



SciTech Development, LLC

Social & Economic Impact Statement

Introduction

SciTech Development is developing a novel nanoparticle formulation of fenretinide for treating a broad range of cancers from lymphomas and lung cancer to prostate, pancreatic, breast and colon cancers. Along the way the company will be delivering a variety of productive societal impacts which make an investment in this opportunity particularly attractive.

Therapeutic Reach

Fenretinide simultaneously targets multiple cancer mechanisms of action (MOA) which gives it a **broad therapeutic reach**. The innate immunological MOA component of fenretinide therapy will be effective **without the need for personalizing the treatment**. The multi-prong MOA impact of this therapy should raise barriers to tumors evolving or mutating around the treatment, thereby **reducing the chances of recurrences and metastatic spread**.

Although dramatic results have been observed in some cancer patients treated with personalized therapies, only a **minority of patients respond to the immunotherapy**. Furthermore, the **durability of the personalized immunotherapy treatment is still unknown**, while **fenretinide has both therapeutic and preventive anti-cancer capabilities**.

The significant **safety profile of fenretinide** is eminently suitable as a standalone drug; or, in combination with; or, in co-administration with existing cancer treatments (immunotherapy, chemotherapy, radiation and surgery). The **benefit of fenretinide's minimal side effects**: non-overlapping toxicity with other cancer treatments. In other words, fenretinide plus other treatments = enhanced therapeutic performance without worsening toxicity.

Fenretinide **offers an additional layer of treatment** in reducing breakout recurrences and metastatic spread after personal immunotherapies and other treatments have done their best.

Quality of Life

This therapy will be delivered via a 4-hour out-patient transfusion treatment versus other therapies which entail week-long in-patient transfusions. Therefore, fenretinide therapy is expected to deliver **transformative clinical outcomes** with **less patient trauma**. Patients will be

able to look forward to regaining normal function and engagement in personal and professional goals, aspirations and deliverables.

Direct Employment

Development of the SciTech drug platform sustains the **engagement of top tiers of professionals in commercial, clinical and academic settings**. As the drug moves through the development cycle it will also sustain teams in **manufacturing infrastructure** and associated **production and distribution**. These are **all significant sectors with highly skilled positions**. Job creation through the clinical development process is expected to be 10 direct FTEs (full-time equivalents), 5 direct PT-FTEs plus multiple fractional FTEs with contractors such as Clinical Research Organizations (CROs). Ultimately there will be hundreds (100s) of jobs associated with the development of the entire pipeline. To fully appreciate the job creation potential, simply multiply the direct jobs by seven (7) in the same manner as State Economic Development Departments do to capture downstream employment effects.

Economic Development

Successfully treating patients with a less invasive therapy should **allow them timely return to fully productive roles in society**. Moreover, their caregivers will also be released back into the economy again. Successful paths to recovery can **add many years of productive participation in the economy** by both patients and their otherwise caregivers. The market potential of the SciTech cancer treatment pipeline is, over time, from \$1B to \$25B per year in sales. The first drug to be approved could be on the market in ≤ 3 years.

Cost of Care & Infrastructure Savings

Developing **one therapeutic approach that is applicable to multiple cancers** is more cost effective than designing individual drugs for specific cancers or even specific subtypes of a given cancer. This approach is also vastly cheaper to both develop and deliver than any personalized immunological therapy. Even so, fenretinide therapy should be suitable for use in combination with other therapies with the goal of providing persistent remission and reducing the overall cost of care. Providing a versatile therapy such as fenretinide will give the clinical team **a powerful tool to manage the cost of care** of one of the most expensive patient cohorts in the hospital. It may simultaneously allow over committed medical teams and associated infrastructure to deliver more efficiently.

Investment Profile

Investments to Date: Contact SciTech Development

Grants: \$2.6M

Not for Profit/Foundation Grants/Services/Boot Strapping (ONGOING): \$3.4M

Convertible Debt Round (OPEN): \$1.24M; Raised: \$240K

Equity Round (OPEN): \$15.0M

Timing of Inflection Points

- **IND Filing:** June 8, 2017
- Two **FDA Orphan Drug Designations:** granted in December 2017 providing 7 years of market exclusivity post NDA approval and substantial investment tax credits
- **Publication of FDA Draft Guidance for Industry**, dated August 13, 2018, pertaining to the use of *Expansion Cohorts: Use in First-In-Human Clinical Trials To Expedite Development of Oncology Drugs and Biologics...* that reinforces SciTech's time to market assumptions
- FDA **Fast Track Designation:** application completed, to be filed post IND approval (~3 mos.)
- **First Clinical Results:** confirmation of safety & determination of maximum tolerated dose (MTD), ≤ 12 months from commencement of the Phase Ia clinical trial
- **Second Clinical Results:** confirmation of efficacy in the treatment of T-cell lymphoma; approximately six months from the commencement of Phase Ib
- **Corporate Collaboration:** Development of a topical version of nanoFenretinide in the treatment of skin cancer with Ferndale Pharma Group (ongoing)
- **Potential Collaboration:** Johnson & Johnson; a letter of interest in place; commencement at first indication of any clinical response