ST-001 & Immunotherapy

ST-001: A potential ancillary cancer treatment with existing immunotherapy agents that also provides innate immuno-therapeutic effects

What is ST-001?
ST-001 is SciTech Development's clinical lead drug product for the treatment of several different types of cancer. ST-001 is a proprietary nanoparticle suspension for intravenous (IV) drug administration that is composed of the active pharmaceutical ingredient (API) fenretinide in patented combination with specifically selected phospholipids (inactive ingredients).

What is immunotherapy?
Cancer immunotherapy (sometimes called immuno-oncology) is the stimulation of the body's own immune system to fight cancer. In essence, immunotherapy enables the body's immune system to recognize, target and destroy cancer cells. It is a growing subspecialty of oncology.

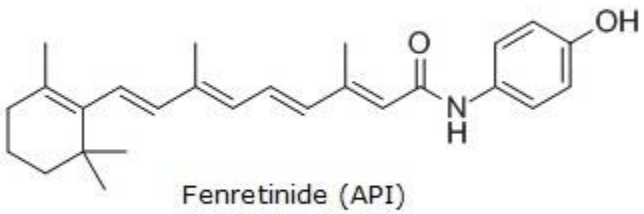
What immunotherapy drugs are approved by the FDA?
Excluding monoclonal antibodies as a targeted therapy regimen, currently there are only a handful of FDA approved immunotherapy drugs (so called immune checkpoint inhibitors or modulators) on the market including Sipuleucel-T (Provenge®) for the treatment of prostate cancer, Tisagenlecleucel (Kymriah®) for the treatment of acute lymphoblastic leukemia (ALL), and Axicabtagene ciloleucel (Yescarta®) for the treatment of diffuse large B-cell lymphoma (DLBCL).

Is SciTech's ST-001 drug product FDA Approved?
No. SciTech has filed an Investigational New Drug Application (IND) which is currently being reviewed by the FDA. Upon IND approval, ST-001 will undergo clinical trials for the treatment of T-cell non-Hodgkin's lymphoma (NHL).

Why is ST-001 a good candidate for an ancillary treatment with immunotherapy agents?
Although dramatic results have been observed in some patients treated with cancer immunotherapies, only a minority of patients respond to immunotherapy; ST-001 could fill the remaining void. The durability of immunotherapy treatment is still unknown, while ST-001 has both therapeutic and preventive anti-cancer capabilities. Unlike chemotherapy and radiation therapy, the active agent in ST-001 does not damage healthy cells nor does it cause loss of hair, nausea and related deleterious side-effects commonly observed with chemotherapy and radiation treatment.

What are the potential side-effects of the active ingredient in ST-001?
The only significant side-effect reported with fenretinide treatment is nyctalopia (night blindness) which has been shown to be reversible upon cessation of fenretinide drug treatment.

What is fenretinide?
Fenretinide is the active pharmaceutical ingredient (API) in SciTech's proprietary ST-001 drug product formulation. It is a synthetic retinoid derivative related to vitamin A (retinol). It is a relatively small drug molecule as shown below.



Fenretinide (API)

Fenretinide was first developed by McNeil Laboratories as an anti-cancer drug in the early 1980s.

If fenretinide is such a beneficial drug, why hasn't it already been FDA Approved?
Fenretinide has inherently poor bioavailability meaning its poor water solubility results in only tiny amounts of fenretinide entering into the blood stream. Such small amounts are unable to bring about a therapeutic effect. SciTech has overcome this bioavailability problem with its proprietary ST-001 drug formulation (nanoFenretinide). Additionally, the competitive cancer drug tamoxifen was first-to-market which resulted in the National Cancer Institute (NCI) and Johnson & Johnson (acquired McNeil Laboratories) abandoning fenretinide irrespective of its significantly better safety profile.

What are ST-001's innate immune-therapeutic effects?
SciTech has recently filed a provisional patent application regarding fenretinide's inherent immune effects; notably, the ability of fenretinide to "reactivate" the body's natural immune system that has been suppressed by cancer cells.

What is the current status of ST-001 drug development?
- U.S. Patent No. 8,709,379 titled "Liposomal Nanoparticles and Other Formulations of Fenretinide for Use in Therapy and Drug Delivery" was issued to SciTech Development on April 29, 2014.
- The FDA has granted ST-001 Orphan Drug Status for the treatment of NHL (December 2017).
- U.S. Provisional Patent Application No. 62/769,822 titled "Use of Fenretinide Nanoparticles for Immunotherapeutic Cancer Treatment" was filed on November 20, 2018.
- ST-001 is currently under review by the FDA (IND Application).
- SciTech is currently seeking funding to conduct ST-001 clinical trials.

Could ST-001 be used in combination with other cancer treatments?
Yes. The safety profile of fenretinide is eminently suitable for ST-001 use as a standalone drug; or, in combination with; or, in co-administration with existing cancer treatments (chemotherapy, radiation and surgery). The benefit of fenretinide's minimal side effects: non-overlapping toxicity with other cancer treatments. ST-001 + other treatments = enhanced therapeutic performance without worsening toxicity.

What is SciTech's current drug product pipeline?
ST-001 – Intravenous fenretinide formulation for the treatment of NHL.
ST-002 – Topical formulation for the treatment of various skin cancers and bed sores.

ST-003 – Intravenous formulation for the treatment of small cell lung cancer (SCLC).
ST-004 – Intravenous formulation for the treatment of metastatic breast cancer (MBC).
ST-005 – Intravenous formulation for the treatment of neuroblastoma (pediatric cancer).
ST-006 – Intravenous formulation for the treatment of T-cell acute lymphoblastic leukemia (T-ALL).

Can you provide more detailed info about the potential innate immune-therapeutic effects of fenretinide and ST-001? And how does SciTech's drug delivery technology and ST-001 work?
Contact SciTech Development for additional information.