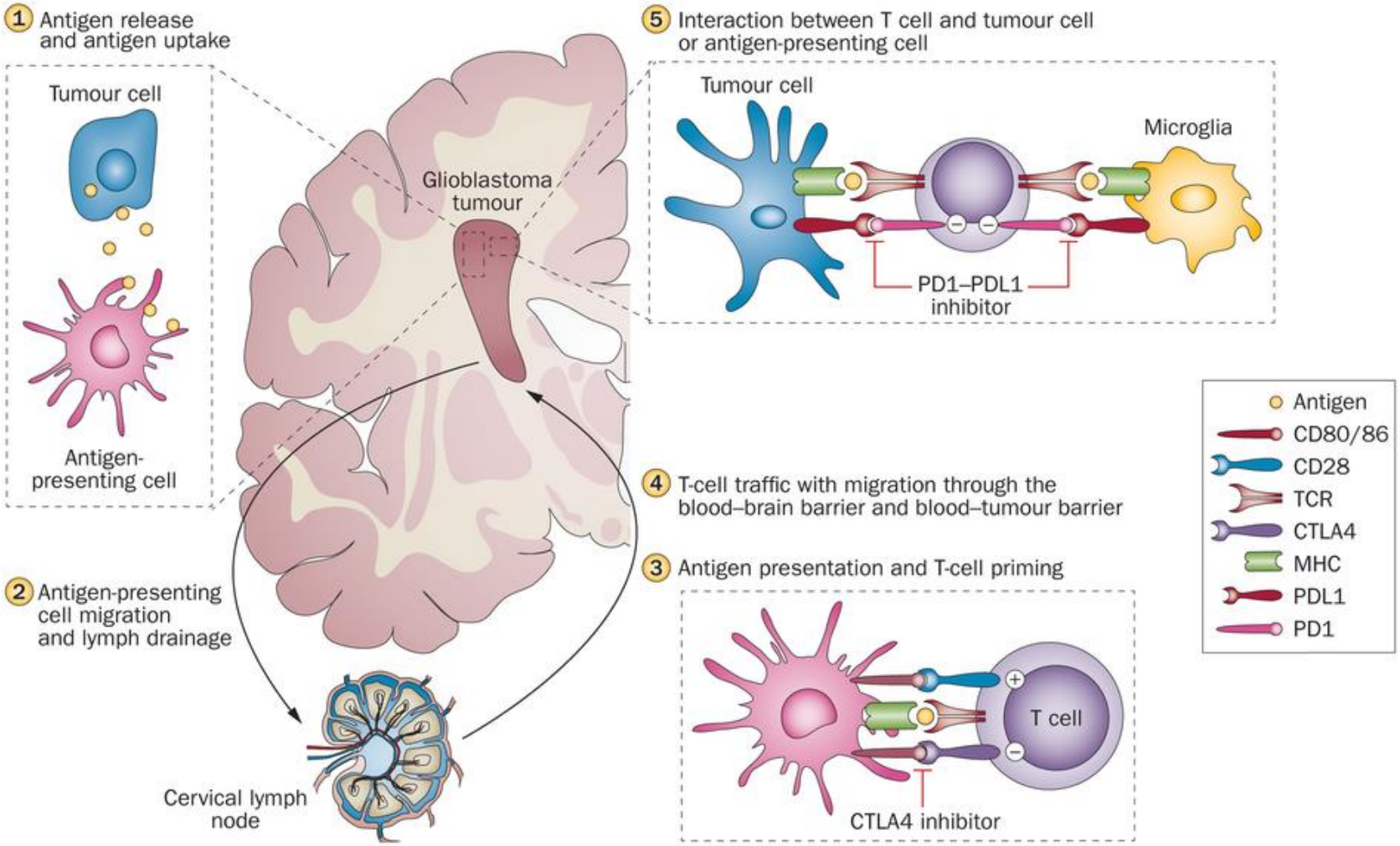
Interplay of Immuno-Oncology Assets

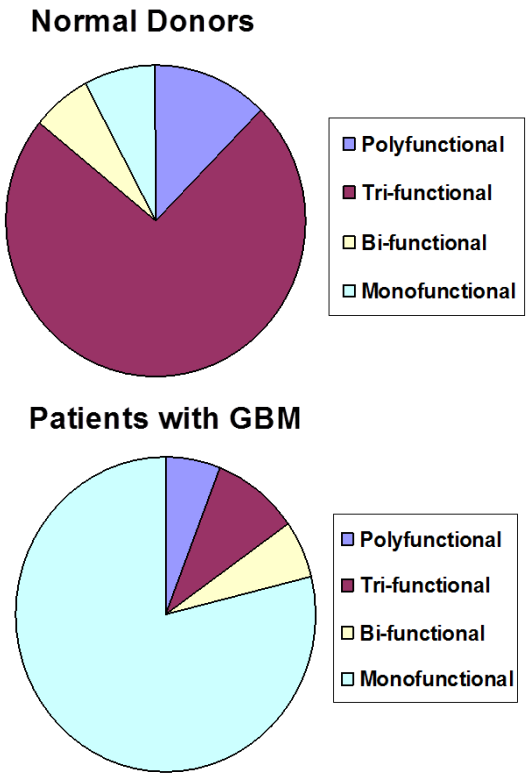


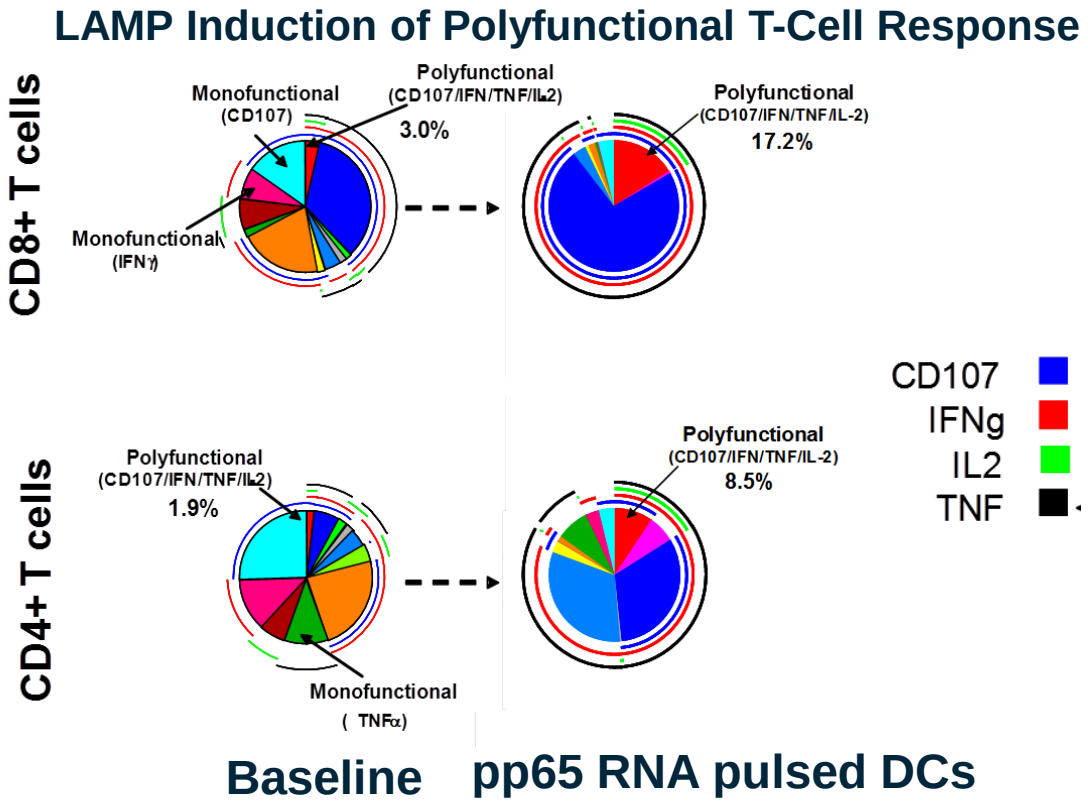
Preusser M et al. *Nature Reviews Neurology.* 10.1038/nrneurol.2015.139

Proof of Principle Data in Glioblastoma

pp65-LAMP-vax DC Therapies

Biological rationale for LAMP-based cancer vaccine in **glioblastoma multiforme** is the restoration or profound immunological dysfunction





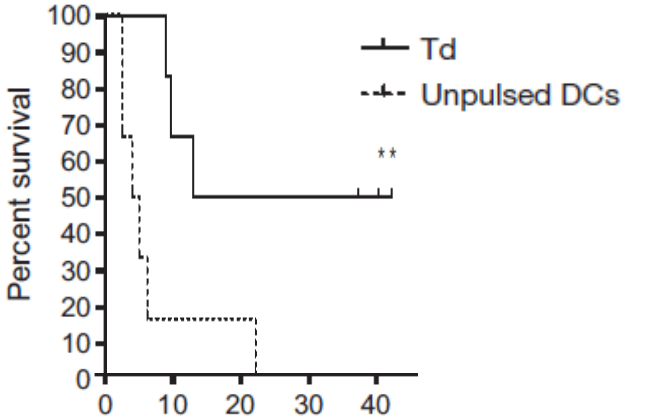
[1] Mitchell DA, Batich KA et al. Nature 2015

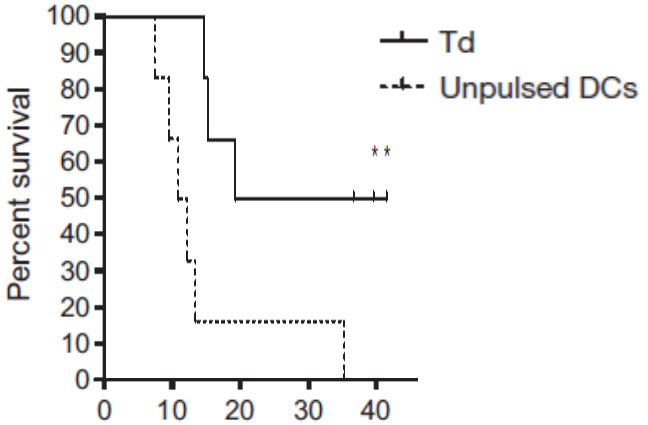
Phase I Data – ATTAC Trials

pp65-LAMP-vax DC Therapies

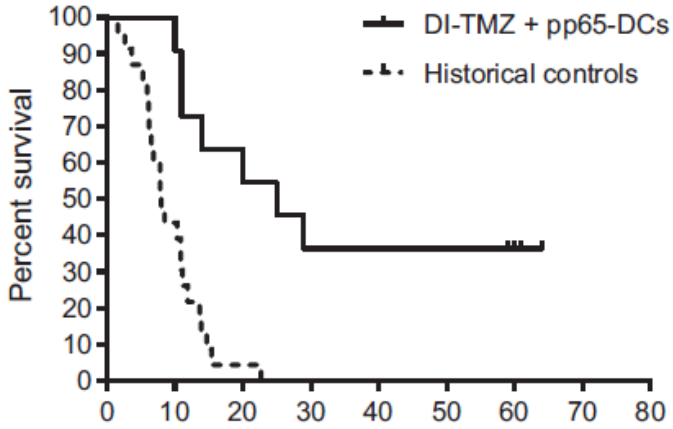
Glioblastoma multiforme patients (n=12) in **Phase I** study with autologous DCs loaded with mRNA encoding **pp65** and **LAMP** after Td toxin prime (+/-)

ATTAC

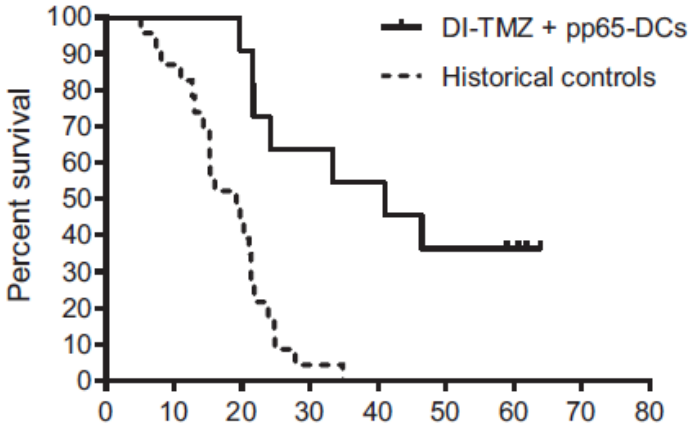




ATTAC-GM Trial



Progression Free Survival
(Months from histological diagnosis)

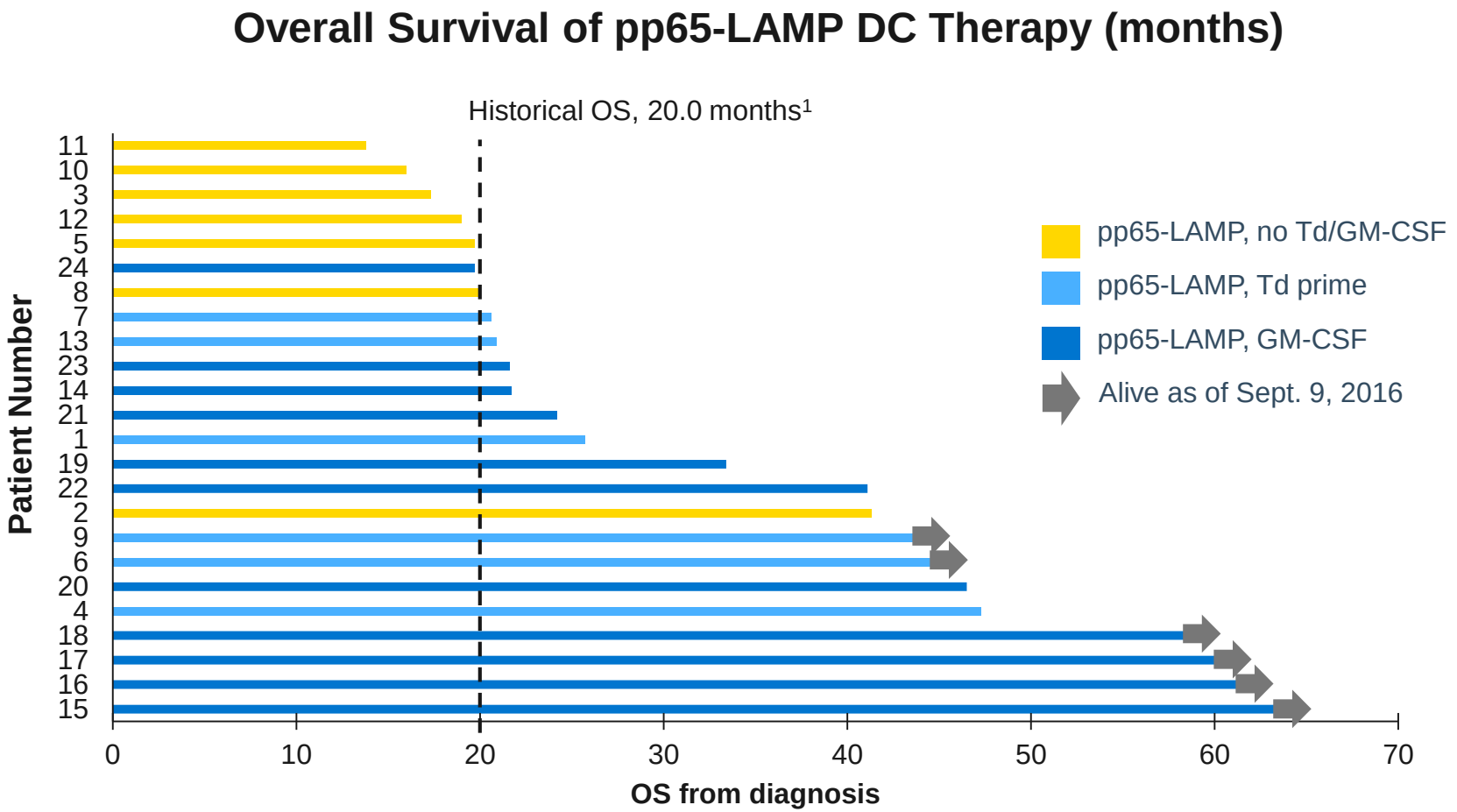


Overall Survival
(Months from histological diagnosis)

[1] **Mitchell DA, Batich KA et al. Nature 2015**
[2] **Batich KA et al., . Clin Cancer Res 2017**

Phase I Data – ATTAC Trials

PFS & OS Data for pp65-LAMP DCs + RT + TMZ



Sources: Mitchell DA et al., 2015. Nature | Vol 51 9 | 19 March and Batich KA et al., 2017. Clin Cancer Res; 23(8) April 15, 2017. [1] ITI analysis of GBM TCGA dataset, restricted to KPS>80 receiving RT + TMZ

Phase I Data & Ongoing Phase II Trial

LAMP DC Therapy Targeting CMV Antigen (pp65) in GBM

Phase II Study Plan - ATTAC II Trial[2]

Newly diagnosed Glioblastoma multiforme patients treated with RT + TMZ, followed by vaccination with autologous DCs loaded with mRNA encoding pp65 and LAMP after Td toxin prime

Study Size: 150 patients across 3 arms

Primary Endpoint:

- OS in newly diagnosed GBM

Secondary Endpoints:

- PFS
- Immunological effects of ss-LAMP vs. fl-LAMP on pp65-specific T-cell responses
  - Phenotype and exhaustion markers on CD4 and CD8 T cells
  - Polyfunctional CD4 and CD8 cytokine responses
  - Lack of expansion of regulatory T cells
  - Pp65-specific humoral responses

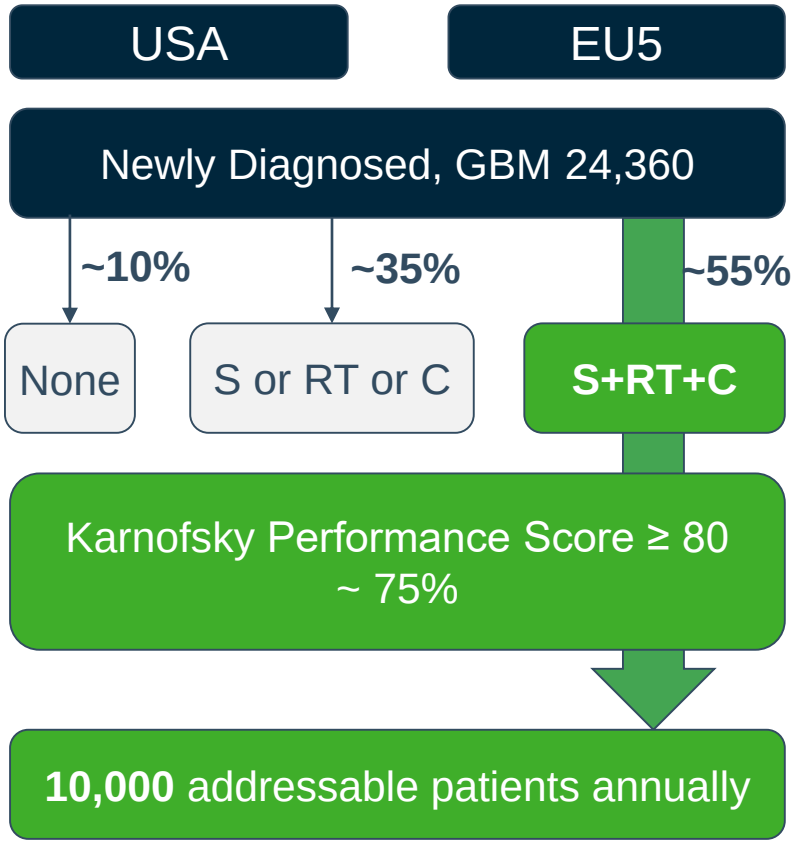
Status: Currently recruiting

[1] Mitchell DA, Batich KA et al. Nature 2015
[2] NCT02465268

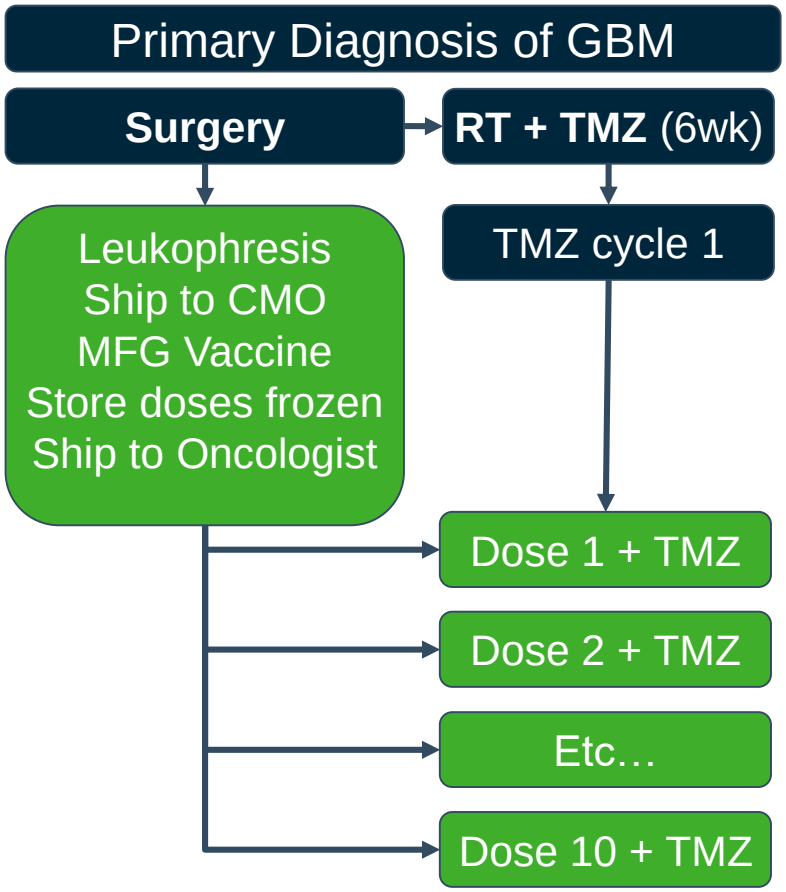
Market Opportunity

Integrating pp65-LAMP-vax into SOC

Addressable Markets



Patient Flow (1st Year of Therapy)



S = Surgery; RT = Radiotherapy; C = Chemotherapy; TMZ = temozolomide

Competitive Landscape

Late Stage Pipeline

- **Nivolumab** (Bristol-Myers Squibb): anti-PD-1 monoclonal antibody
  - In three **Ph. III** trials that collectively aim to enroll over 1,300 patients in newly diagnosed and recurrent GBM
- **ICT-107** (ImmunoCellular Therapeutics): Autologous DC vaccine targeting six different antigens
  - **Ph. III** trial currently enrolling at 68 sites aiming to randomize 542 patients
  - Orphan drug designation in US and Europe
- **Durvulumab** (AstraZeneca): anti-PD-L1 monoclonal antibody
  - In two **Ph. II trials**, aims to enroll over 200 patients in newly diagnosed and recurrent GBM
- **Pembrolizumab** (Merck): anti-PD-1 monoclonal antibody
  - In three **Ph. II trials**, aims to enroll ~50 patients in newly diagnosed and recurrent GBM
- **DNX-2401** (DNAtrix): Oncolytic virus in a 50 person **Ph. II**
- **IMA950** (Immatics Biotech): Multi-Peptide Vaccine and neo-antigen based peptide vaccines in **Ph. I**

Business Opportunity

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Conclusions

- GBM is uniformly fatal disease affecting 10,000 and 14,000 in the US and EU respectively
  - Orphan disease with high medical need
- No approved drugs in 1L GBM since TMZ
  - Optune TFF device approved in recurrent therapy at a cost of $21K per month
- Standard of care is surgery followed by cycles of radiotherapy and TMZ
  - Adding pp65-LAMP-vax could increase OS to >25 months, if trend from P1 holds
  - Ability to combine with PD-1 and PD-L1 antibodies in late stage development
  - Potential billion dollar product opportunity over several geographic markets
- Phase II study in progress with expected initial read-out in 2019
  - UF and NCI providing majority of funding for P2 150 person study
  - Duke IP provides competitive advantage over other DC therapies
- ITI management has expertise in GBM clinical development, DC manufacturing and LAMP

Seeking Business Development Opportunities

Summary, Timeline & Objectives

LAMP-Vax enrolling in a Phase II study in GBM.

Data/information available under CDA in 2017:

- Existing body of Phase I and II data employing LAMP
- Mechanism of action (MoA) data (support from allergy work)
- Animal data with candidate LAMP-Vax in various tumor models w/ preferred platform for LAMP-Vax.
- Additional information (IP, regulatory, manufacturing)

In 2017, initiating formal BD discussions with Pharma for transaction/collaboration:

- Exclusive WW rights for all oncology applications OR
- Focus on specific cancer(s), products OR geography
- Willing to consider alternatives

Thank You

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