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 antigen-specific 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 cell-based therapy designed to provide acute and potentially chronic treatment of a specific tumor/cancers.
- Autologous Cell based therapies work (Provenge™).
The immune system ignores the growing cancer

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

Injecting cancer cells into the skin as if they were external pathogens stimulates a targeted immune response.
Producing cancer-specific killer T cells for cancer treatment

Cancer-specific T cells that recognize but don’t kill cancer cells are activated into killer T cells ex-vivo.
Cancer-specific killer T cells are administered intravenously.

Cancer-specific killer T cells attack the cancer. Cancer spread is arrested and the cancer shrinks.
TVI-Brain-1 Process

**VACCINATION**
- **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

Survival Distribution Function

- **Personalized Immunotherapy**
  - TVI
  - n=43

- **Historical Controls**
  - n=143

Months

0 10 20 30 40 50 60 70
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
  - Phase 2 study
    - 39 patients

**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) 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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