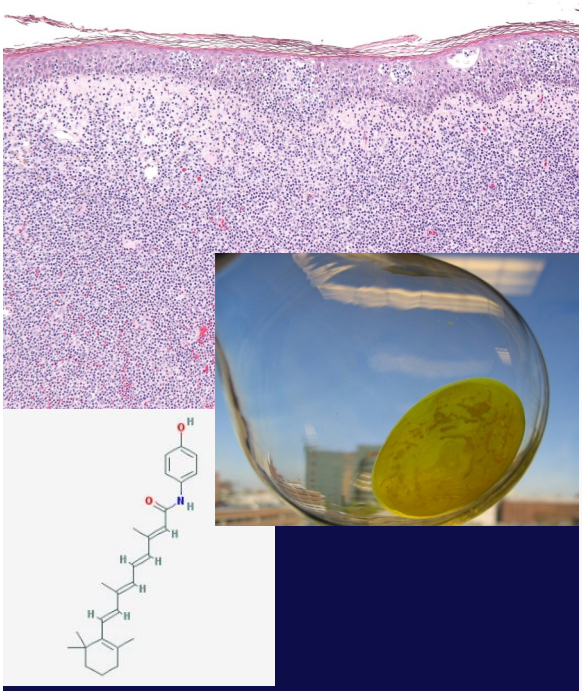
SciTech Development LLC

Intelligent Technology
to Solve Unmet
Clinical Needs



SciTech: Intelligent Technology to Solve Unmet Clinical Needs – Why Fenretinide makes good sense

Often the difference between success and failure is the dedication and persistence of the executive team. SciTech Development's principal asset, fenretinide, is guided by a deeply experienced team in the broad portfolio of pharmaceutical development, clinical strategy, and scientific formulation. Just as importantly, each member of this team is energized and driven to deliver on the promise of fenretinide for many reasons, some quite personal. To help you understand the motivations and get a sense for the compelling reasons for developing fenretinide, please read on…

Timothy Kuzel, MD

Principal Investigator, Fenretinide

Dr. Kuzel is a leading authority on developing innovative immunotherapy treatments for cancer, and was appointed professor of internal medicine and division chief of Hematology, Oncology and Cell Therapy at Rush Medical Center in Chicago, IL in June 2016. Kuzel was previously director of Northwestern University's Driskill Immunotherapy Research Program, was a professor of medicine and dermatology at the Northwestern University Feinberg School of Medicine, and oversaw the Genitourinary and Cutaneous Oncology Programs at the Robert H. Lurie Comprehensive Cancer Center.

Dr. Kuzel has more than 20 years of developing innovative therapies - especially those that harness the immune system. He is a past winner of the American Cancer Society Clinical Oncology Career Development Award and served as president of the Illinois Medical Oncology Society. He has authored or co-authored more than 250 journal articles, editorials and book chapters and edited a series of leading cancer treatments text books including 'Cancer Treatment and Research: Immunoconjugate Therapy of Hematologic Malignancies.'

Dr. Kuzel completed his residency in Internal Medicine and a fellowship in hematology/ oncology at Northwestern University after receiving his medical degree from the University of Michigan. He is board-certified in internal medicine, hematology and oncology and is a diplomate of the National Board of Medical Examiners.

"I have been a clinical and research hematologist and oncologist for over 27 years and a major focus of this practice has been the treatment of patients suffering from the life-long complications of cutaneous lymphomas. Despite several therapies available, the limitations of these agents due to biologic limitations and side effect profiles leaves considerable need for additional agents that can systemically treat progressing or refractory disease.

I am pleased to be the named Principal Investigator for the upcoming Phase I clinical trial to confirm the safety of ST-001. There is a significant volume of reported data with fenretinide in over 1500 patients in various cancer tumor-types. The new formulation developed by SciTech, ST-001, is an intravenously administered form of fenretinide. In reviewing accumulated data and reported experience with fenretinide, it appears that this agent may prove to be a well-tolerated, effective treatment when compared to commonly used chemotherapy regimens. Formal clinical evaluation of ST-001 appears well warranted.

We hope to rapidly advance this needed agent into human clinical trials and to potentially create an important treatment alternative for patients with cutaneous lymphomas."

Earle T. Holsapple III, President & CEO

Mr. Holsapple has successfully served as CEO/COO of six profitable midsize companies. He developed and raised the initial funding for the SoftVue™ technology for Karmanos Cancer Institute. It is a novel breast cancer detection product now in clinical trials with Delphinus Medical Technologies, Inc.

"Dr. Ralph Parchment and I founded SciTech, at the behest of the National Cancer Institute and the management of the Karmanos Cancer Institute, to solve the clinical performance problems of the anticancer agent, fenretinide, ergo its inability to be sufficiently or uniformly absorbed by cancer cells because it failed to adequately mix with water.

Based on the availability of prior clinical trial data, both institutions are convinced that this drug has significant potential in the treatment of a whole host of aggressive cancers including lymphoma, small cell lung, renal cell, ovarian and breast cancers. In addition, lab studies suggest that additional cancers would also respond well to its use.

It was with this in mind that Ralph and I took on the challenge of creating SciTech to discover a new drug/delivery combination that would consistently deliver safe and effective doses of fenretinide to achieve the therapeutic drug levels necessary for successful cancer treatment. We were blessed to be surrounded by an exceptional team of scientists and technicians who, under Ralph's guidance, were able to create the phospholipid based drug suspension product (ST-001) that has likely, clinically enabled fenretinide.

Our current clinical challenge is to reconfirm the safety and efficacy of fenretinide in its new configuration in the treatment of the initially targeted diseases to, once and for all, realize its potential as a effective anticancer agent in the treatment of the above referenced cross-section of cancer indications.

We have assembled an exceptionally talented internal and external team of clinicians, scientists and managers to help us achieve the goal of confirming fenretinide's clinical and commercial value. We have crafted a clinical testing protocol and development plan that bodes well for the future of SciTech and the war on cancer.

I am confident that we will be successful in testing and developing this newly designed anticancer agent. The science is compelling as is the availability of vast amounts of third-party confirmatory human data. I strongly urge you to learn more about this unprecedented, clinical and commercial opportunity."

Michael Burns, PhD

Senior Vice-President, Product Development

Dr. Burns has nearly 40 years of pharmaceutical industry experience that includes R&D, product development, sales & marketing, licensing & acquisitions. He is the President and Chief Operating Officer of Ferndale Pharma Group which comprises companies that specialize in the development, manufacture, marketing, sale and distribution of a wide variety of healthcare products including prescription and over-the counter drug products and medical devices.

"The pharmaceutical development initiatives undertaken by the scientific team at Sci-Tech have been remarkably creative and very compelling.

Based on numerous animal and human studies, the drug fenretinide indisputably has the potential to treat and prevent many forms of cancer yet it cannot be readily used in victims because of very poor systemic bioavailability leading to suboptimal dosing. Past attempts to safely and effectively improve its bioavailability and consistently deliver adequately therapeutic doses have failed.

The Sci-Tech team has solved this problem elegantly and systematically. Their ST-001 fenretinide suspension promises to deliver adequately high therapeutic doses of the drug consistently and safely.

ST-001 is ready to enter Phase 1 clinical trials and will there show definitive evidence of safety and efficacy in humans. It will progress rapidly into Phase 2 studies and on to fast track approval of the NDA, initially for cutaneous lymphomas. From there, by virtue of its innate safety profile, it will progress to become a widely used chemotherapeutic/immunotherapeutic asset in the general armamentarium to treat and prevent many types of cancers.

I am excited and honored to be part of an initiative that is capable of increasing the life expectancy and positively improving the quality of life of many thousands of cancer sufferers."

Ayad Al-Katib, MD
Medical Director

"ST-001 has high likelihood of success as effective anti-cancer drug which is the reason for my interest and participation in SciTech.

Some of the clinical trials with previous formulations of the active ingredient, fenretinide, were conducted at my academic institution, Wayne State University (WSU) in Detroit. Results were suboptimum either because of poor absorption of the drug from the gut (in the oral formulation), low potency, or harmful effects of the delivery vehicle in which fenretinide was dissolved in the intravenous preparations. Despite these limitations, those trials showed encouraging results. So, it was my conclusion that fenretinide can become an effective anticancer drug if we can develop a more potent formulation, which is exactly what SciTech invented.

I look forward with great excitement to initiating the phase 1 clinical trial in T-cell lymphoma and to conduct further research on ST-001 in my research laboratory at WSU. ST-001 was tested in a lymphoma animal model, WSU-DLCL2, that I had established from one of my own patients who suffered from lymphoma. I am committed to conducting additional laboratory research which will guide further clinical development of ST-001 most efficiently."

Dr. Al-Katib is a tenured professor of medicine at the Wayne State University School of Medicine (WSUSOM). He is a physician-scientist whose teaching, research and patient care has focused on lymphoma for more than 30 years. He has established and runs the Lymphoma Research Laboratory at WSUSOM and has established a number of animal models for human lymphoma in SCID mice. These models are widely sought after by pharmaceutical companies to test new treatment agents for lymphoma. Dr. Al-Katib has published over 130 research papers in peer-reviewed professional journals and is recipient of NIH grants to conduct laboratory research and clinical trials testing new anticancer agents. Moreover, he has extensive leadership experience as division head of Hematology Oncology at WSU, section chief of Hematology-Oncology at St John Hospital and Medical Center, medical director of the Van Elslander Cancer Center and the East Region of St John Providence Healthcare Oncology Center of excellence in Michigan. Dr. Al-Katib is member of several professional societies like the American Society of Clinical Oncology (ASCO), American Association for Cancer Research (AACR) and the American Society of Hematology (ASH). He is a registered clinical investigator with the US National Cancer Institute (NCI).

Louis M. Scarmoutzos, PhD

Clinical / Regulatory Management

Dr. Scarmoutzos brings 20+ years technology commercialization to bear at SciTech. He is Principal Advisor (PA) to the Los Angeles Regional Technology Alliance's (Larta) Life Sciences Technology Group, a PA in the National Institutes of Health and National Science Foundation Commercialization Assistance Programs (NIH CAP & NSF CAP) and Founder of MVS Solutions and Kollodis BioSciences.

"I first encountered SciTech several years ago when I was assigned to them as their Principal Advisor in the National Institutes of Health Commercialization Assistance Program (NIH CAP). The NIH CAP provided me with the opportunity to work with many dozens of small companies. What struck me then was the uniqueness and simplicity of SciTech's ST-001 drug product and technology, albeit very difficult to execute in practice- but a nut they successfully cracked. The implications were huge- a viable cancer drug alternative to current chemotherapy drugs but without the serious side effects of chemotherapy.

This is not your typical liposomal drug delivery technology. A "quick read" of the SciTech technology does it no justice- nor would you walk away with any sort of understanding of SciTech's phospholipid drug delivery technology. The details are in the subtleties enmeshed in the phospholipid-fenretinide complex. ST-001 is the first drug product being commercialized utilizing the company's phospholipid drug delivery technology- with potentially many more to come.

The potential use of ST-001 in a vast number of cancer indications as well as potential combination drug products makes for a large number of iterations that often prove to be too desultory for many small companies; however, this is not the case with SciTech. What has impressed me most is the team's carefully thought out and rational commercialization pathway that keeps us on track in delivering a potential blockbuster drug.

SciTech certainly piqued my interest while in the NIH CAP- an interest that continues since their successful completion of the NIH CAP program. Earle Holsapple has assembled a truly outstanding team that is both a pleasure and privilege to work with- folks from different, complimentary backgrounds that, together, provide a unique perspective on business and drug development. For me, this is an exciting time to be working with them- and I would bet the same for you."

Michael W. Young

Clinical & Commercial Consultant

Mr. Young is a leading expert in commercialization and patient advocacy in the field of orphan cancers, specifically cutaneous lymphomas. He has been responsible for the launch of several agents in this arena including Targretin® (bexarotene) capsules, Targretin® (bexarotene) gel, ONTAK® (denileukin diftitox) and Panretin® (alitretinoin). Additionally he has provided commercial launch support for Istodax® (romidepsin), Valchlor® (mechhlorethamine), and nearly a dozen other anti-cancer agents. He has held several senior management roles with large pharma, biotech, and CRO organizations prior to founding biomedwoRx: Life Sciences Consulting. His consultancy provides C-Suite level clinical strategy and commercialization expertise to biopharma and life science companies around the world.

"The management of the indolent Non-Hodgkin Lymphoma, Cutaneous T-Cell Lymphoma is typically a many decade clinical course for most patients once they have been effectively diagnosed. Treatment choices progress over time from topical approaches such as corticosteroids and nitrogen mustard gel when the disease is manageable as isolated skin manifestations to oral medication drugs such as bexarotene capsules as a more systemic approach is needed. Unfortunately, in those patients whose disease continues to progress or becomes more aggressive, chemotherapy often offers the best chance for remission and reduction in tumor burden and other common symptoms such as significant pruritus.

One of the principal goals of therapy in patients with CTCL is to preserve their immune system over the lifetime of treatments. Missing from the current treatment armamentarium are significant systemic drugs which have demonstrated anticancer activity, can be safely and easily administered, and produce prolonged remission without exposure to chemotherapy's impact on immune status and quality of life. Providing clinicians with an intravenously administered agent which could offer a meaningful alternative prior to chemotherapy would be a significant improvement.

For this reason, the development and further evaluation of fenretinide is needed and should be aggressively pursued. The active drug, fenretinide, has accumulated a voluminous experience base in over 1500 patients in multiple tumor-types but due to solubility issues, was heretofore unsuitable for clinical development. Recent pharmacologic improvements to the formulation have resulted in an elegant intravenously administered phospholipid complex of fenretinide known as ST-001. Given the potential utility and proposed benefits of this new formulation, ST-001 deserves full and immediate development efforts to determine its safety and efficacy, initially in CTCL, but also in several other larger patient populations with potentially susceptible tumors."