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# Breakthrough Nanoparticle Drug Delivery Platform Enabling Lead Compound nanoFenretinide (ST-001)



## **Proprietary Nanoparticle Drug Delivery Breakthrough**

## SciTech Delivery Vehicle (SDV) A Platform for Formulating Lipid Soluble Drugs into Potent Therapeutics

- » Biocompatible delivery platform for lipid soluble drugs
- » Delivery system incorporating FDA approved phospholipids
- » Engineered for high therapeutic potency
- » Multilamellar nanoparticles possess high drug carrying capacity
- » Triglyceride free formulation
  - » Avoids delivery system related side effects
- » Designed for outpatient infusions vs. inpatient treatment
- » Applicable to a broad range of therapeutic agents
- » Enables the reformulation of a highly studied anti-cancer agent

## Fenretinide – A Proven Anti-Cancer Drug

### **Oncolytic/IO Formulations Promises Potent Therapeutic**

- » Direct & immune effect on cancer cells (2 MOAs)
- » De-risked initial program built on extensively studied therapeutic agent
  - » Clinical safety & efficacy established by Johnson + others
- » SDV ——— New potent therapeutic
  - » Solves absorption & bioavailability challenges
  - » High potency, avoids delivery side effects, triglyceride free
- » Disruptive Products
- » Targeting T-cell lymphoma & small cell lung cancer (SCLC)
- » Topical application in development, IND soon
- » Stand-alone product & based on safety profile, may be used in combination therapy including CAR-T
  - » Prevent relapses & metastases

## **Unique Investment Opportunity**

#### \$15M Series A Round

- ✓ Intellectual Property runway extended to ~2036 new IP

  USE OF FERENTINIDE NANOPATICLES FOR IMMUNOTHERAPEUTIC

  CANCER TREATMENT
- ✓ ST-001 market potential \$5B \$25B
  - Targeting Fenretinide-responsive cancers
- ✓ Confirmatory not Exploratory studies
- ✓ Low Cost of Goods, considerable margin
- ✓ Orphan Drug Designation granted, others to follow
- ✓ FDA IND review 11/15/18;
  - Pending quick reconfirmation of clinical mfg. data
  - Short Time to Market: 2-3 years
  - Example Astra Zeneca's Tagrisso®
  - FDA guidance on receiving NDA quickly

## **Independent 3rd Party Corroboration**

A Key Opinion Leader (KOL) who is a true world-class expert for ST-001 (fenretinide expertise) provided SciTech the highest scores possible in all 8 review categories for an independent third party investor.

#### **Independent 3rd Party Review Summary**

- » ST-001 has immense potential to have a major impact on translational and clinical research for the treatment of cancers for which there is presently no cure.
- » SciTech's nanoparticle fenretinide formulation is highly original and novel.
- » This is strong science.
- » Clear and rapid path to clinical trials and market.
- » SciTech has an excellent team with extensive experience.
- » High likelihood of regulatory success for NDA from FDA.
- » Optimistic about market success: (1) fenretinide known to be safe with many mechanisms of action; (2) new drug products still needed to treat large number of incurable cancers, ST-001 is applicable and pertinent to curing these cancers.

## Realizing the Fenretinide Therapeutic Promise

For 30+ years, big pharma and the National Cancer Institute (NCI) spearheaded Fenretinide's development but failed to find a safe and effective delivery system

#### Strong case for a new formulation of Fenretinide

- Synthetic vitamin A analog (retinoid) anticancer agent
  - » Exceeds the capabilities of other retinoids
- » First developed by McNeil Laboratories (J&J)
  - » Proven safe in a 3,000 patient breast cancer prevention study
    - » Although effective, beaten to market by Tamoxifen
- » NCI attempted to develop as a cancer therapeutic
  - » Result: clinical proof-of-concept studies
  - » No studies overcome the bioavailability shortcomings while administering the drug safely

## **Recent Anticancer Successes & Current Challenges**

#### Efficacy achieved with intravenous Fenretinide emulsion Current embodiment makes the emulsion impractical

- » Proven human efficacy or activity in six cancers\*
  - » Solid tumors: SCLC, neuroblastoma & ovarian cancers
  - » Blood disorders: AITL, CTCL & B-cell lymphoma

#### A complete response (CR) after all other therapies failed









Before

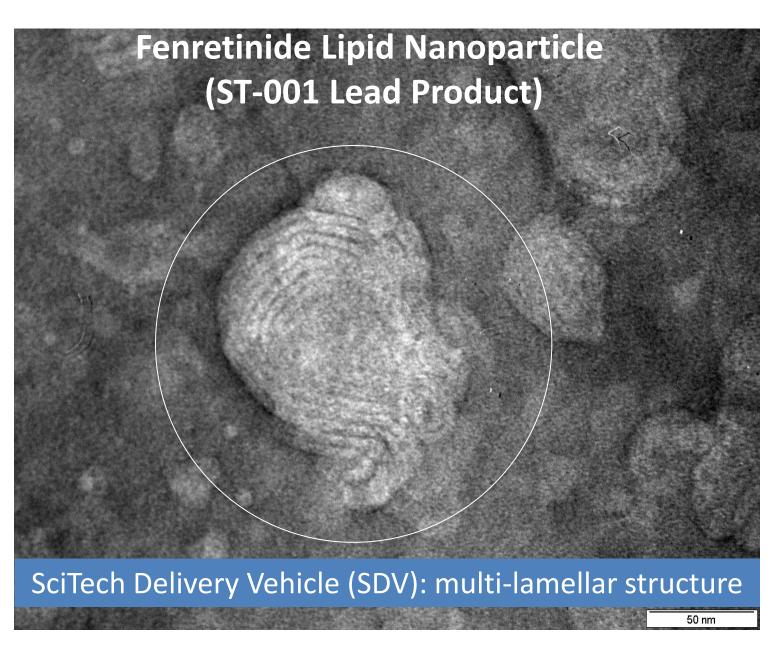
After

Before

After

## Origins . . . . Discovery and Opportunity

## A patented, biocompatible, phospholipid nanoparticle platform designed for high drug loads



#### SciTech's invention

- Nanoparticle drug delivery vehicle
- Composed of FDA accepted phospholipids
- Selected to incorporate water insoluble drug compounds
- No triglycerides
- Fenretinide first lead compound

#### • Why is that important?

- High payload (carrying)
   capacity for lipid soluble
   drugs
- Biocompatible and well tolerated

## **ST-001:** nanoFenretinide Therapeutic Profile

# Multiple Mechanisms of Action (MoA) Including Modulation of Tumor Immunity

#### Clinical Hypothesis in CTCL: 2-prong MoA that Restores Tumor Immunity

- treats deficient adaptive immunity
  - > reverse cytokine suppression of CD8+ CTL TILs (likely RAR & RXR)
- treats lack of innate immunity by NK cells
  - → upregulates NKR ligands (likely RXR)
- plus direct action on malignant cells (RAR & DES-1/ceramide apoptosis)
- minimal side effects may be due to immune homeostasis in healthy tissues
- proven clinical activity in the treatment and prevention settings

#### **Implications**

- multiple MoA's offer advantages over first-generation retinoids (RA's)

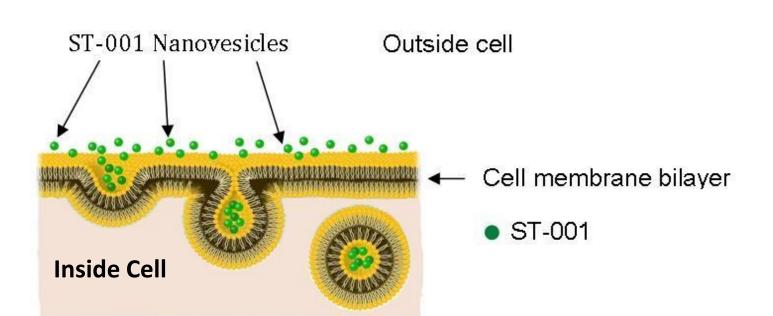
## ST-001 Delivery and Direct Mechanism of Action

## Once inside the cancer cell Fenretinide affects multiple biochemical pathways ultimately causing cell death via apoptosis

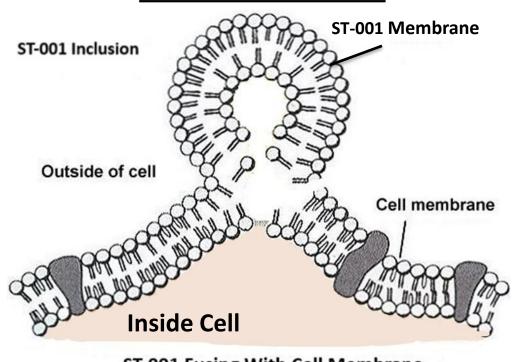
These pathways include retinoid receptors, oxygen radicals and inhibition of ceramide (unlike retinoic acid)\*

[YouTube Video: <a href="https://www.youtube.com/watch?v=tsx8jNVZbO8&feature=youtu.be">https://www.youtube.com/watch?v=tsx8jNVZbO8&feature=youtu.be</a>]

<u>Direct Targets:</u> RAR/RARE, DES-1, Mitochondrial OXPHOS







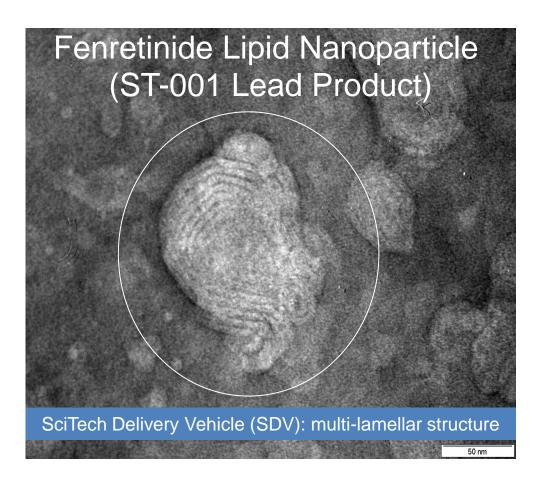
ST-001 Fusing With Cell Membrane

#### Systemic ST-001 nanoparticles may enter cells like Exosomes and Ectosomes

<sup>\*</sup>Kalemkerian, G.P., et al., Growth inhibition and induction of apoptosis by fenretinide in small-cell lung cancer cell lines. J Natl Cancer Inst, 1995. 87(22): p. 1674-80.

## **New Compositions of Matter & Use Patent**

### Strong IP: Co-Owned with & Licensed from Wayne State University



- Orphan Drug Designation –
   Granted for CTCL 12/2017
  - 7 years market exclusivity
  - Development tax rebates
  - More diseases to follow

- US 8,709,379 issued Apr 29, 2014
- Expires Feb 6, 2030 (1,045 day USPTO extension)
- Patent coverage extends to the EU, Canada,
   Australia and New Zealand
- Patent protects drug substances incorporated with phospholipids into nanoparticles
- Fenretinide as a key example:
  - high-strength Fenretinide(Claims 1, 14-16)
  - both IV and topical uses(Claims 24, 33)
  - combination drug products(Claim 20)

No known claims on IP or revisions

## **Origins .... Discovery and Opportunity**

## IP to be enhanced & extended with claims derived from data collected during clinical trials and new product innovation



Fenretinide Phospholipid Suspension
Intravenous Infusion
750 mg / 60 mL 60 mL / Vial

Store: At 2 °C to 8 °C (Refrigerate)
FOR SINGLE USE ONLY

Caution: New Drug - Limited by Federal (U.S.A.) law to investigative use.

ST-001 Investigative Drug Label

Provisional immunotherapy patent application filed in November 2018

- Optimize value by enhancing and extending the IP runway and prolonging protection of the SciTech product line
- Innovation derived from ST-001 clinical use
  - Expanded indications
  - Combination therapies
  - Product improvements
  - New mechanisms of action
- Innovation derived from new products
  - Specific combinations with other promising poorly water-soluble drugs
  - IND: topical product in CTCL, AK, other cancers, and skin conditions
  - Other medically important compounds (vitamin deficiencies due to rare diseases)

## **Orphan Drug Designation**

#### **Advantages to Utilizing Orphan Drug Status**

Granted to SciTech by FDA, 12/2017 for T-Cell Lymphoma Indication

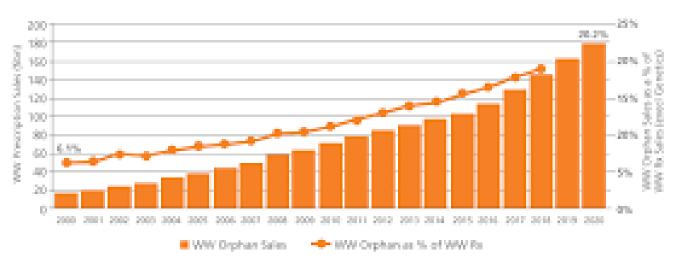
#### Includes:

- 7 year market exclusivity post NDA (10 years EU)
  - Exclusivity can run concurrent for multiple indications
- Development tax rebates

#### Additional Applicable Orphan Indications for SciTech

- Small Cell Lung Cancer (SCLC)
- Cervical
- Colo-rectal
- Head and Neck
- Ovarian
- Pancreatic

Worldwide Orphan Drug Sales & Share of Prescription Drug Market (2000-2020)



Servic Selectorhame\* 37 September 3715

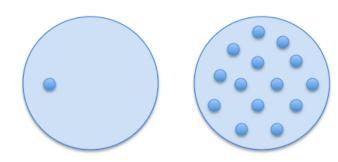
## **Analysis Of The Competition**

#### Competitive risk is low because of ST-001's superior technology

#### **One Active Competitor**

#### Comparative drug to lipid ratio for:

- CerRx Emulsion = 1:110 (.9%)
- ST-001 = 1:7.5 (13.3%)



CerRx Emulsion SciTech ST-001
[Depiction of relative fenretinide concentrations]

#### Ease of Use of ST-001 (nanoFenretinide IV)

#### The practical solution for administering intravenous Fenretinide

Product	Dose Level (mg/m²)	Dose for 2 m <sup>2</sup> (mg)	Formulation Strength	Volume Administered	Infusion Time @ 50 cc/hr	Lipid Dose (g)	Triglyceride Dose (g)
ST-001 <sup>1</sup>	1,200	2,400	12.5 mg per cc	192 cc	< 4 hours	18	0
comparator product <sup>2,3</sup>	1,200	2,400	2 mg per cc	1,200 cc	24 hours	264	240

<sup>&</sup>lt;sup>1</sup>SciTech Development nanomedicine, US Patent No 8,709,379 (claims 15, 17)

<sup>&</sup>lt;sup>2</sup>CerRx Inc, Fenretinide Injection, US Patent No 7,169,819 (claim 7)

<sup>&</sup>lt;sup>3</sup>Tomáš Frgala, PhD Thesis (2007), Masaryk Memorial Cancer Institute, Brno, Czech Republic

## **Share of Initial Global Target Market ~ \$2B**

## There is significant market potential associated with cancers already shown to respond to Fenretinide

#### **Short Term Addressable Mkt: \$2.0 Billion**

Initial Targeted Diseases	Mkt. Potential	# of Patients
T-Cell Subsets:		
Mycosis Fungoides & Sézary Syndrome	\$175 M	~2,600
AITL	\$75 M	~1,100
Solid Tumors:		
SCLC	\$1.1 B	~16,000
Breast (Metastatic)	\$ 612 M	~9,000

- » Fenretinide has been previously proven remarkably safe
  - » Only significant side effect = temporary loss of night vision (reversible)
  - » Data from ~3000 patients & ~ 40 clinical trials

## Future \$5B - \$25B Global Market Potential

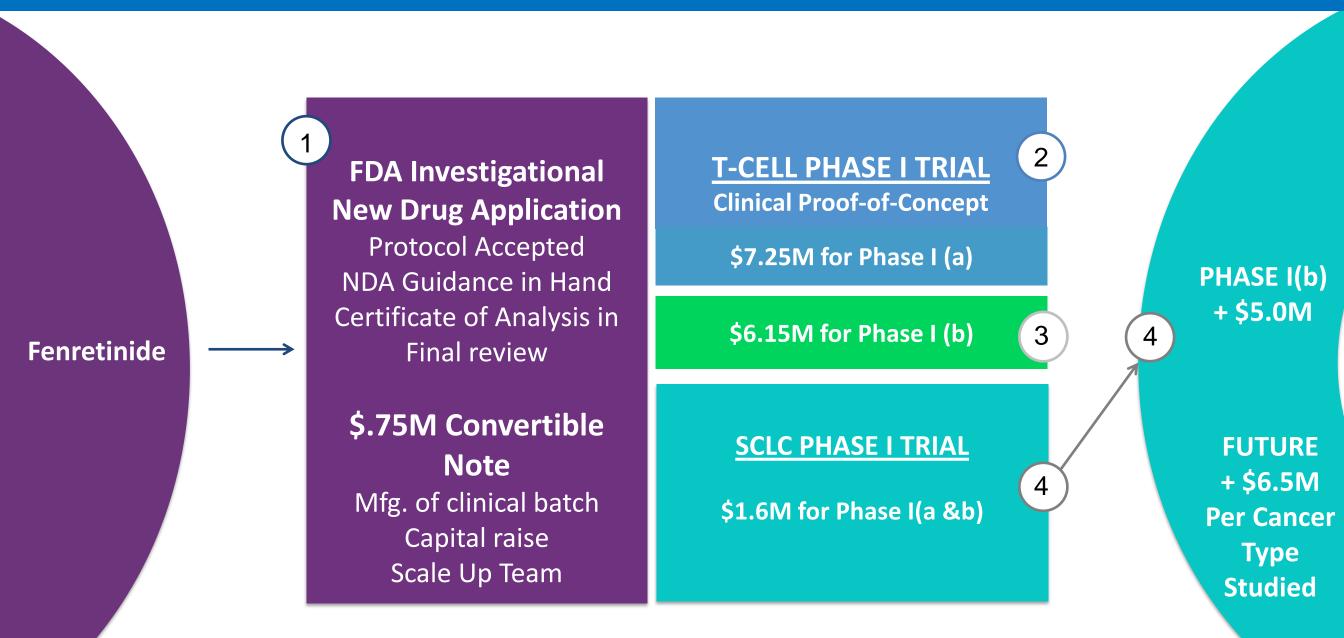
### ST-001 is anticipated to target many other cancers

Scientific & clinical data: Unparalleled data covering Fenretinide Market potential: Studies make the case for treating the following cancers:

Targeted Cancers	~ US Deaths/Year	<b>US New Patients*</b>
Breast	40,500	252,710
Cervical	4,170	13,240 Unme
Colo-rectal	50,630	97,220 medic
Head and neck	13,360	63,030 need
Leukemia	24,370	60,300
Ovarian	14,070	22,240
Pancreatic	40,330	55,440
Prostate	29,340	164,609
Total	216,770	728,789

#### **Use Of Funds & Value Inflection Points**

## \$750K Convertible Note Round + \$15M Series A Round \$13.4M Phase | CTCL Clinical Trial + \$1.6M toward SCLC Trial



**RECONFIRMATION OF EFFICACY** 

## **FDA Regulatory Strategy**

#### FDA Approvals sought for ST-001 formulation of IV nanoFenretinide

#### **Use of Expedited Review Programs**

- » Expedited time to market approval
- » Phase 1 trial designed to Reconfirm, not Explore, clinical activity
- » NDA approval guidance previously given by FDA
- » IND filed; negotiated; Protocol approved
  - » Approval anticipated within weeks
- » FDA Orphan Drug Designation received:
  - » T-cell lymphoma (12-23-2017)
- » Fast Track Application drafted; file upon IND approval

## **Optimized & Expedited Clinical Trials Plan**

Approval should be in 2-3 years - by targeting diseases with limited therapeutic Options & by using FDA Fast Track protocols & FDA Expedited Review programs

# IND APPROVAL Mfg.

PHASE 1
(a) clinical
trials

PHASE 1
(b) clinical trials

REGISTRATION
PHASE
clinical trials

Pre-clinical tasks:

- Mfg. clinical batch
- Fast TrackDesignation @IND
  - Application completed
- Finish recruiting clinical trial sites
- Pharma collaborations

Dose escalation in:

- CTCL cohort
- Solid Tumor

For either site:

- Expansion cohort(s) for efficacy signals or
- Completion of dose escalation

Focused efficacy trials targeting:

- Diseases without therapeutic options
- Lead to expedited NDA approval (CTCL)
- FDA Fast
   Track/expedited
   programs

Confirm efficacy for NDA approval:

- Diseases without therapeutic options
- Studies sponsored by industry
- NDA in CTCL
- Expand Indications via Phase 2 Trials

### **ST-001 Clinical Development Plan in Place**



#### **Manufacturing Site:**



Pilot Production Plant cGMP Compliant Manufacturing & Scale-up at Campbell Evaluating future large scale sites

**Lead Clinical Trial Site:** 



**Source of API:** 



Fenretinide supplied gratis

#### **ST-001 Other Clinical Sites**

## SciTech has held dialogs with several institutions expressing an interest in participating in the clinical trials







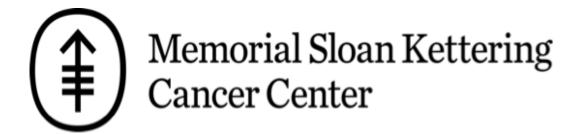








Yale University





### **Management Team**

## Expertise in cancer developmental therapeutics and clinical trials biotech/oncology product development & commercialization and launch

**Earle Holsapple, President & Co-Founder**; CEO/COO of medium sized companies, managed incubator for Karmanos Cancer Institute, serial entrepreneur, raised funding for other biotech startups, i.e., *Softvue* (~\$17M)

Ralph Parchment, PhD, CSO, Inventor, Co-Founder; Managing Director, Laboratory Program, National Cancer Institute at Frederick, Oncology drug national leader

**Ayad Al-Katib**, **MD**, **CMO**; Professor WSU School of Medicine, Cancer Center Medical Director (ret.)

Mike Burns, PhD, SVP Product Development; Retired President, Ferndale Pharma Group Louis Scarmoutzos, PhD, SVP Operations; contractor to the NIH CAP Program

Christine Copple, PhD, CStO; serial bio-entrepreneur, founder Microfluidics

Michael W. Young; Principal, biomedwoRx: life sciences consulting, former executive Andrew Stumpf, Acting CFO; Partner, Storm Lake Capital, Auditor, Ernst & Young Elizabeth Kraus, Esq, General Counsel; Immix Law Group, former CEO – pharma startup

#### **Technical Board**

#### **Advisors**

Abhinav Deol, MD

Oncologist, Karmanos Cancer Institute



John Doux, MD, MBA

Palo Alto Investors



**Gregory Kalemkerian, MD** 

Professor of Medicine, University of Michigan



Timothy Kuzel, MD,

Hematologist/Oncologist, Rush University
Medical Center



#### Kenneth Massey, PhD

Senior Director, Venture Development, WSU



#### Steve Munk, PhD

Deputy Director, The Biodesign Institute, Arizona State University



### **Potential Exit Events**

#### Strategic Partnering, Product Licensing & Value Creation Events

✓ Corporate discussions already ongoing



- ✓ Monetize nanoparticle delivery platform
- Company divestment
- ✓ Series B & C, Regulation A+, Tier 2 capital raises
- ✓ IPO
- ✓ Broad applicability across many therapeutic sectors
- Letter of interest from Johnson Johnson

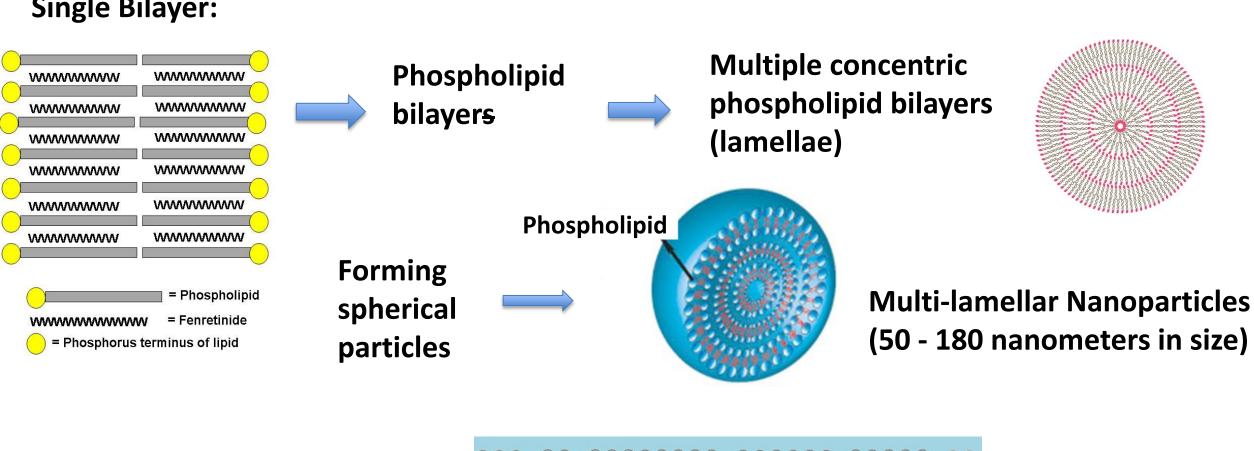




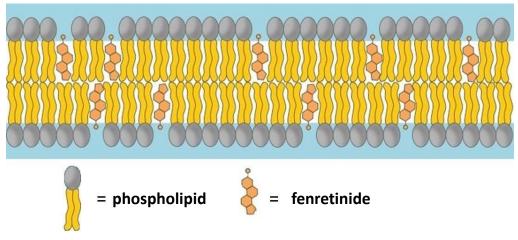
## ST-001: SciTech Delivery Vehicle (SDV) + Fenretinide

#### ST-001 a multi-lamellar phospholipid nanoparticle containing Fenretinide THIS IS HOW IT WORKS

#### **Single Bilayer:**



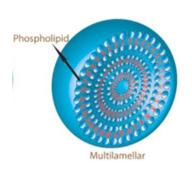
**ST-001: Fenretinide** incorporated into the phospholipid bilayers



# Comparison of ST-001 SDV & Biological Lipid Particles

ST-001 is similar to other biological lipid nanoparticles
The distinguishing feature is the multiple phospholipid bilayers
that make high dose delivery possible

#### SCI's SDV



Multiple Phospholipid <u>bi</u>layers
Interior core = empty

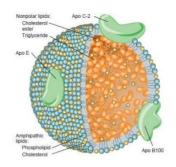
Size = 50 nm - 180 nm

SDV for Drug Delivery

ST-001 = SDV + fenretinide

#### **Compared with:**

#### **Chylomicron**

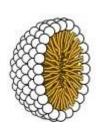


Single Phospholipid <u>mono</u>layer Lipoprotein particle consisting of triglycerides, phospholipids, cholesterol, and proteins

Size = 80 nm - 600 nm

Transports dietary lipids from intestine to other locations in body

#### Micelle (emulsion)

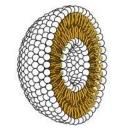


Single Phospholipid monolayer
Interior core = oily

Size = 5 nm - 1000 nm

Oil solubilizing vehicle for aqueous media

#### Liposome

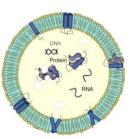


Single Phospholipid <u>bi</u>layer Interior core = water

Size = 20 nm - 3000 nm

Vehicle for delivery of nutrients & drugs

#### **Exosome**



Single Phospholipid <u>bi</u>layer
Interior core = intracellular fluid/matrix

Size = 40 nm - 140 nm
Intercellular Communication

## **Uniquely Designed Multi-Lamellar Nanoparticles**

### ST-001: Custom Designed Phospholipid Drug Delivery

#### **Deliberately Selected Suite of Phospholipids**

- Generating a stable nanoparticle IV formulation
- Using all non-triglyceride lipids
  - Removing possibility of triglyceride toxicity
- Ideal for dissolving Fenretinide in a custom lipid protection vehicle
  - > Intrinsically protecting Fenretinide from aqueous degradation in the bloodstream
- Key phospholipid combination seamlessly maximizes Fenretinide loading
  - > Vastly improving the ratio of Fenretinide to carrier phospholipids
- Prospectively allowing much reduced therapeutic volumes vs conventional formulations
  - Thereby promising substitution of long-term IV inpatient treatments with short-term outpatient regimen.
    - Prospectively leading to competitive advantage driven by economies in cost of care

## **Uniquely Designed Multi-Lamellar Nanoparticles**

#### ST-001: Custom Designed Phospholipid Drug Delivery

#### **Deliberately Selected Suite of Phospholipids Based Upon:**

- Pharmacology and chemistry expertise within the SciTech team
- 30+ years of medical research
- Collaboration with university and medical center laboratories
- Key in vitro and in vivo published studies







### **ST-001: SDV + Fenretinide**

## Phospholipid Selection The foundation of the unique qualities of ST-001

- All previously used in human studies (see FDA UNII identifiers below)
- All are commercially available
- Unique selection ensures incorporation of exceptionally high concentrations of Fenretinide

Phospholipid	Amount	% of Total Phospholipids	FDA UNII*
DPPC	64 mg/mL	68.16 %	319X2NFW0A
DPPC is the API in the drugs colfosceril palmitate, Survanta® and Exosurf Neonatal® (pulmonary surfactant drugs).			
DOPC	25 mg/mL	26.62 %	H026DM5V6U
DepoCyt® (cytarabine liposome injection) and DepoDur™ (morphine sulfate) contain DOPC.			
DMPC	4.14 mg/mL	4.41 %	52QK2NZ2T0
Abelcet® (amphotericin B) contains both DMPC and DMPG.			
DMPG	0.76 mg/mL	0.81 %	L34S99KZCX
Abelcet® (amphotericin B) contains both DMPC and DMPG.			
Total Phospholipids	93.9 mg/mL	100.00%	
Fenretinide	12.5 mg/mL	-	-

<sup>\*</sup>FDA Substance Registration System - Unique Ingredient Identifier (UNII).

## **ST-001: FDA Approved Phospholipid Structures**

"Due to the history of safe use of DPPC, DOPC, DMPC and DMPG in already approved FDA injectable drugs (alone or in dual combination)... the applicant expects no safety issues associated with the ST-001 formulation..." (IND 135475)

Name (Abbreviation)	Molecular Structure	CAS Number
1,2-Dipalmitoyl-sn-Glycero-3- Phosphocholine (DPPC)	$\begin{array}{c} O \\ CH_{3}(CH_{2})_{13}CH_{2} \\ CH_{3}(CH_{2})_{13}CH_{2} \\ \end{array} \begin{array}{c} O \\ O \\ O \\ \end{array} \begin{array}{c} CH_{3} \\ O \\ O \\ \end{array} \begin{array}{c} CH_{3} \\ O \\ O \\ \end{array} \begin{array}{c} CH_{3} \\ O \\ CH_{3} \\ \end{array}$	63-89-8
1,2-Dioleoyl-sn-Glycero-3- Phosphocholine (DOPC)	CH <sub>2</sub> (CH <sub>2</sub> ) <sub>6</sub> CH <sub>3</sub> CH <sub>2</sub> (CH <sub>2</sub> ) <sub>5</sub> CH <sub>2</sub> O  CH <sub>2</sub> (CH <sub>2</sub> ) <sub>5</sub> CH <sub>2</sub> O  CH <sub>2</sub> (CH <sub>2</sub> ) <sub>6</sub> CH <sub>3</sub>	4235-95-4
1,2-Dimyristoyl-sn-Glycero-3- Phosphocholine (DMPC)	$\begin{array}{c ccccccccccccccccccccccccccccccccccc$	18194-24-6
1,2-Dimyristoyl-sn-Glycero-3- [Phospho-rac-(1-glycerol)] (sodium salt) (DMPG)	$CH_3(CH_2)_{11}CH_2$ $O$	200880-40-6

# Competitive Analysis Enabling Lead Compound Fenretinide

### ST-001 is designed to be more practical clinically and economically

#### Significance of the Recent Phase 1 Clinical Trial of Fenretinide Emulsion\*

- Continuous intravenous delivery obtained high plasma drug levels
- High drug levels evidenced antitumor activity in peripheral T-cell lymphomas
- Dose limiting toxicity attributed to hypertriglyceridemia from the emulsion vehicle
- Toxicity severely limited dosing to sub-therapeutic levels
- Low strength formulation required in-patient infusions for 24 hrs. for 5 days

#### **ST-001**

- Comprised of nanosized phospholipid bilayers
- Triglyceride-free, high active pharmaceutical ingredient (API) concentration
- Low lipid to API ratio; high delivery of Fenretinide (animal studies)
- Designed to be practical: 4-hr. infusions for 5 days translates into out-patient care

<sup>\*</sup>Mohrbacher, A.M., et al "Phase I Study of Fenretinide Delivered Intravenously in Patients with Relapsed or Refractory Hematologic Malignancies: A California Cancer Consortium Trial", Clin Cancer Res. 2017 Aug 15;23(16):4550-4555. doi: 10.1158/1078-0432.CCR-17-0234. Epub 2017 Apr 18.

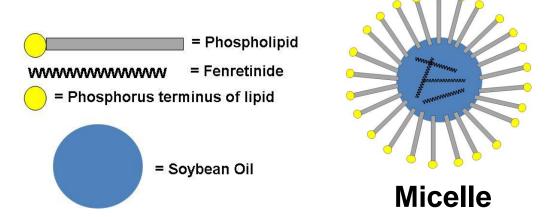
#### **Fenretinide IV Products**

ST-001 delivers therapeutically effective drug doses while avoiding dose limiting toxicities found with inappropriate inactive ingredients

#### Intravenous (IV) Fenretinide

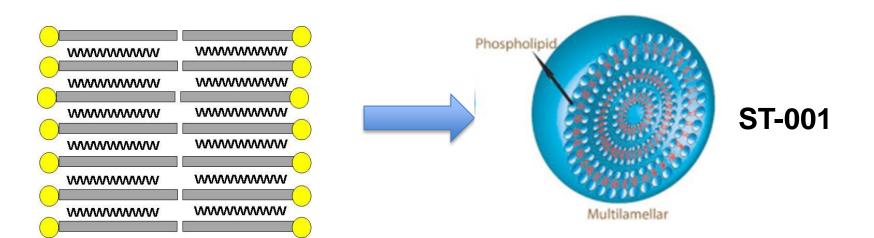
#### **CerRx Fenretinide Emulsion (Entering Phase 2)**

- An oil in water emulsion comprised of micelles
- API dissolved in triglyceride-rich oily compartment (soy oil)
- Limited API available in micelle oil compartment

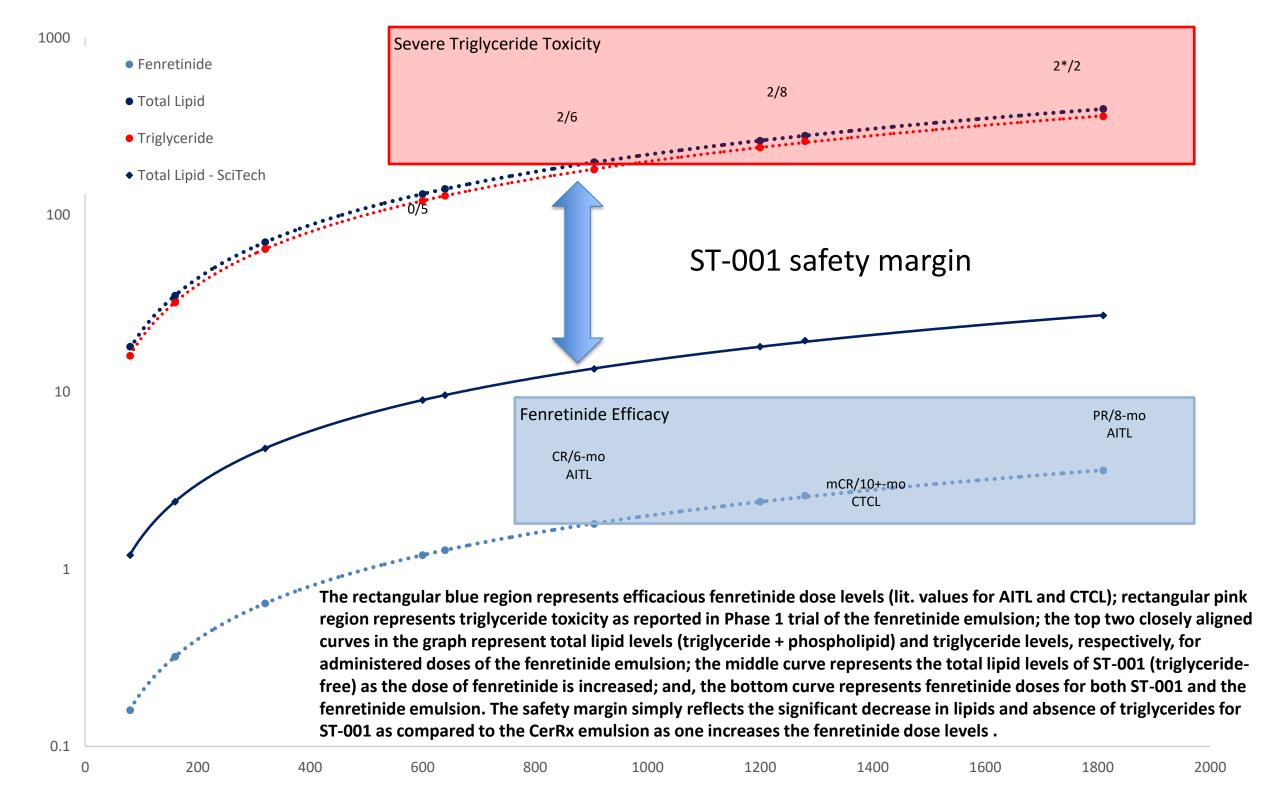


#### ST-001 (Entering Phase 1)

- Oil-free, phospholipid bilayers (similar to cell membranes)
- API incorporated into bilayers (similar to cell membrane bound cholesterol)
- Multiple concentric spherical bilayers (lamellae) incorporate large quantities of API (≥15x as compared to CerRx)



### **Safety Margin with ST-001**



Fenretinide Dose Level (mg/m)

### FDA Approved Products for CTCL & Other T-cell Lymphomas

### Currently approved products provide inadequate therapeutic outcomes

#### Chemotherapeutics

temozolomide (Temodar, Temodal and Temcad), cyclophosphamide, chlorambucil gemcitabine (Gemzar®), deoxycoformycin (Pentostatin), methotrexate, fludarabine etoposide (VePesid®, Toposar®, Etophos®)

#### Retinoid Subgroup

bexarotene (Targretin®)

### Histone Deacetylase (HDAC) Inhibitors

vorinostat (Zolinza®), romidepsin (Istodax®), belinostat (Beleodaq®)

### Therapeutic Antibodies

brentuximab vedotin (Adcetris®) targeting CD30+ disease mogamulizumab (Poteligeo®) targeting CCR5

### **Emerging Competition**

# In addition to the CerRx, Inc. fenretinide emulsion, the following emerging technologies are currently undergoing PTCL clinical trials

### **Zarnestra** (Tipifarnib)

- Kura Oncology, Inc. (San Diego, CA).
- Ongoing Phase 2 clinical trial.
- Oral, nonpeptidomimetic farnesyl transferase inhibitor.
- To date, objective response rate (ORR) = 53%; treatment-related adverse events (grade ≥3) were hematology-related, including thrombocytopenia, neutropenia, leukopenia, anemia, febrile neutropenia and lymphopenia.

### **SP-02 (Darinaparsin)**

- Solasia Pharma K.K. (Tokyo, Japan).
- Asian multinational phase II clinical trial.
- Intravenous, organic arsenical (S-dimethylarsino-glutathione arsenic).
- Dose-limiting toxicity of 300 mg/m2/day; treatment-related adverse events (grade ≥3) included occurrence of diffuse large B-cell lymphoma (1 patient), anemia (1), leukopenia (1), neutropenia (2), febrile neutropenia (1), lymphopenia (2), thrombocytopenia (2), hepatic dysfunction (1), nausea (1) and activated partial thromboplastin time (APTT) prolonged in 1.

### **Emerging Competition**

# In addition to the CerRx, Inc. fenretinide emulsion, the following emerging technologies are currently undergoing PTCL clinical trials

### Masitinib (AB1010; masitinib mesylate)

- AB Science (Paris, France).
- Ongoing Phase 2/3 clinical trial.
- Oral, tyrosine kinase inhibitor.
- Combination study with gemcitabine (chemotherapeutic) and dexamethasone (steroid).

Fenretinide drug safety profile significantly better than emerging technologies currently undergoing clinical trials; PTCL remains incurable

# The Cutaneous T Cell Lymphoma (CTCL) Strategy Rapid Time-to-Market with Market Protection

The time-to-market short (2-3 years)
Why: 1) recent clinical trial precedents, 2) expected ST-001 results,
3) new FDA guidance on study design and 4) cohort expansion

- HDAC inhibitors Zolinza™, Istodax® and Beleodaq® <u>received US market</u> <u>approval based on open-label, non-randomized Phase 2 trials</u> because they were clinically active in CTCL in Phase 1 no Phase 3 trials were required
  - HDACi shortened pathway will apply to ST-001
- Why: T-cell/CTCL activity is expected with the ST-001 Phase 1 trial
- New FDA Draft Guidance validates time to market assumptions\*

<sup>\*</sup>Expansion Cohorts: Use in First-In-Human Clinical Trials to Expedite Development of Oncology Drugs and Biologics, Guidance for Industry, FDA Draft Guidance, August 2018

### Origins .... Discovery & Opportunity .... Investment History

### The Milestones allowing SciTech to move to the Next Development

Type of Funding	Amount	Trigger	Milestones
SBIR Phase 1 grant (NCI)	\$200K + gratis NCI fenretinide	multiple potential solutions to move to IV dosing	discovery of feasibility of lipid nanoparticles
SBIR Phase 2 grant (NCI)	\$1.5M + gratis NCI Fenretinide	superiority of lipid nanoparticle approach	developed ST-001 validated cGMP process
LLC members and friends ("SBIR Phase 3")		end of SBIR Phase 2	patent application filed clinical protocol in CTCL study PI onboard (Tim Kuzel) clinical batch of ST-001 IND application filed
→convertible note	\$1M +gratis NCI Fenretinide	patents issued IND allowed	prepare and activate T-cell trial manufacture study drug optimize value by extending IP runway
→Series A	\$10M +gratis NCI Fenretinide	clinical batch ready T-cell trial activated (Rush )	clinical activity in CTCL and others Staggered start to SCLC trial plan Phase 2 registration trial w/FDA
2 <sup>nd</sup> round	TBD	confirm clinical activity (1b)	Pharma partner/licensing Fenretinide manufacturer

### SciTech Delivery Vehicle (SDV) Pre-Clinical Data

### Preclinical Testing of SDV Platform Evaluating Lipid Soluble Fenretinide Formulated into a Potent Therapeutic

- » Bioavailability in Rats Oral Fenretinide vs. Intravenous ST-001
- » Antitumor Activity of ST-001 in Xenografts of the DLCL2 Human B-cell Lymphoma in a Mouse Model
- » ST-001 Activity Against T- and B- cell Lines In Vitro

#### **SDV PLATFORM TECHNOLOGY**

New drug products [ST-00X] are possible for IV and topical administration by changing the phospholipids to accommodate different drug properties leading to robust structural integrity enabling high dose delivery

### Varying Phospholipids To Fit Other APIs



**ST-001** = Fenretinide Bilayer Matrix

**ST-00X = API Bilayer Matrix** 

### **ST-001 Pre-Clinical Studies**

# Compelling animal data validated the clinical potential of ST-001 Clinical data from dozens of human trials reinforced therapeutic potential Accordingly, FDA has accepted SciTech's IND and clinical trial protocol\*

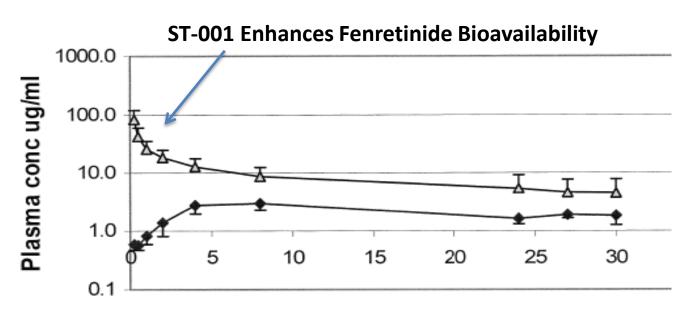
- Increased Fenretinide bioavailability demonstrated in animal model (rat)
- > Fenretinide plasma concentrations maintained for at least 25 hours
- Inhibited tumor growth demonstrated with in vivo animal grafts (mouse) (human DLCL2 cell line xenograft)
- > Demonstrated in vitro cytotoxicity in non-Hodgkin's lymphoma (NHL) human cell types

### ST-001 *In Vitro* Activity JURKAT cells are an immortalized line of human T-cells derived from acute lymphoblastic leukemia (ALL)

#### 150-140 **JURKAT T-Cell ALL** 130 Percent (%) of Viable Cells 120 110 100· 80-70 60-50 ST-001-10uM 40-20-96

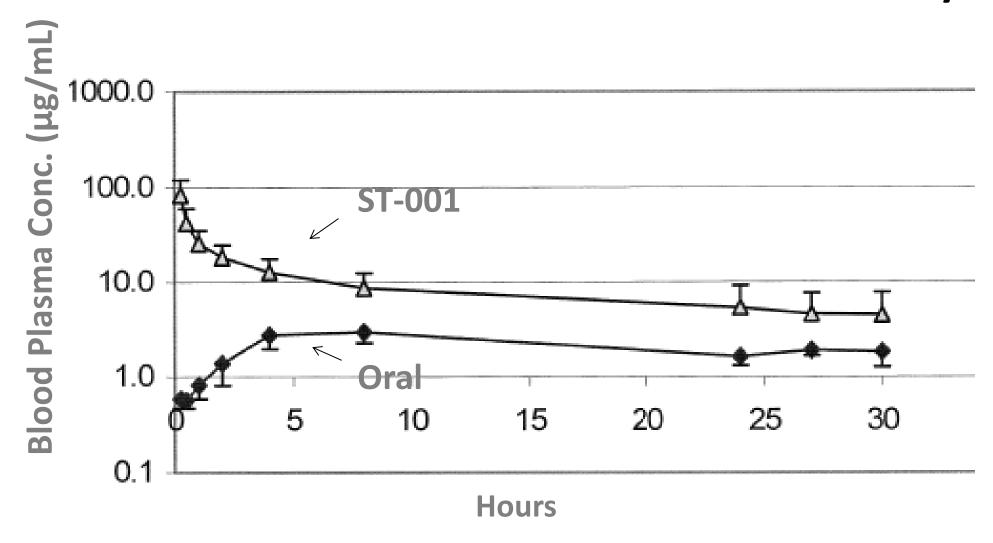
Time (Hours)

### ST-001 *In Vivo* Activity Rat Model Studies Oral Fenretinide vs. ST--001



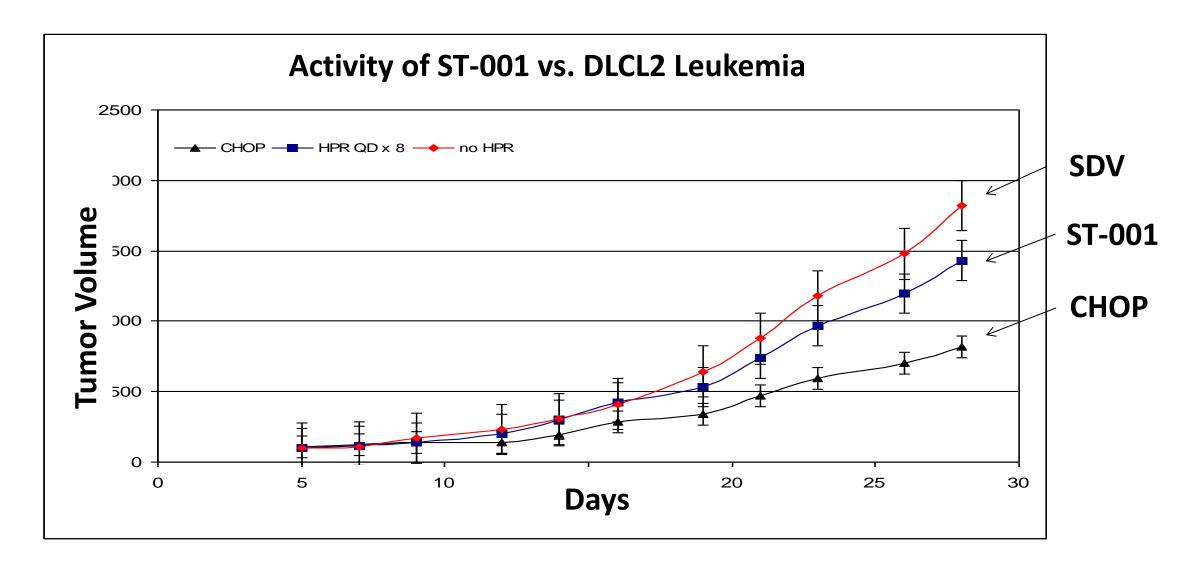
### Bioavailability in Rats Oral Fenretinide vs. Intravenous ST-001

### **ST-001 Enhances Fenretinide Bioavailability**



Filled diamonds represent fenretinide as a corn oil suspension administered orally at 200mg/kg body weight (n=7). Open triangles represent ST-001 administered i.v. at 74mg of fenretinide/kg (n=6).

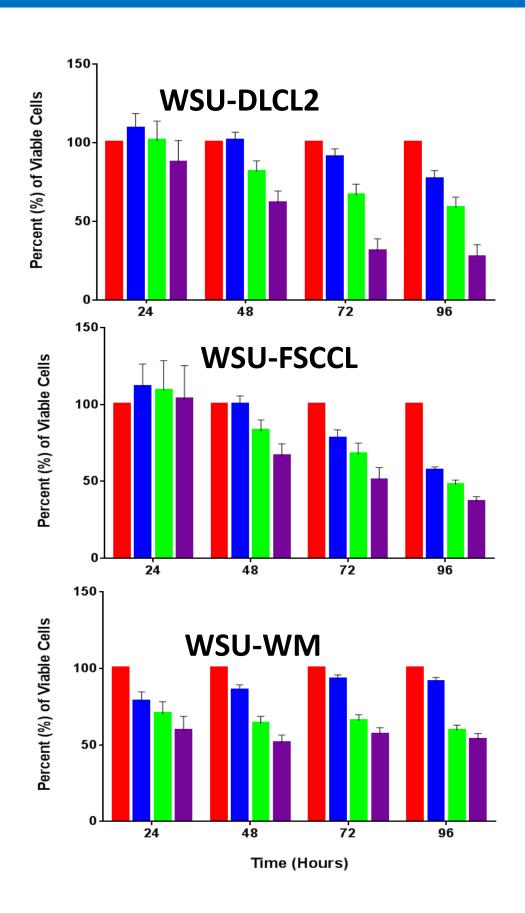
### Antitumor Activity of ST-001 in Xenografts of the DLCL2 Human B-cell Lymphoma in a Mouse Model

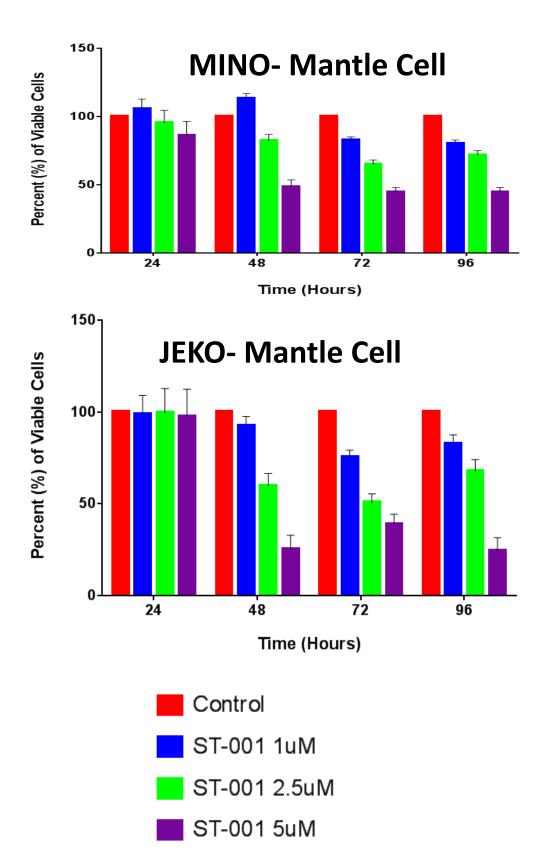


ST-001 is effective in slowing the growth of the DLCL2 human non-Hodgkin's lymphoma compared to SDV (no fenretinide).

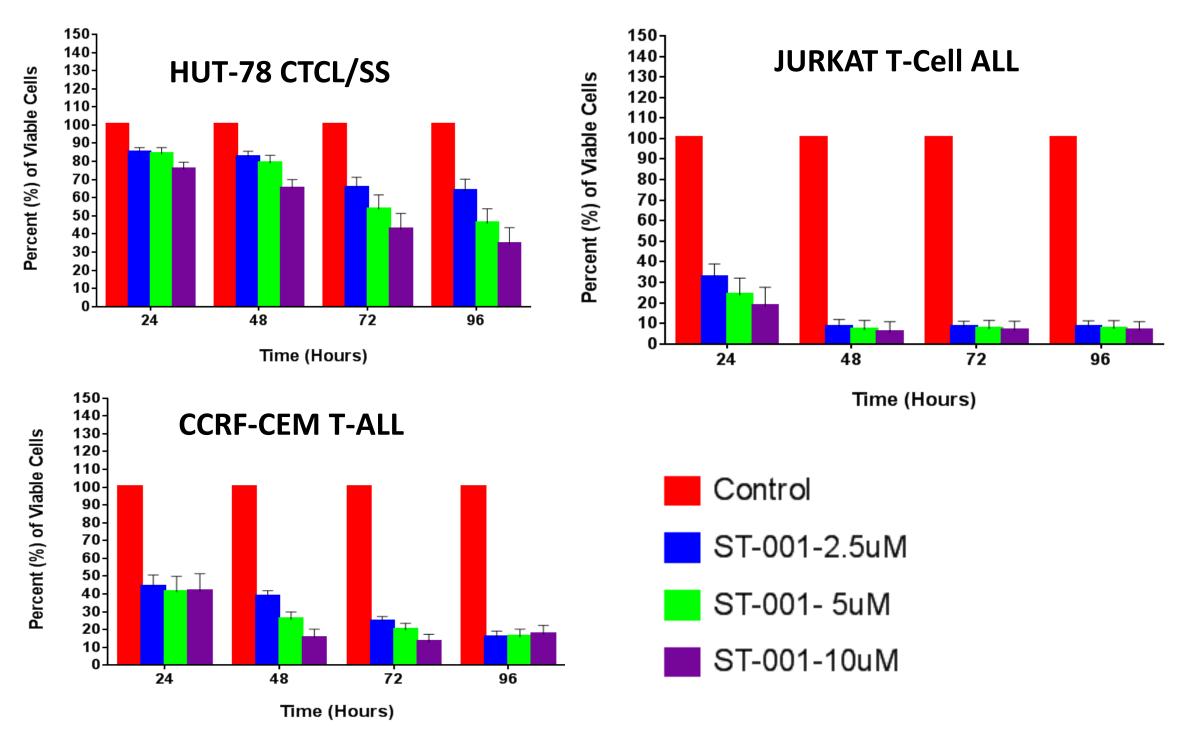
The standard first line clinical therapy for this lymphoma is the combination of cyclophosphamide, doxorubicin (hydroxydaunomycin), vincristine (Oncovin®), and prednisone (CHOP) which strongly inhibits the growth of the DLCL2 tumor under the conditions of this mouse model experiment.

### ST-001 In Vitro Activity Against B-Lymphoma Cell Lines





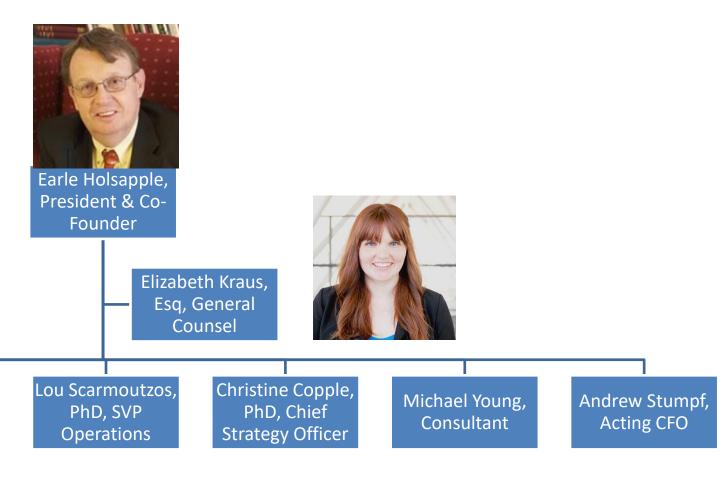
### **ST-001** In Vitro Activity Against T-Cell Lines



HUT-78, CCRF-CEM & JURKAT are names of cell lines; ALL: Acute Lymphoblastic leukemia CTCL/SS: Cutaneous T-cell lymphoma/Sézary Syndrome



### **Organization Chart**





Ralph Parchment,

PhD, CSO & Co-

Founder



Ayad Al-Katib,

MD, Chief

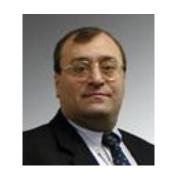
**Medical Officer** 



Mike Burns, PhD,

**SVP Product** 

Development









- Future hires include CFO, consultants (CRO, regulatory, drug logistics) & scientific staff
- > Management anticipates changes to the organization upon milestone and exit events