

# Reprogramming Immunity Redefining Cancer Treatment

Presented at BIO CEO & Investor Conference February 11, 2013

## **Corporate Highlights**

- □ Positive Phase 2 clinical results for two lead oncology programs
  - Favorable safety profile relative to radiation and chemotherapy
  - Median survival of patients treated with TVAX Immunotherapy was significantly greater than historical controls
- □ FDA authorized pivotal trials for brain cancer and kidney cancer
  - Orphan product designation for brain cancer
- Proprietary combination of cancer cell vaccination & "killer" T cell treatment with extensive clinical proof-of-concept
  - Broad clinical opportunity includes most forms of cancer
  - Technology offers a novel model for delivery of cancer treatment
- Strong exclusivity position & intellectual property

## **TVAX Immunotherapy**

Personalized and proprietary cellular immunotherapy combining vaccination with infusion of genetically unique cancer-antigen-specific "killer" T cells

## **TVAX Immunotherapy Rationale**

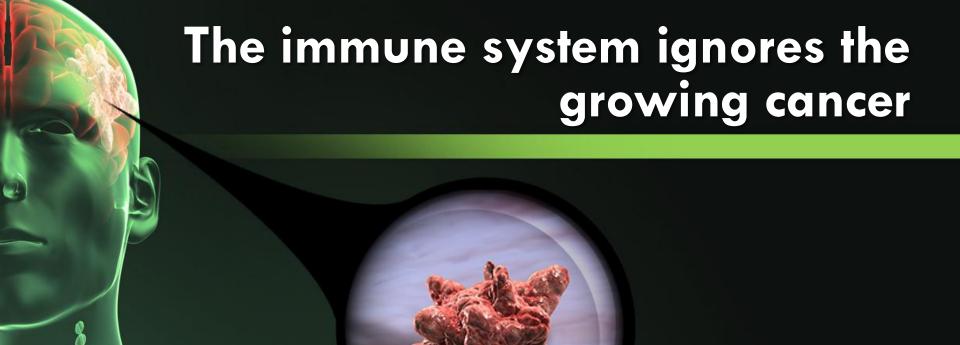
- Cancers can be successfully treated with cancer antigenspecific effector T cells
  - Unlimited numbers of cancer antigen-specific effector T cells can be generated from cancer-bearing individuals
- Successful cancer antigen-specific immunotherapy is unlikely to conform to the 'one size fits all' therapeutic models of chemotherapy

## **TVAX Immunotherapy: Differentiation**

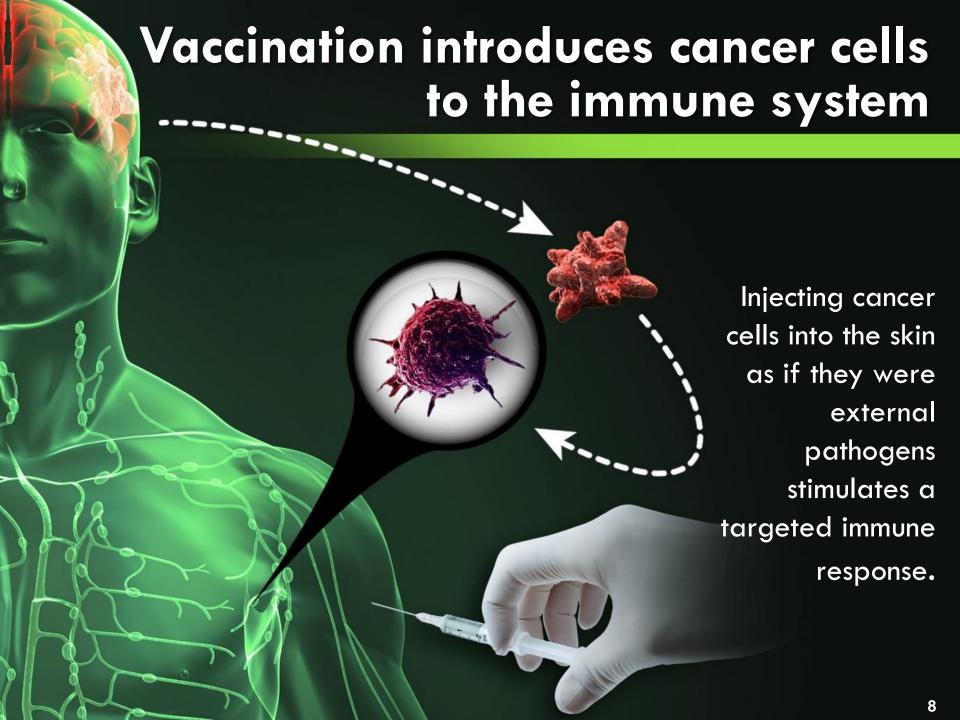
- Unlike other cancer treatments, TVAX immunotherapy uses a cancer's complexity as the basis for successful treatment
- Opportunity to fundamentally change the way we treat cancer
- Potential for acute cures and chronic prevention
- □ Autologous, natural approach minimizes side effects
- Our goal is to treat cancer not "kick the can down the road"

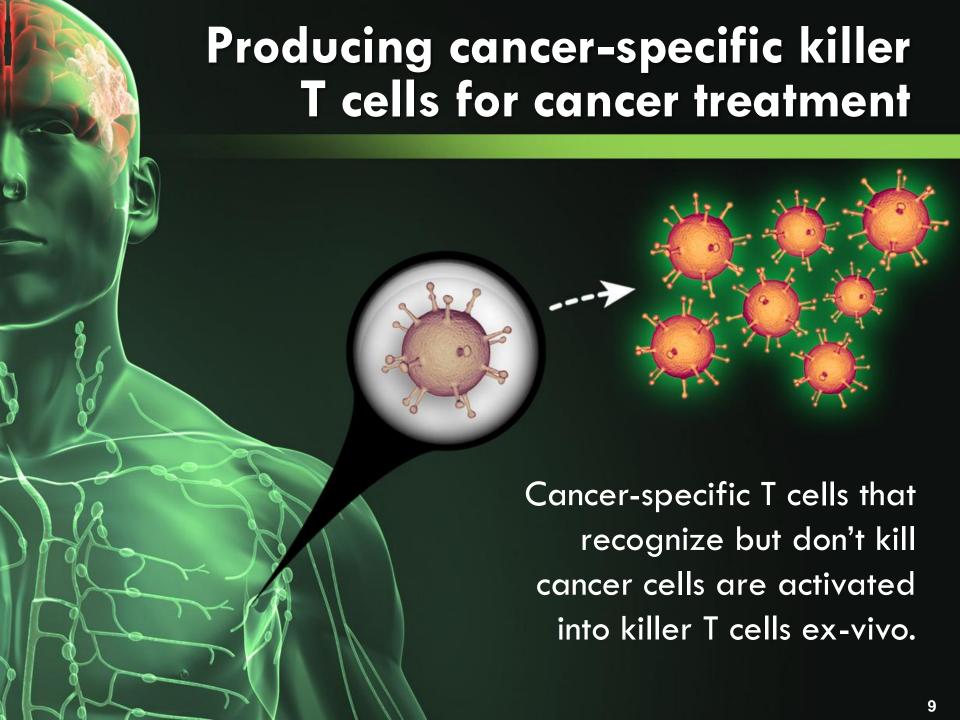
## TVAX Immunotherapy is not a Vaccine

- Vaccines are a mass produced, preventative approach to disease management
- Cancer vaccines fail to effectively treat cancer because vaccines never effectively treat disease
- TVAX Immunotherapy is a potent autologous T cellbased therapy designed to provide acute and potentially chronic treatment of a specific tumor/cancers
- □ Autologous Cell based therapies work (Provenge<sup>™</sup>)



Cancer cells, which invade the body from within, fail to trigger a targeted immune response.







Cancer-specific killer T cells attack the cancer.
Cancer spread is arrested and the cancer shrinks.

## **TVI-Brain-1 Process**

# TREATMENT + Surgery Vaccination TREATMENT T cell creation T cells released

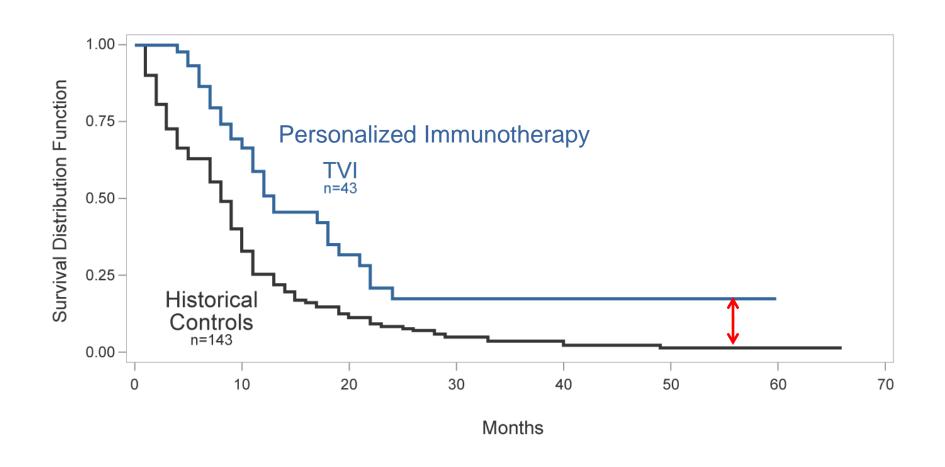
Cancer cell + adjuvant vaccinations (x2) to induce immunity	2 weeks
Apheresis to collect immune T cells	1 week
Manufacture and transfuse 'killer' T cells	1 week
Rest week	1 week
Repeat treatment cycle	5 weeks

Total treatment time 10 weeks

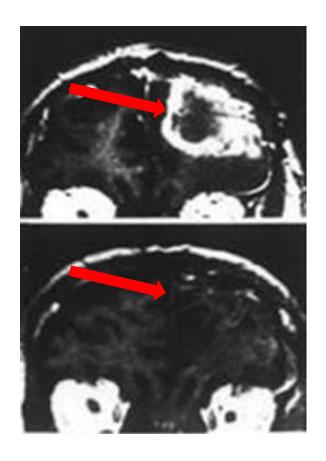
# Phase 1/2 Brain Cancer Trials

- Patients enrolled
  - □ 43 patients with recurrent grade 3 and grade 4 gliomas
  - Previously failed surgery, radiotherapy and chemotherapy
- Study Results
  - Median survival of patients treated with TVAX Immunotherapy was significantly increased over historical controls
  - Significant number of patients' cancers underwent objective clinical responses
  - Minimal adverse effects fever, chills, headache, nausea

### **Phase 2 Recurrent Brain Cancer Data**



## **Brain Cancer Complete Response**



Tumor location after surgery

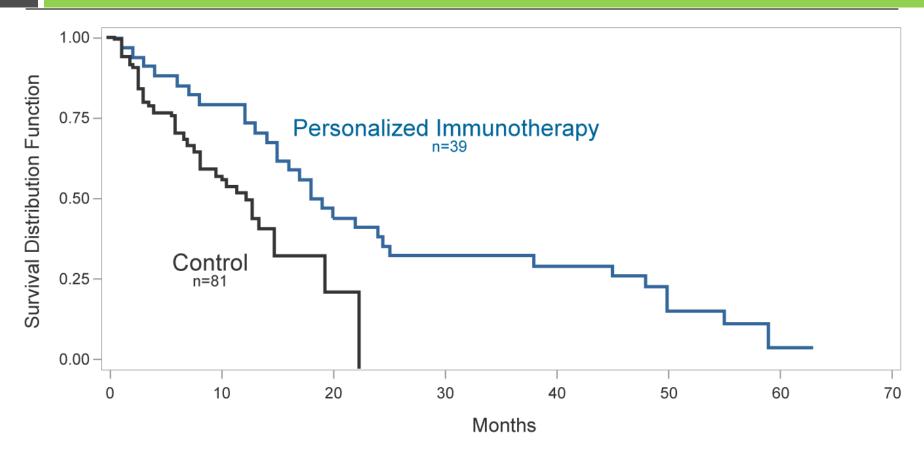
8 months after TVAX treatment

#### > 5 Year Survival

# Phase 1/2 Kidney Cancer Studies

- Independent validation of TVAX studies
  - □ Phase 1/2 study
    - □ 12 patients
    - □ Chang, et al. J. Clinical Oncology. 15:796-812 (1997)
  - Phase 2 study
    - □ 39 patients
    - □ Chang, et al. J. Clinical Oncology. 21:884-90 (2003)
- Study Results
  - Significant number of objective clinical responses (n=9) each of which was associated with significantly prolonged survival
  - Overall survival for enrolled patients (n=39) significantly (p<0.0001)</li>
     prolonged compared to historical control group (n=81)

#### Phase 2 Metastatic Renal Cell Carcinoma

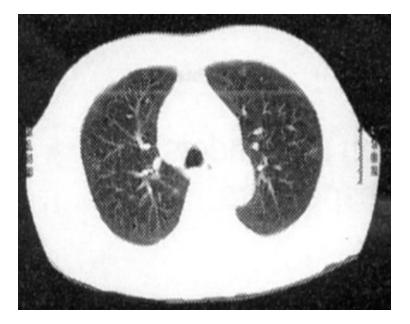


**Historical Controls** 

## Renal Cell Carcinoma Complete Response

#### Lung Metastases





**Pre-treatment** 

Post-treatment

#### **Clinical Path Forward**

- Protocol in final stages of development
- FDA has approved pivotal clinical study design in both brain and renal cancer
- Preferred development route is in the treatment of newly diagnosed glioblastoma patients
- Anticipate initiation of Phase 2b in 2H 2013 using "drug" manufactured at our GMP facility in Kansas

## TVI-Brain-1 Clinical Strategy

- Pivotal 2b trial
  - Newly diagnosed glioblastomas
    - □ Approximately ~60 subjects
    - □ 2:1 randomization, open-label
    - Continuous data review
    - Radiotherapy & TVI-Brain-1 vs. radiotherapy & temozolomide
  - Primary endpoint: Overall survival
    - Secondary endpoints: Progression-free survival and response rate

## 2013 – 2014 Strategic Plans

- Complete Series C raise in Q3 2013
- Refine and expand business development activities including licensing, M&A, etc.
  - Develop specific commercial strategy
  - Expand Manufacturing Operations to support clinical development
- Execute on a global PR strategy to support financing & partnering
- Generation of positive "randomized" data in any indication is highly significant and necessary to achieve value inflection

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#### Thank you

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