

# **CEL-SCI Corporation**

NYSE American: CVM

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## Forward Looking Statements

This presentation includes forward-looking statements regarding CEL-SCI's proprietary drug candidates, the timing of the start and conclusion of ongoing or planned clinical trials, the timing and outcome of regulatory decisions, and future availability of clinical trial data. Actual results could differ materially and these statements are subject to important risks detailed in CE-SCI's filings with the SEC including the Form 10-Q filed on February 9, 2018. CEL-SCI undertakes no obligation to update forward-looking statements as a result of new information or otherwise.

Multikine is the trademark that CEL-SCI has registered for this investigational therapy, and this proprietary name is subject to FDA review in connection with our future anticipated regulatory submission for approval. Multikine has not been licensed or approved for sale, barter or exchange by the FDA or any other regulatory agency. Similarly, its safety or efficacy has not been established for any use. Moreover, no definitive conclusions can be drawn from the early-phase, clinical-trials data summarized in this presentation involving the investigational therapy Multikine (Leukocyte Interleukin, Injection). Further research is required, and early-phase clinical trial results must be confirmed in the well-controlled Phase 3 clinical trial of this investigational therapy that is currently in progress. Each page of this presentation must be looked at in the context of the whole presentation, not by itself, and is merely meant to be a summary of the full and detailed information on the Company in its public filings and its website. Potential conclusions could only be drawn if the initial observations in the early-phase studies relating to the potential adverse events associated with Multikine administration in treating head and neck cancer are confirmed in the well controlled Multikine Phase 3 clinical study, CEL-SCI's Phase 3 study is completed successfully, and the FDA licenses the product following their review of all of the data related to Multikine submitted in CEL-SCI's license application.

## Equity Summary

**CEL-SCI Corporation:** NYSE American: CVM

**Clinical Trial Stage:** Phase 3 cancer immunotherapy and early stage Rheumatoid Arthritis vaccine

**Market Capitalization:** About \$38 million

**Trading Volume:** About 250,000 shares per day

**Shares Outstanding:** 16.6 million

**Share Price:** About \$2.25

Share based information dated May 3, 2018

## Cancer Immunotherapy - The Future?

Cancer immunotherapy is now the 4<sup>th</sup> modality of cancer treatment. Up to now all cancer immunotherapies have been developed for recurrent cancer patients, after they have undergone surgery, radiation and/or chemo-therapy. Their immune system is no longer intact.

We are the first company in the world to use a cancer immunotherapy before surgery, radiation and chemo-therapy because boosting the healthy immune system should have the greatest impact on survival.

## Boosting Immune System Before Ravages of Radiation/Chemotherapy

- Multikine, our Phase 3 investigational immunotherapy, is a patented heterologous (mass produced) mixture of human cytokines produced at the company's manufacturing facility near Baltimore, MD
- Multikine is being tested in a Phase 3 clinical trial for the first treatment in advanced primary (newly diagnosed) head and neck cancer patients, before they receive the conventional standard of care (SOC) therapy (surgery, radiation and chemotherapy)
- Multikine is designed to help the immune system "see" the tumor at a time when the immune system is still relatively intact and thereby better able to mount an attack on the tumor

## Phase 3 Cancer Immunotherapy Study

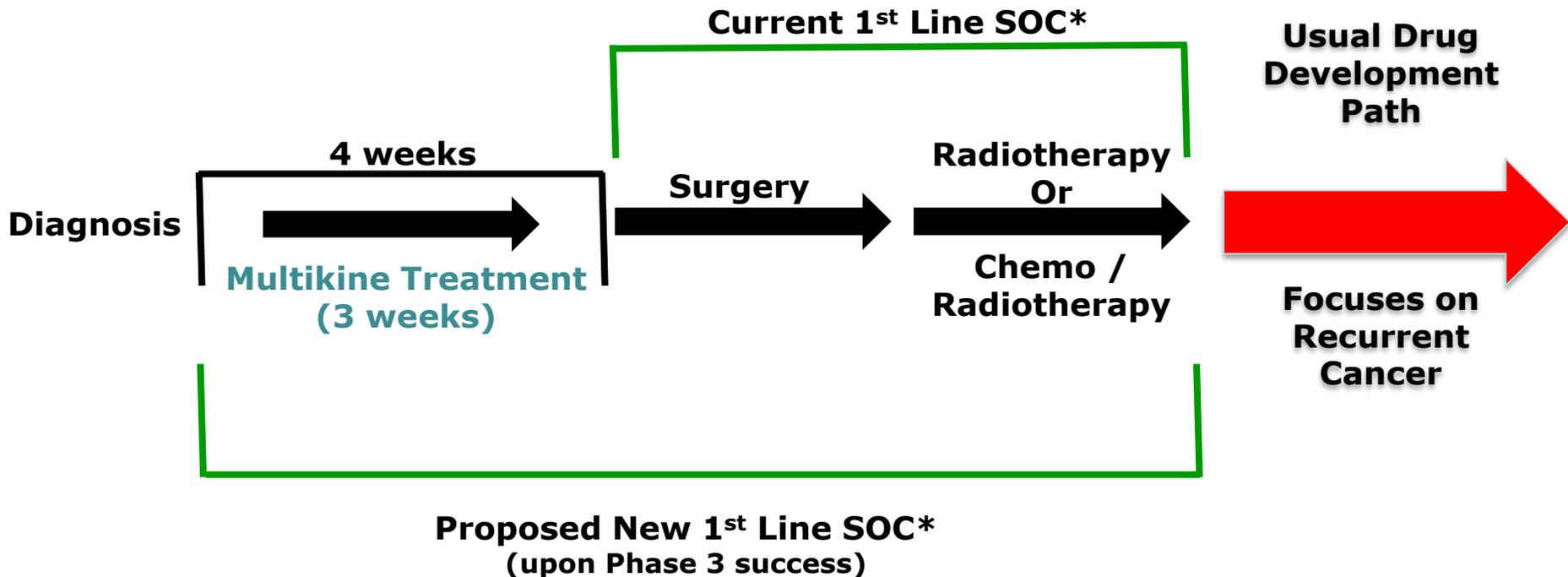
- 928 patients are enrolled in world's largest Phase 3 trial in head and neck cancer (about 600,000 cases p.a. worldwide, 6% of all cancers)
- The study is fully enrolled. Last patient was enrolled in September 2016
- We are now following the patients for overall survival and other protocol specified endpoints. We need 298 events among the 2 main comparison groups to prove the primary endpoint of this pivotal study:

A 10% improvement in overall survival in patients treated with Multikine plus Standard of Care (SOC) vs. patients treated with SOC alone

- Advanced primary head and neck cancer represents an unmet medical need. It has been 60+ years since FDA approved a drug for the treatment of this disease
- FDA granted Multikine Orphan Drug designation in this indication
- Marketing approval would give CEL-SCI's Multikine a chance to become part of a new worldwide Standard of Care

## Timing of Multikine Treatment Regimen

### Advanced Primary Head and Neck Cancer



\* Standard of Care

## Are Checkpoint Inhibitors Opdivo (BMS) and Keytruda (Merck) competitors?

They are not competitors because:

- Checkpoint inhibitors have been developed for recurrent head and neck cancer, *after* the initial treatments have failed. Multikine is being developed for advanced primary head and neck cancer, *before* the initial treatments. These are very different patient populations even though they are both in head and neck cancer patients.
- Multikine works via natural killer (NK) cells. Checkpoint inhibitors work via CD-8 killer cells. In theory they could work well together.

## Multikine is A Novel Approach to Immunotherapy

- Multikine is a patented defined mixture of 14 human cytokines
  - Pro-inflammatory cytokine mixture includes interleukins, interferons, chemokines and colony-stimulating factors
  - Manufacturing process is validated in our dedicated GMP manufacturing facility
- Contains elements of the body's natural mix of defenses against cancer
- Research at the US National Institute of Health has shown that the cytokines in Multikine (shown in **red** in the table) are the ones that are required to reject any tumor
- Injected for 3 weeks before any other cancer therapy around the tumor and near adjacent lymph nodes to stimulate the immune system to recognize the cancer cells and micro-metastases
  - Once the immune system is able to "see" the cancer, the still intact immune system does what it is meant to do – destroy the cancer

### Major Cytokine(s) and other Cellular Products in Multikine

**IL-1 α**

**IL-1β**

**IL-2**

**IL-3**

**TNF-α**

**IFN-γ**

**GM-CSF**

**IL-6**

**IL-8**

**TNF-β**

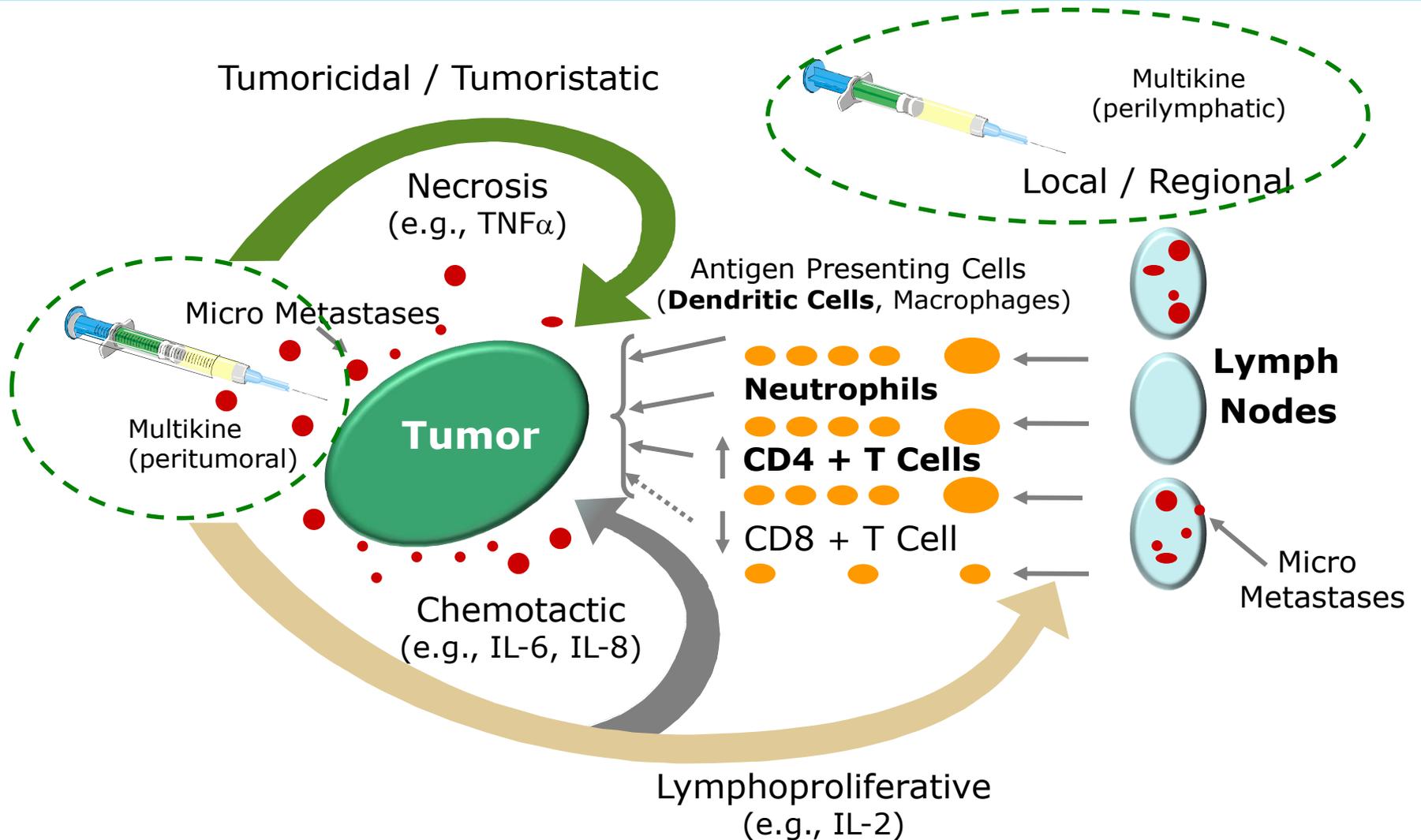
**G-CSF**

**RANTES**

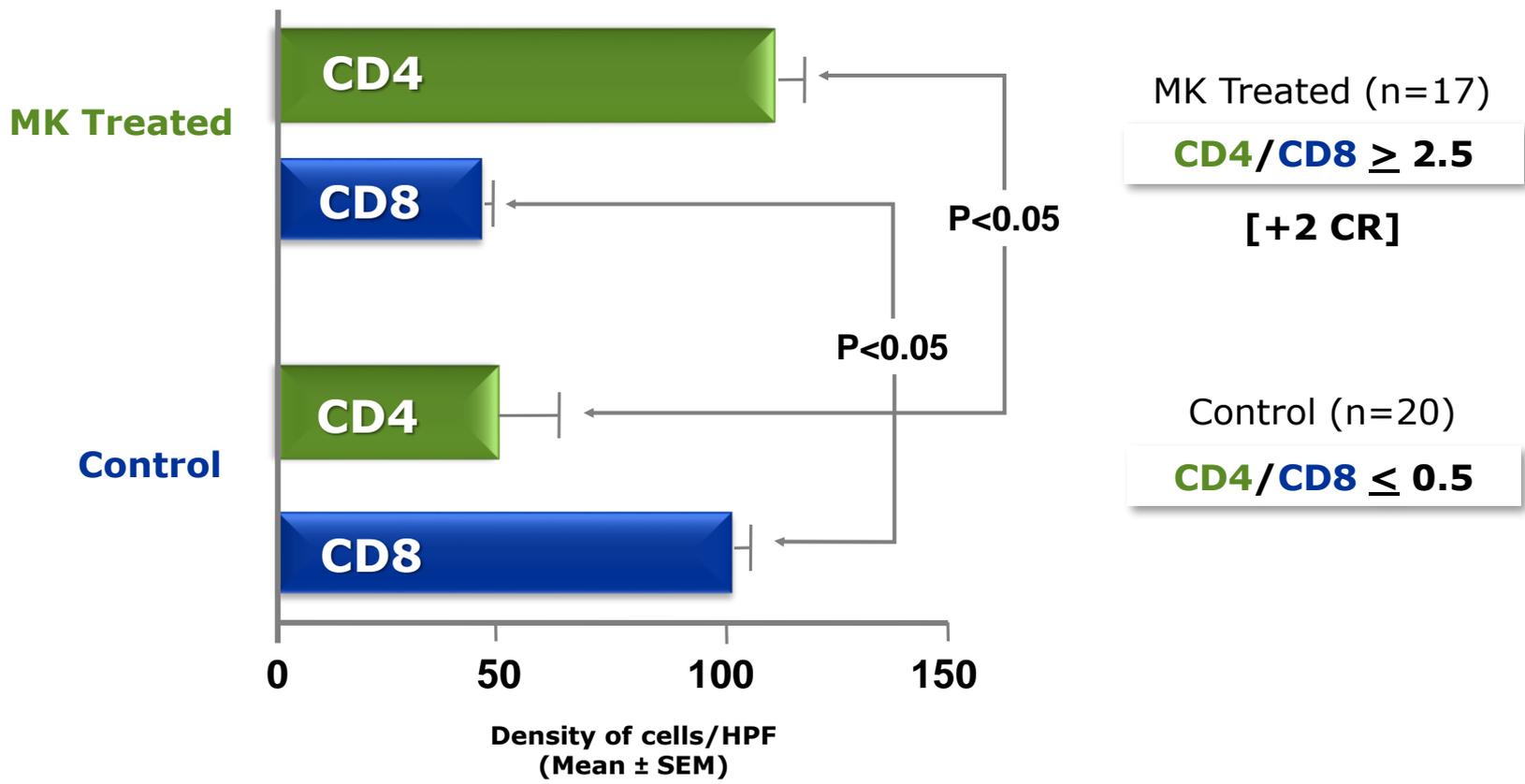
**MIP-1α**

**MIP-1β**

**Mechanism of Action Stimulates an Immune Response at the Injection Site**



**A Paradigm Shift in Tumor Microenvironment – Final Phase II Study**

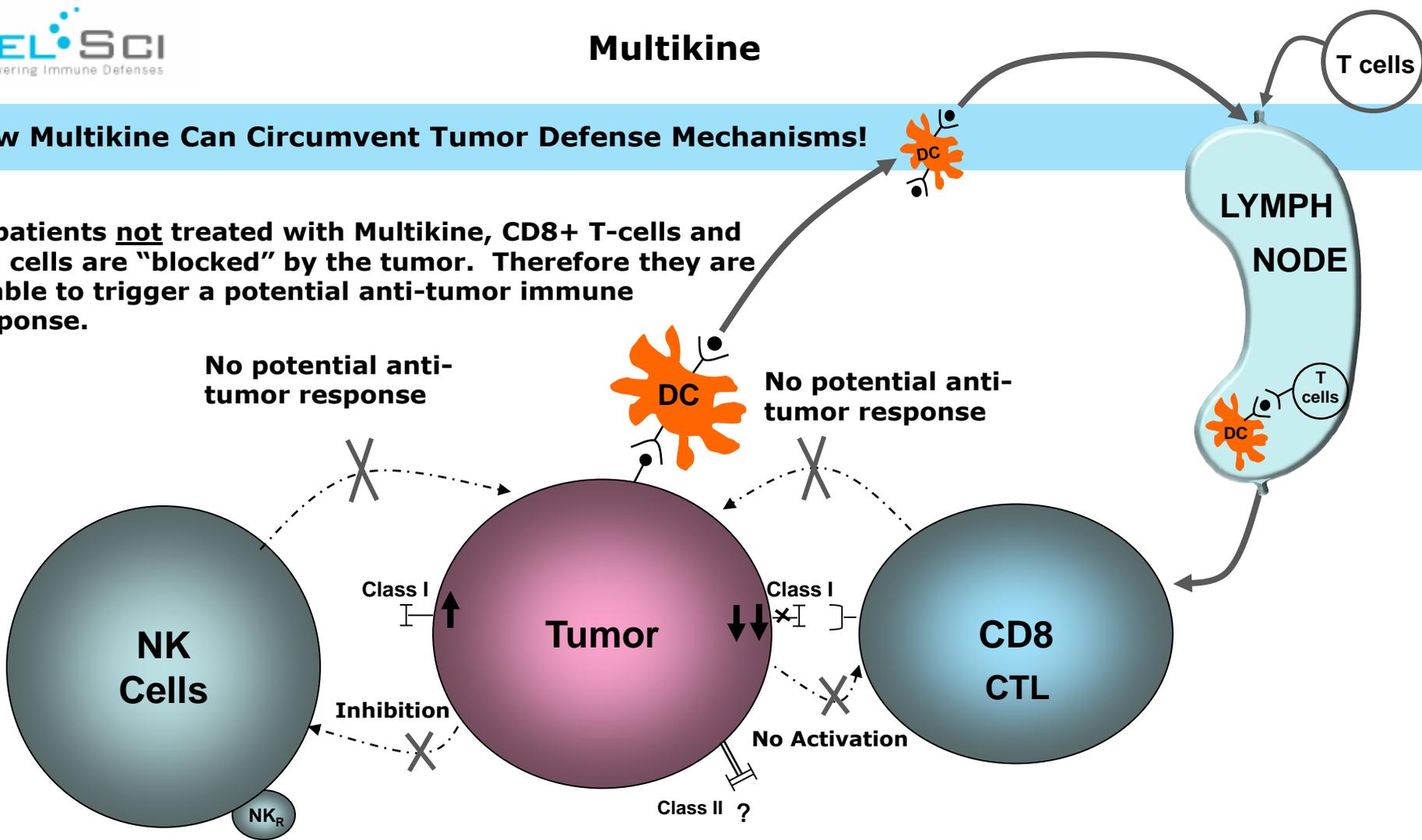


\* Talor et al., ASCO Annual Meeting Proceedings 22(14S): 189S, 2004  
Timar et al., Journal of Clinical Oncology 23(15) May 20, 2005

# Multikine

## How Multikine Can Circumvent Tumor Defense Mechanisms!

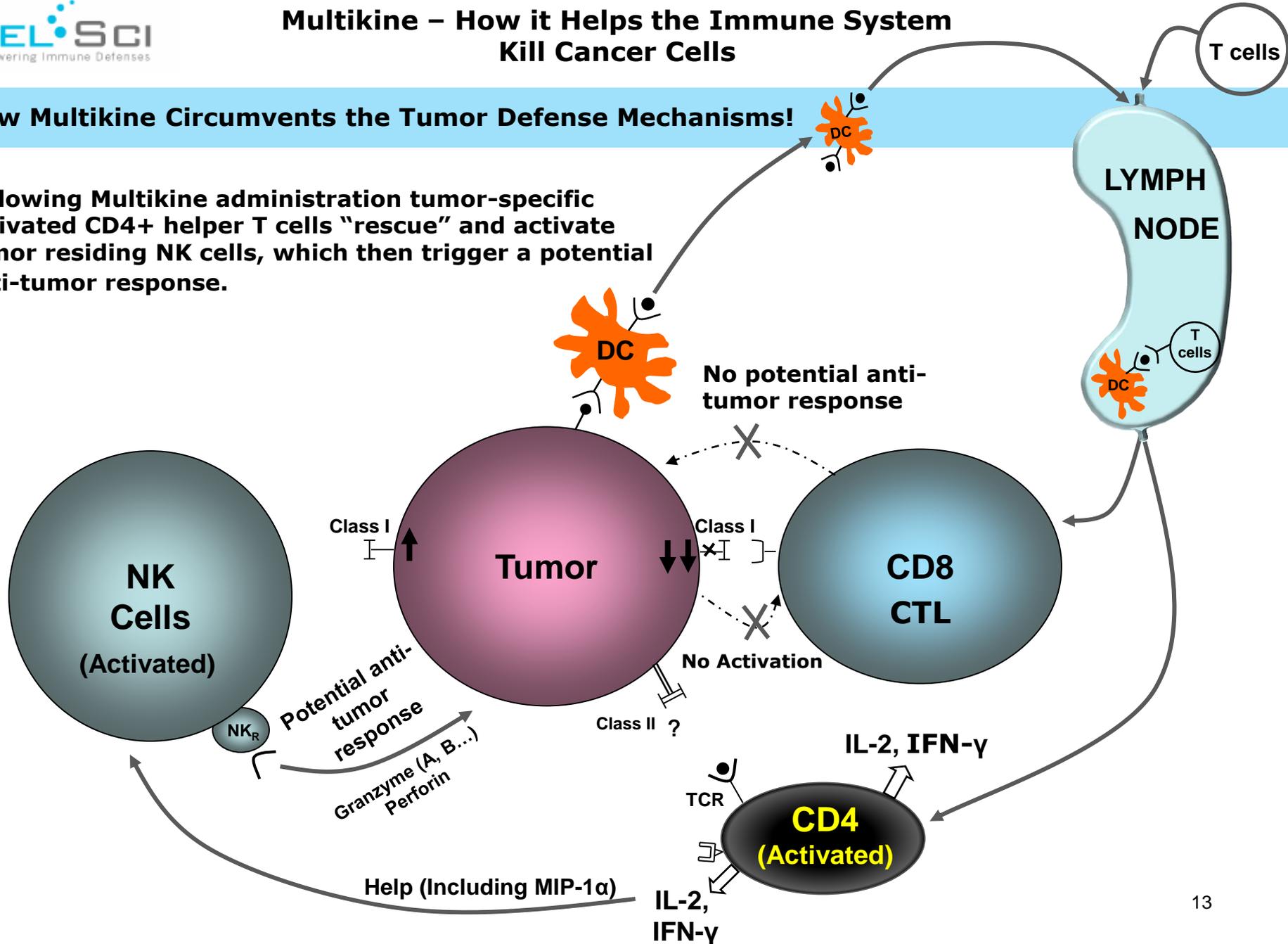
In patients not treated with Multikine, CD8+ T-cells and NK cells are "blocked" by the tumor. Therefore they are unable to trigger a potential anti-tumor immune response.



# Multikine – How it Helps the Immune System Kill Cancer Cells

## How Multikine Circumvents the Tumor Defense Mechanisms!

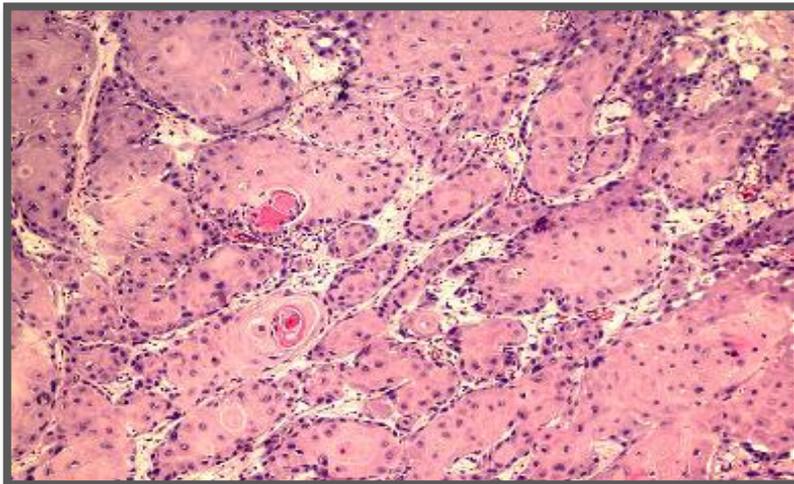
Following Multikine administration tumor-specific activated CD4+ helper T cells “rescue” and activate tumor residing NK cells, which then trigger a potential anti-tumor response.



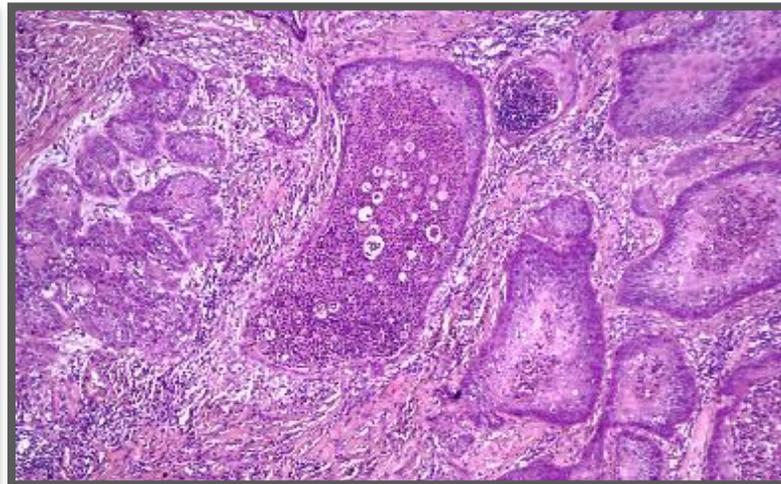
## Pathology: Multikine Treated – vs. – Non-Treated (Final Phase II)

### Oral Squamous Cell Carcinoma (Locally Advanced Primary H&N Cancer)

**Histological appearance of necrosis in Oral Squamous Cell Carcinoma (OSCC) [HE staining]:**



**Non-Multikine treated**



**Multikine treated**

**Non-Multikine treated:** Lack of necrosis in the epithelial nests of OSCC

**Multikine treated:** Entire cancer nest is necrotic and filled with debris and leukocytes

## Results: Final Phase 2 Study

A total of 224 patients were treated before the Phase 3 study. The final “Proof of Concept” Phase 2 study (21 treated patients and 20 controls for pathology evaluation), following multiple Phase 2 studies that tested different treatment regimens, selected the best treatment for patients. The treatment regimen in this final Phase 2 study is the same as used in the Phase 3 study.

Only 3 weeks of treatment with the Multikine regimen, then surgery. This study design is different from a recurrent cancer Phase 2 study because surgery must be performed right after the 3 week Multikine treatment. Our patients are newly diagnosed & not yet treated:

- Of the evaluable patients - 10.5% of patients had no remaining cancer cells by pathology following 3 weeks of Multikine regimen *Timar et al: Journal of Clinical Oncology 23 (15) May 20, 2005 and Talor et al, Oral Oncology Supplement (2) No. 1, May 2007*
- 50% average reduction in the number of cancer cells (by pathology) following 3 weeks of Multikine regimen *Timar et al: Journal of Clinical Oncology 23 (15) May 20, 2005*
- 42.1% Overall Response Rate (RECIST) *Timar et al: Journal of Clinical Oncology 23 (15) May 20, 2005*  
Other observations:
  - Reduction in pain. Patients are able to open their mouths more easily. Patients with tongue cancer can move their tongues again within a few days (as reported by clinical study investigators)
  - Many patients gained weight (as reported by clinical study investigators)

## 33% Increase in Overall Survival in Phase 2 Study

- Approximately three years after the same “Proof of Concept” Phase 2 study we obtained the patients’ and their families’ consents for a survival follow-up
- Survival results in this Final “Proof of Concept” Phase 2 study were compared to results from 55 clinical trials in the same patient population (Advanced Primary SCCHN) treated with SOC only

Follow-up Endpoint	Standard of Care (SOC)* +/- All other Treatment Modalities	Multikine** + Standard of Care	% Improvement over SOC***
Overall Survival (at 3.3 years from treatment)	47.5%	63.2%	33.1%

Following discussions with FDA, primary end point of Phase 3 study is 10% improvement in Overall Survival over Standard of Care control group (event-driven).

\* survey of 55 clinical trials; advanced primary H&N cancer (published 1987 - 2007)

\*\* Multikine Treatment: Phase 2 Clinical Trial (Timar et al, JCO, 23(15): May 2005)

\*\*\* Talor et al, Oral Oncology Supplement (2) No. 1, May 2007 Literature survey of 55 clinical trials; advanced primary H&N cancer (published 1987 - 2007)

## When will the Phase 3 Study end?

- Study is fully enrolled and all patients have completed treatment
- A December 2017 Independent Data Monitoring Committee (IDMC) review of the data found no significant safety issues
- We need 298 events in the two main groups to determine the study outcome
- The last patient was enrolled in the study in September 2016. Approximately 135 patients were enrolled in the study from 2011 to 2013, about 195 were enrolled in 2014, about 340 in 2015, and about 260 in 2016.
- The study protocol assumed an overall survival rate of about 55% at 3 years for the SOC treatment group alone.

## Why did I invest in CEL-SCI this past summer?

- My family trust and I purchased \$500,000 worth of CEL-SCI stock in the summer of 2017. Why?
- We are near the end of this long Phase 3 study in advanced primary head and neck cancer.
- We are also almost at the end of a four year arbitration against a former CRO in which we are seeking damages in excess of \$50 million.

## A Separate Technology: LEAPS

CEL-SCI's LEAPS technology is a platform technology for therapeutic vaccines

- A new class of drug with a novel approach, acting earlier in the pathway of the specific disease
- Efficacy demonstrated in six human diseases by animal challenge models, two infectious (Herpes Simplex Virus and influenza A), three autoimmune (myocarditis and two different arthritis [representing Th1 and Th17 conditions]) and oncology (breast cancer)
- Research has been funded via collaborations with the U.S. Army, Navy, Universities and National Institutes of Health grants (e.g., SBIR)
- Primary focus: development of a therapeutic vaccine for Rheumatoid Arthritis (RA)
- Sept 2017: CEL-SCI was awarded a \$1.5 million SBIR grant from NIH to fund GMP manufacturing, IND enabling studies, and additional mechanism of action studies to advance its first LEAPS product candidate for RA towards an IND application

## In Closing: 3 Major Value Drivers

- Phase 3 Results could lead to Worldwide Approval in Head and Neck Cancer
  - Head and neck cancer accounts for 650,000 new cases p.a.
  - World's largest head and neck cancer Phase 3 study fully enrolled with 928 patients
  - Now following the patients until 298 deaths ("events") in the two main groups have occurred
  - 10% improvement in overall survival in the Multikine group over SOC (alone) is the primary endpoint
- Almost at the end of over \$50 million-plus arbitration filed against former CRO
  - Suing for (i) breach of contract, (ii) fraud in the inducement, and (iii) common law fraud
  - Suit being funded by litigation funding firm that has an excellent track record that allowed it to raise \$125 million at the end of 2017
  - Closing statements occurred on April 24 and 25, 2018; we are waiting for the arbitrator's decision
- Rheumatoid Arthritis Vaccine under development, funded by \$1.5 million in U.S. government grant from the NIH