



## COMPANY PROFILE

TVAX Biomedical is a clinical stage biotechnology company testing TVAX Immunotherapy™, a unique vaccine-enhanced adoptive T cell therapy. TVAX Immunotherapy uses vaccination combined with *ex vivo* T cell activation to maximize the number and effect of cancer neoantigen-specific effector T cells in cancer tissue.

**A key distinction** between TVAX Biomedical and other immunotherapy companies that use effector T cell-based treatments is that TVAX Immunotherapy could potentially be used to safely and effectively treat any patient's cancer and is able to be delivered with only transient inflammatory-type side effects and no long-term toxicity.

## CLINICAL PLATFORM

### TVAX Immunotherapy

1. Vaccinate the patient with their own cancer cells combined with a powerful immunological adjuvant (GM-CSF).

*Rationale: Vaccination generates an immune response that produces high numbers of cancer neoantigen-specific effector T cell precursors in the body.*

2. Collect immune cells by leukapheresis from vaccinated patient's blood and stimulate to differentiate into effector T cells and multiply *in vitro* using T cell activating agents.

*Rationale: Generates large numbers of fully activated effector T cells that does not occur efficiently in vivo.*

3. Adoptively transfer effector T cells into the patient by IV infusion.

*Rationale: Effector T cells are carried to cancer tissue throughout the body, enter cancer tissue and initiate a cascade of immunological events that produce killing of significant numbers of cancer cells, and, sometimes, complete elimination of the patient's cancer.*

4. Treat patient with a course of interleukin 2 (IL-2).

*Rationale: IL-2 stimulates continued multiplication of infused effector T cells thereby increasing effect of T cells.*

### Benefits of Combining Vaccination and Adoptive T cell Therapy:

Vaccination enhances adoptive T cell therapy by greatly increasing numbers of neoantigen-specific T cells in the body. Adoptive transfer of *ex vivo*-activated cancer neoantigen-specific effector T cells delivers high numbers of effector T cells into cancer tissue to attack and kill cancer cells.

### TVAX Immunotherapy

- Unique, proprietary, cancer type-agnostic immunotherapy platform combining vaccination & adoptive T cell therapy
- Highly positive (curative) preclinical outcomes with wide range of syngeneic rodent cancers, including brain cancer and other cancers growing in the brain
- Highly positive outcomes in canine metastatic osteosarcoma (model for all metastatic cancers)
- Highly positive human adult and pediatric high-grade glioma outcomes and favorable safety profile
- FDA Fast Track Designation and \$2 million grant from FDA Orphan Products Division
- Currently active IND-13135 on file with Food and Drug Administration with phase 2b MGMT negative glioblastoma protocol
- cGMP compliant in-house manufacturing – highly portable and expandable
- Phase 2b clinical trial program in newly diagnosed surgically resectable adult glioblastoma
- **Advantages relative to other immunotherapies:**
- Potentially curative – T cells can kill all cancer cells
- Favorable safety profile – no long-term toxicity
- Cancer type agnostic – all cancers are immunogenic and susceptible to T cell killing
- Complementary – can be combined with standard therapy to eliminate minimal residual disease
- Complementary – can potentially be combined with other immunotherapies to increase efficacy
- **Unique – no companies currently pursuing development of comparable therapy**

### WORLDWIDE MARKET OPPORTUNITY

- Potential annual market for lead program
  - High-grade glioma = **\$1.5 billion**
- Potential use of TVAX Immunotherapy in multiple other cancer indications including bladder, breast, colon, kidney, leukemia, lung, lymphoma, melanoma, ovary, pancreas and prostate
- Anticipated treatment price in line with current immunotherapies, e.g., checkpoint inhibitors

## PIPELINE

Indication	Phase 1	Phase 2	Sites
Glioblastoma (MGMT neg)		Phase 2b	8-10
Multiple other cancers		Phase 2 ready	

## CLINICAL STRATEGY Glioblastoma (MGMT neg)

### Rationale:

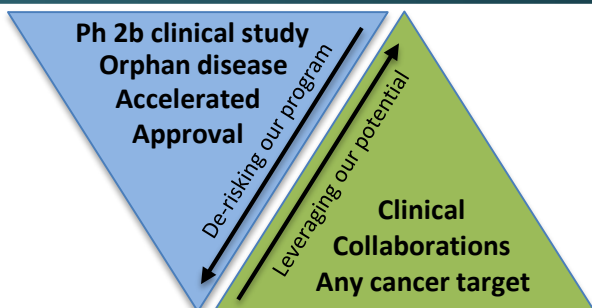
TVAX has tested TVAX Immunotherapy in >200 patients with various types of cancer, including high-grade glioma. Surrogate outcomes demonstrated that ~90% of patients developed neoantigen-specific immune responses, thereby demonstrating all cancers' potential susceptibility to neoantigen-specific effector T cells. The basis for use of neoantigen-specific effector T cells in TVAX Immunotherapy is similar to use of these cells in highly effective checkpoint inhibitor and tumor infiltrating lymphocyte therapies.

Glioblastoma patient prognosis is dismal; current therapies are not delivered with curative intent and provide only a few months additional survival. There is a serious unmet medical need for safer and more effective treatments for adult and pediatric high-grade glioma patients. TVAX Immunotherapy is effective against high-grade gliomas.

### Clinical trial rationale:

Our current study is a 120-subject two-arm, multi-institutional phase 2b clinical trial to assess TVAX Immunotherapy as a treatment for newly diagnosed adult glioblastoma (MGMT neg). TVAX Immunotherapy will be integrated with standard therapy such that immunity is generated prior to chemoradiotherapy-induced immune suppression and effector T cells are delivered after chemoradiotherapy reduces cancer tissue-associated immune suppression and patients have minimal residual disease.

## BUSINESS STRATEGY



### TVAX Biomedical, Inc.

**Chief Executive Officer: Wayne Carter, DVM, PhD**, served as CEO BioNexus KC for 6 years; 11 years Clinical Development at Pfizer leading technology development as Executive Director and 5 years VP R&D Colgate. PhD in Immunology from Purdue University.

**Chief Scientific Officer: Gary Wood, Ph.D.**, TVAX's Chief Scientific Officer and Chairman of the Board of Directors is the inventor of TVAX Immunotherapy and the founder of TVAX Biomedical, Inc. Dr. Wood is also CSO of ELIAS Animal Health, LLC. Dr. Wood is the author of 100+ scientific publications and a book. Dr. Wood has a Ph.D. from the State University of New York at Buffalo.

**Chief Financial Officer: Tammie Wahaus.** Currently also CEO, Elias Animal Health. Ms. Wahaus has more than 25 years finance and business development experience. Ms. Wahaus was Vice President-Finance at Epiq Systems, Inc., responsible for finance and accounting. Prior to that, she was an audit partner at Ernst & Young, LLP and Global Controller/Principal Accounting Officer at GE Global Insurance Holding Corporation.

**Chief Medical Officer: Barry S. Skikne, M.D.** has been Chief Medical Officer since 2017, served as a director since 2011 and has been a scientific advisor since the company's inception. Dr. Skikne is Professor of Internal Medicine at the University of Kansas Medical Center in Hematology/Oncology. Prior to re-joining KUMC in 2016, Dr. Skikne served as the Executive Director of Clinical Research at Celgene Pharmaceuticals from 2008 to 2016. At Celgene, Dr. Skikne oversaw several large international Phase III clinical trials. Dr. Skikne is the author of more than ninety journal articles and book chapters. He has a B.S. (M.B.B.Ch.) from the University of Witwatersrand, Johannesburg, SA and an M.D. and residency in Hematology and Oncology from the College of Physicians of South Africa.

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