

# **CEL-SCI Corporation**

NYSE MKT: CVM

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Statements made during the course of this presentation that state the Company's or management's intentions, hopes, beliefs, expectations or predictions of the future are forward-looking statements. It is important to note that the Company's actual results could differ materially from those projected in such forward-looking statements. This presentation only highlights some of the progress CEL-SCI has made to date. It is not meant to be a complete document as it forms only the visual basis of the company's presentation.

Additional information in general and concerning factors that could cause actual results to differ materially from those in the forward-looking statements is contained from time to time in the Company's SEC filings, including but not limited to the Company's report on Form 10-K for the year ended September 30, 2014. Copies of this presentation may be obtained by contacting the Company.

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 III 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 III clinical study, CEL-SCI's Phase III 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 Profile

- Name of Company: CEL-SCI Corporation
- Location: Washington, D.C. (USA) metro area
- Stock symbol: NYSE MKT: CVM
- Shares outstanding: 91 million
- Cash September 30, 2014: \$9 million,  
plus \$7 m raised in Oct. 2014
- Current valuation: About \$65 million
- Current daily trading volume: 400,000 shares daily
- 52 week range: \$0.54 - \$1.90
- No. of employees: 47
- Funds raised to date: \$250 million

Note: Of these \$250 million, approximately \$80 million were invested in the full validation of the Multikine manufacturing process. Plus, \$25 million were invested in the Multikine manufacturing plant near Baltimore, MD, USA.

**Empowering Immune Defenses for Cancer and HPV**

CANDIDATE	PRECLINICAL	PHASE I	PHASE II	PHASE III	Marketing approval
<b>MULTIKINE</b>					
Squamous cell carcinoma of the head and neck (first-line)	[Progress bar spanning Preclinical, Phase I, and Phase II]				
<u>HPV</u> : initially HIV/HPV co-infected in collaboration with U.S. Navy in anal warts	[Progress bar spanning Preclinical and Phase I]				
<u>HPV</u> : Cervical dysplasia in HIV/HPV co-infected (in planning stage)	[Progress bar spanning Preclinical and Phase I]				
<b>L.E.A.P.S. Technology</b>					
Pandemic Flu treatment (NIAID)	[Progress bar spanning Preclinical and Phase I]				
Rheumatoid Arthritis CEL-2000 (Grant)	[Progress bar spanning Preclinical and Phase I]				
Breast Cancer	[Progress bar spanning Preclinical and Phase I]				



## **Immunotherapy: Our Unique Vision**

Our drug, called Multikine, is a cancer immunotherapy with potential application to many diseases.

- Multikine is in a global pivotal Phase III trial against head and neck cancer and
- a Phase I study against anal warts caused by Human Papillomavirus (HPV) in HIV-infected patients in collaboration with the U.S Navy.

A very unique approach:

We give Multikine before the immune system is severely weakened by radiation, chemotherapy and surgery. Other immune therapies are usually given after the initial cancer treatment has failed.

We believe that the stimulation of the immune response prior to radiation and chemotherapy may have a better chance of success since the immune system should still be in better shape.

## What is Multikine?

### **Composition:**

- Multikine is a patented defined mixture of human cytokines. The manufacturing process is fully validated and we have a dedicated manufacturing facility to manufacture Multikine.
- Contains the body's natural mix of defenses against cancer.
- Injected around the tumor to help the immune system recognize the cancer. Once the immune system is able to "see" the cancer, it flags the problem and does what it is trained to do – destroy the cancer.
- What evidence, in addition to the company's studies published in top peer reviewed journals, points to the usefulness of a cytokine mixture in the treatment of cancer?

Research at the US National Cancer Institute has shown that the cytokines in Multikine are the ones that are required to reject any tumor.

## CEL-SCI Partners

- U.S. National Cancer Institute (NCI), USA.
- U.S. National Institute of Allergy and Infectious Diseases (NIAID, part of the U.S. NIH).
- U.S. Navy.
- Teva Pharmaceuticals, Israel (NYSE:TEVA).
- Orient Europharma, Taiwan.
- Ergomed, UK.
- Top medical research institutes, universities and hospitals around the world.

**National Cancer Institute**  
at the National Institutes of Health





## Clinical Background

### Multikine:

- Over 400 people have been treated with Multikine.
- Currently in a Pivotal Global Phase III – 81 Clinical Sites on 3 continents
- Clinical activity from Multikine in humans was shown in
  - 1) several tumors types,
  - 2) as an immune modulator to strengthen the immune system of HIV-infected patients and
  - 3) as an immune agent against the Human Papillomavirus (HPV).
- 11 human clinical studies have been completed.
- Close to 100 publications/presentations have been published on our work.
- Proprietary full scale validated manufacturing plant near Baltimore, Maryland (\$25 m). This is critical because biologics such as Multikine are controlled through manufacturing.

## Making the First Cancer Treatment More Successful

- Multikine is given before surgery, radiation and chemotherapy since that should be the best time to stimulate an immune response.
- Multikine is given for only a very short time, 3 weeks, since it must be given before the current Standard of Care.
- The primary goal of this short treatment is help the immune system see the cancer and kill the micrometastases around the tumor and in the lymph nodes.
- Why? Micrometastases are the key to cancer recurrence. Most people die from the recurrence of cancer.
- In most cases recurrences are local/regional.
- We treat locally to kill the local/regional micrometastases.
- Killing these micrometastases should lead to lower recurrence rates, which in turn should lead to higher survival rates.

## Head and Neck Cancer as a First Indication

- Advanced primary (not yet treated) head and neck cancer represents an unmet medical need. Last approval for advanced primary head and neck cancer in US was methotrexate 60 years ago (1954).
- Received Orphan Drug Designation for head and neck cancer from FDA.
- Head and neck cancer represents about 600,000 new patients per year (a \$6 billion plus market).
- Conducting the largest Phase III trial in the world for the treatment of head and neck cancer.
- 880 patients, to achieve 780 evaluable patients, in about 100 clinics in more than 20 countries. So far about 330 patients are enrolled.
- Aiming for full enrollment by end of 2015.
- Since there is one world-wide standard of care, a win in the Phase III study should translate into Multikine becoming the first treatment of a new worldwide standard of care.

**Anecdotal – early Multikine development**

**Phase I Study  
(USA)  
Recurrent  
Metastatic  
Disease –  
Before  
Multikine  
treatment**



**Day 1**



**Day 21**

**Same  
Subject at  
day 21 of  
MK  
treatment**



**Day 42**

**Same Subject at day 42  
following MK treatment**

**Head & Neck Cancer – Tumour Pictures**



**Before - baseline**



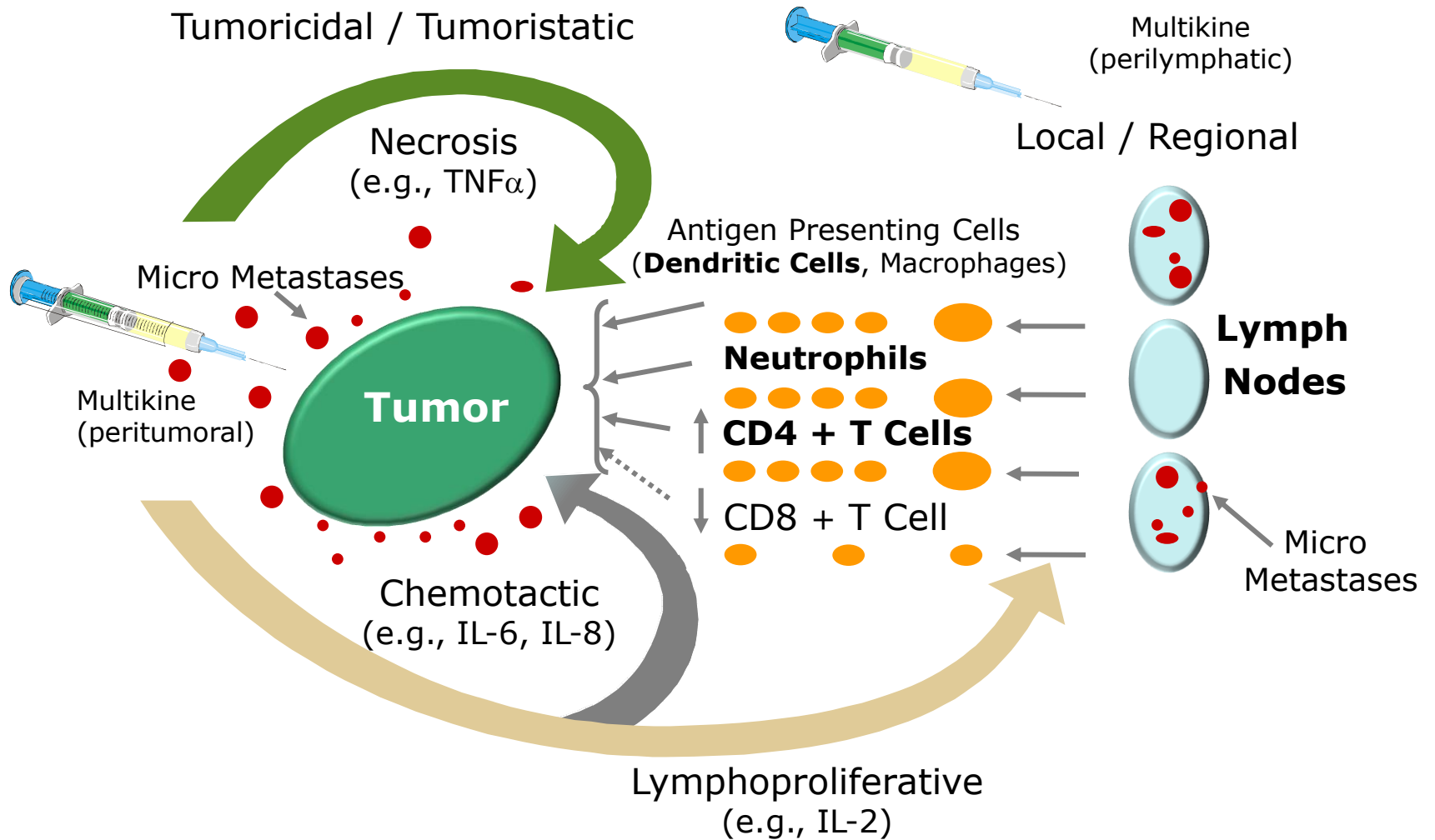
**After 2 weeks of MK Treatment –  
prior to surgery**

**Phase II Study (Israel) SCC (Lateral Tongue) Stage II**

## List of Completed Clinical Studies

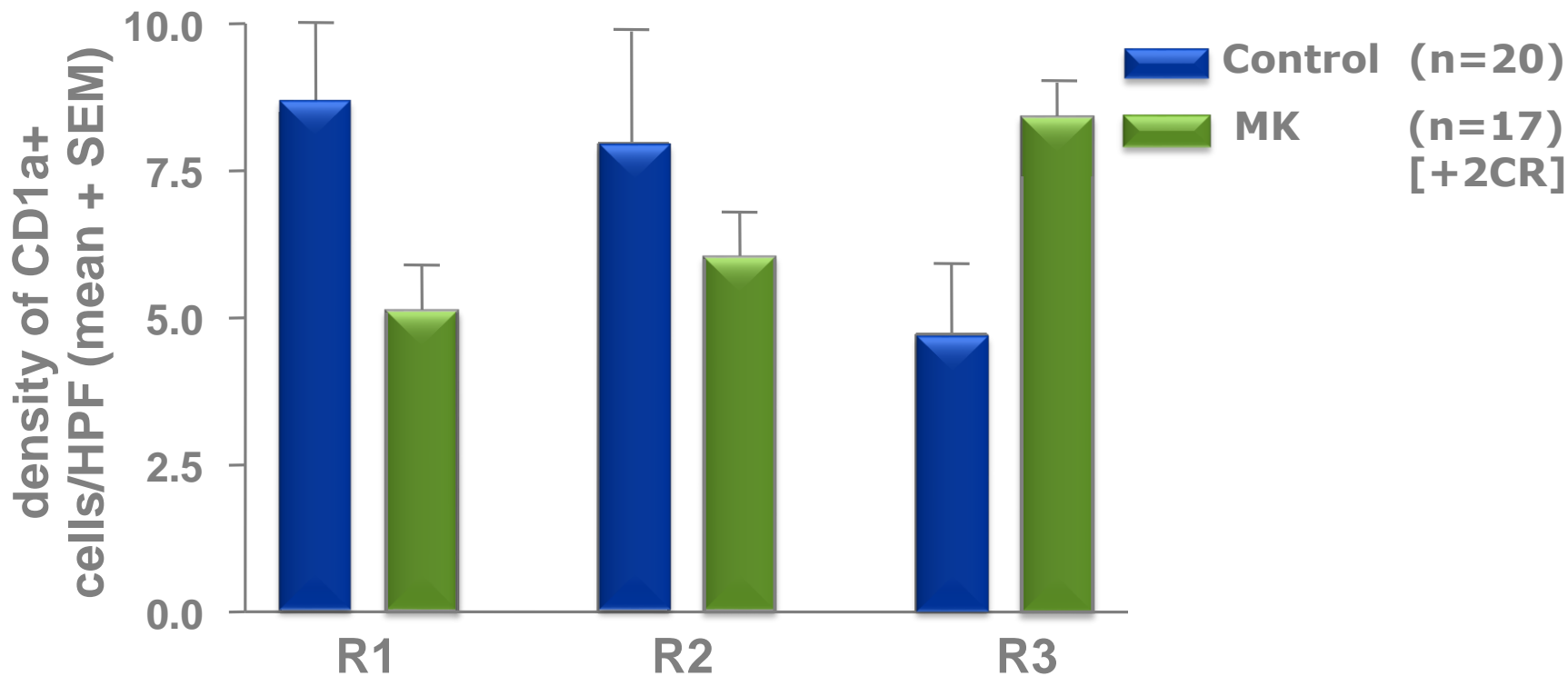
Phase	Indication	No. of subjects	Countries	Published paper
Phase I/II	Head & Neck Cancer Recurrent	16	U.S. & Canada	N/A
Pilot Study	Head & Neck Cancer Recurrent	4	U.S.	Arch Otolaryngol Head and Neck Surgery
Phase I/II	Head & Neck Cancer Pre-surgery	12	Israel	Arch Otolaryngol Head and Neck Surgery
Phase II	Head & Neck Cancer Pre-surgery	28	Canada	N/A
Phase I/II	Head & Neck Cancer Pre-surgery	31	Hungary	Laryngoscope
Phase II	Head & Neck Cancer Pre-surgery	21	Hungary	ASCO Annual Meeting
Phase II	Head & Neck Cancer Pre-surgery	30	Poland & Czech Republic	N/A
Pilot Study	Prostate Cancer Pre-Surgery Treatment	5	U.S.	Seminars in Oncology
Pilot Studies	Different cancer tumors	54	U.K. & others	Lymphokine
Phase I	Cervical Dysplasia in HPV Induced Cervical Cancer	8	U.S.	Annals of the 33 <sup>rd</sup> International Congress of the Society of Gynecological Oncologists
Phase I/II	HIV	15	U.S.	Antiviral Therapy

**Published Mechanism of Action**



Published Pathology Data – Final Phase II study

**Dendritic cells (CD1a) Infiltrate Redistribution\***  
[Locally Advanced Primary H&N Cancer]



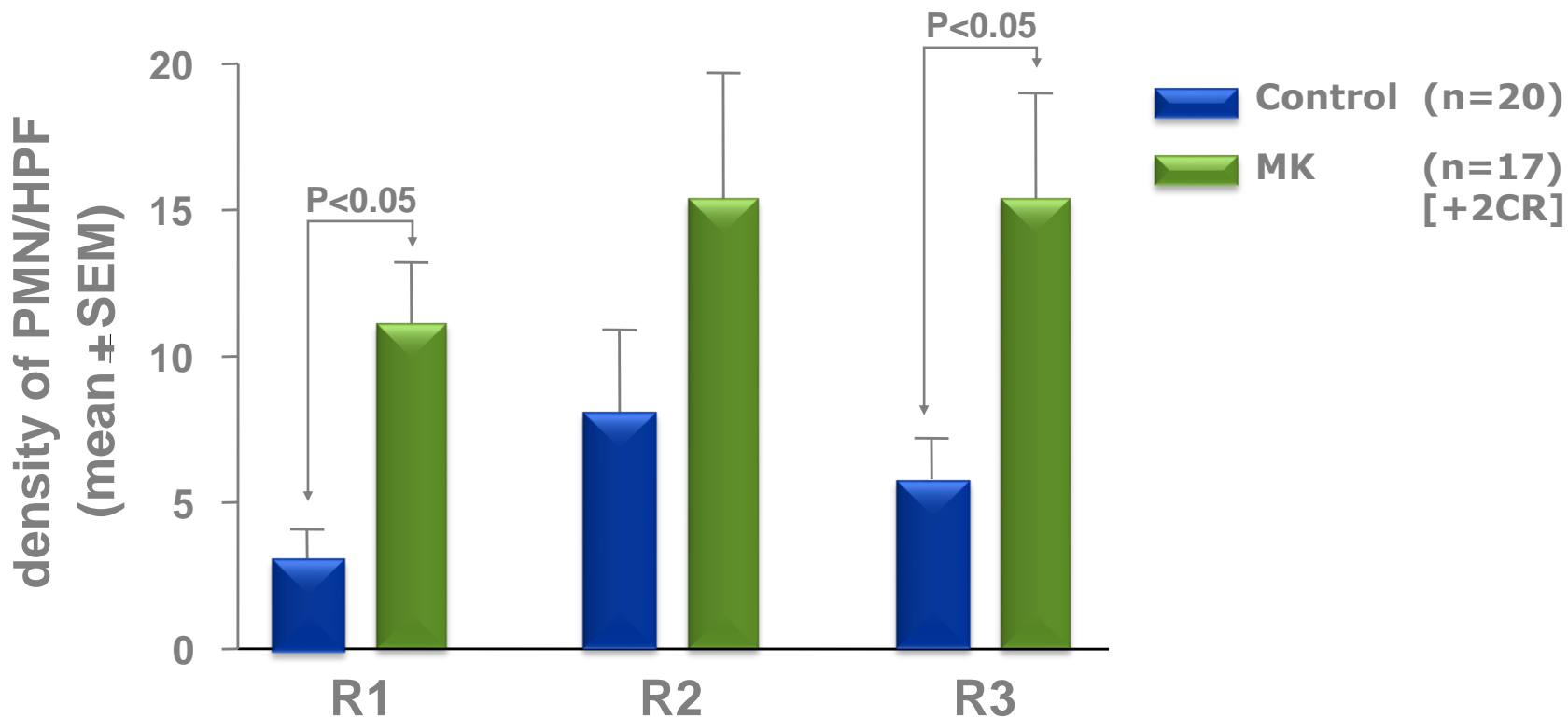
R1 = Tumor Surface R2 = Tumor Center R3 = Tumor Stroma Interface

\* Timar et al: Journal of Clinical Oncology 2005



Published Pathology Data – Final Phase II study

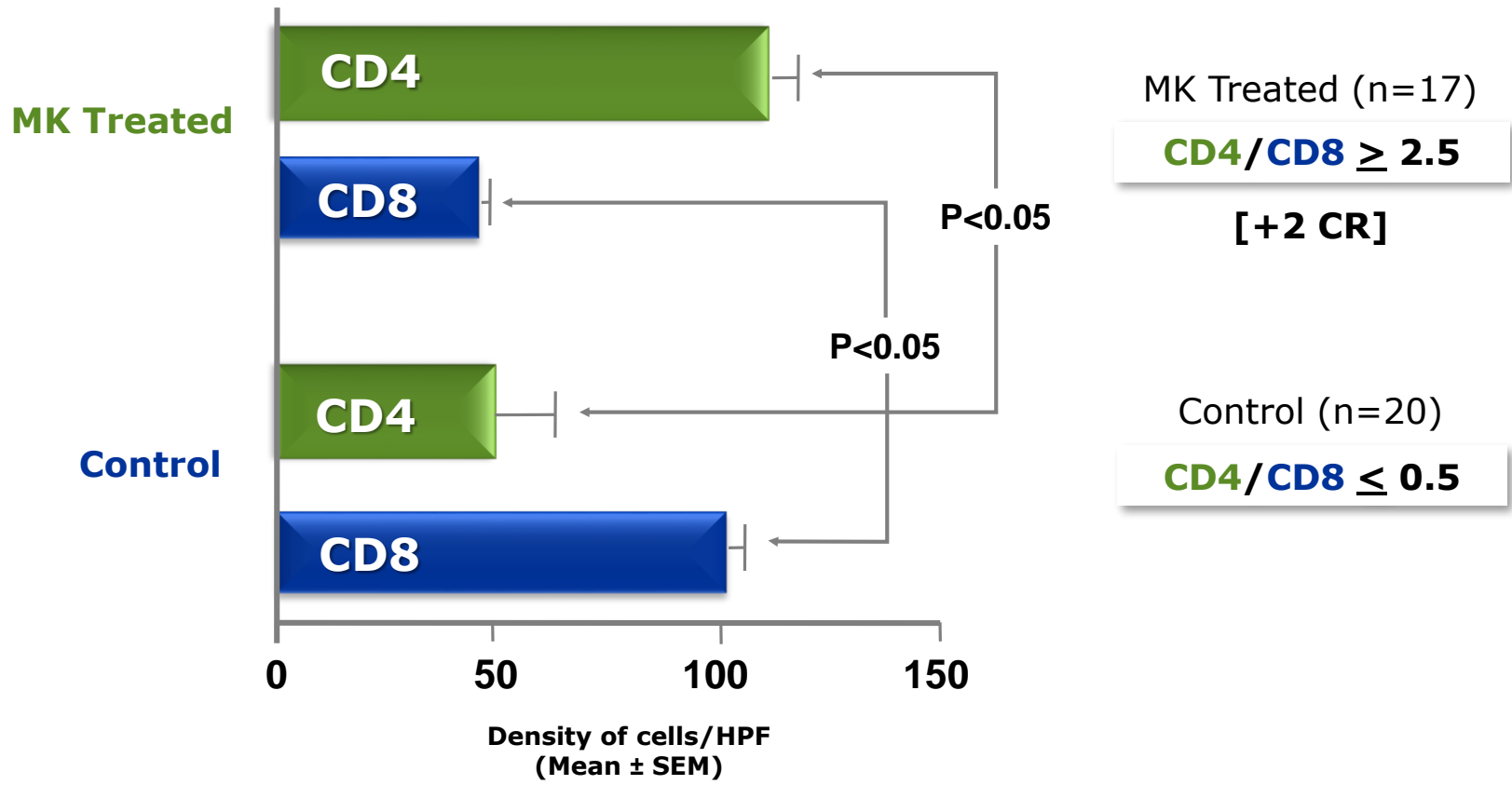
**Increased Neutrophil (MPX) Infiltrate\***  
[Locally Advanced Primary H&N Cancer]



R1 = Tumor Surface R2 = Tumor Center R3 = Tumor Stroma Interface

\* Timar et al: Journal of Clinical Oncology 2005

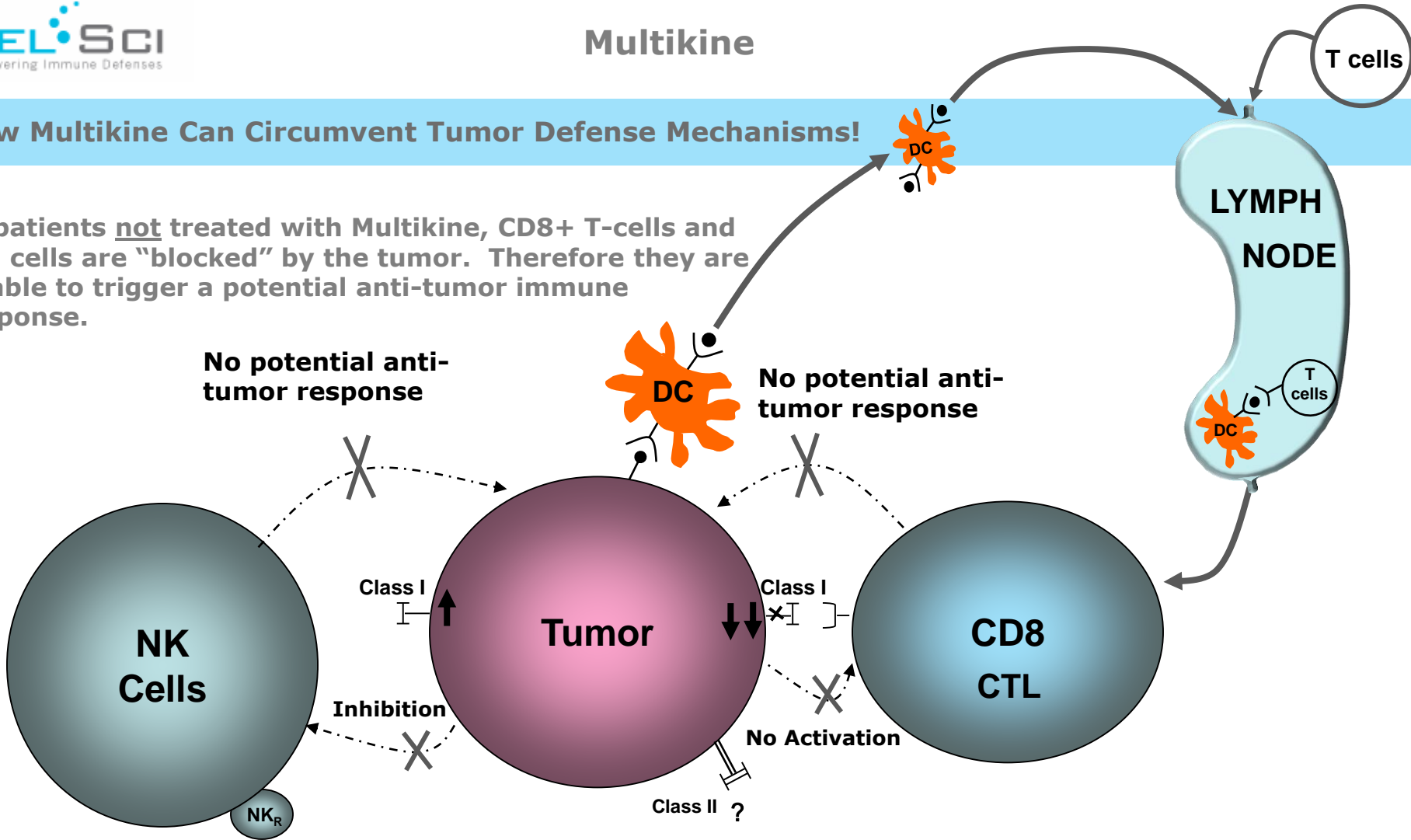
A Paradigm Shift in Tumor Microenvironment – Final Phase II Study



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

**How Multikine Can Circumvent Tumor Defense Mechanisms!**

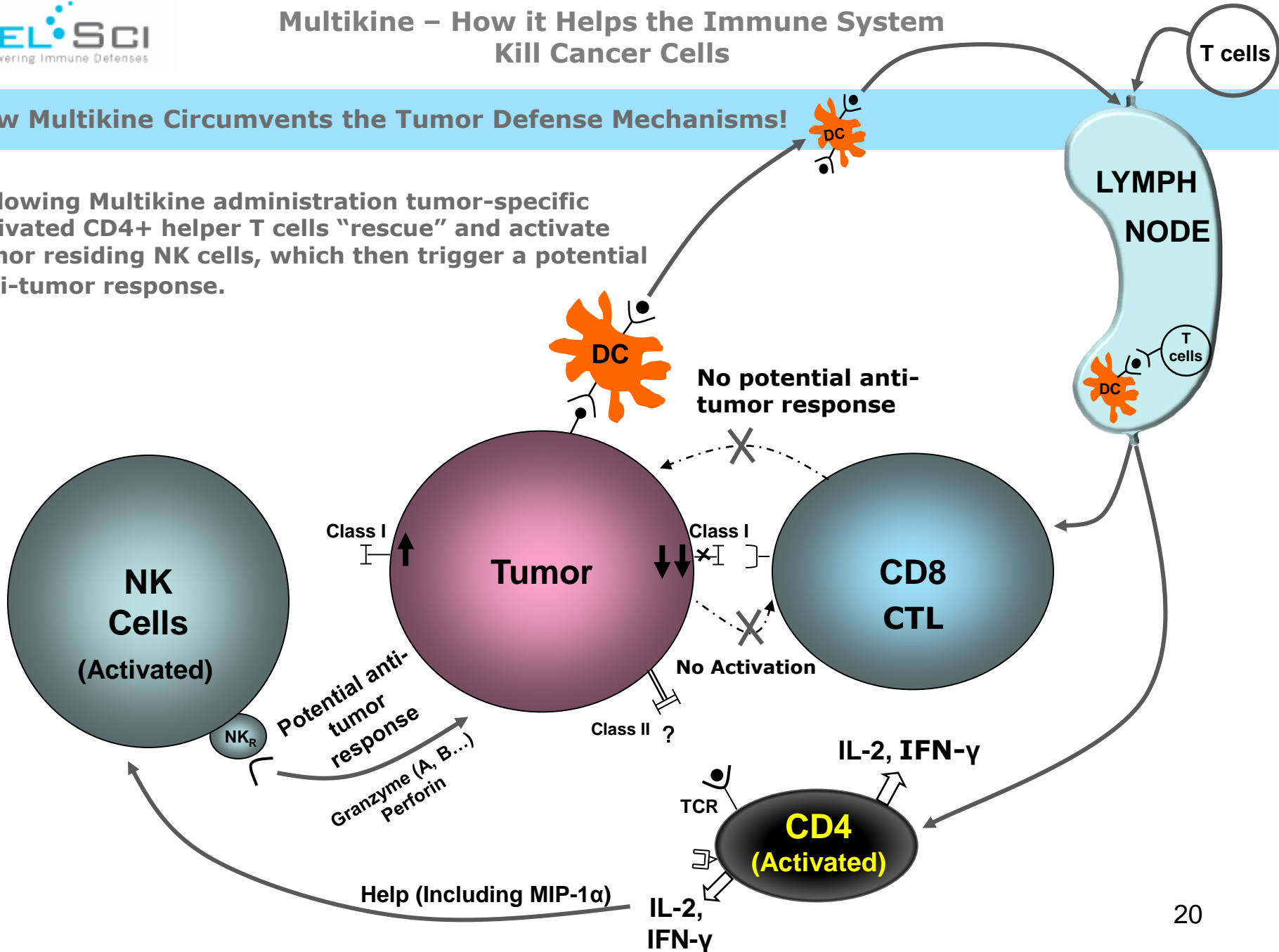
In patients not treated with Multikine, CD8+ T-cells and NK cells are "blocked" by the tumor. Therefore they are unable to trigger a potential anti-tumor immune response.



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

## How Multikine Circumvents the Tumor Defense Mechanisms!

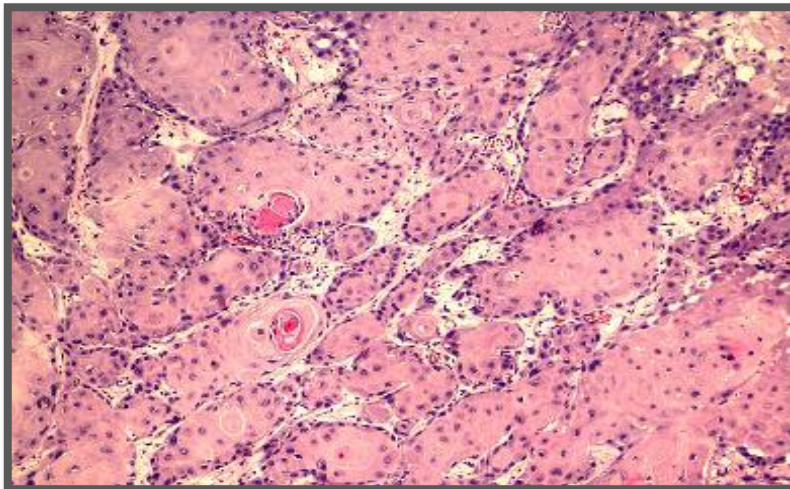
Following Multikine administration tumor-specific activated CD4+ helper T cells “rescue” and activate tumor residing NK cells, which then trigger a potential anti-tumor response.



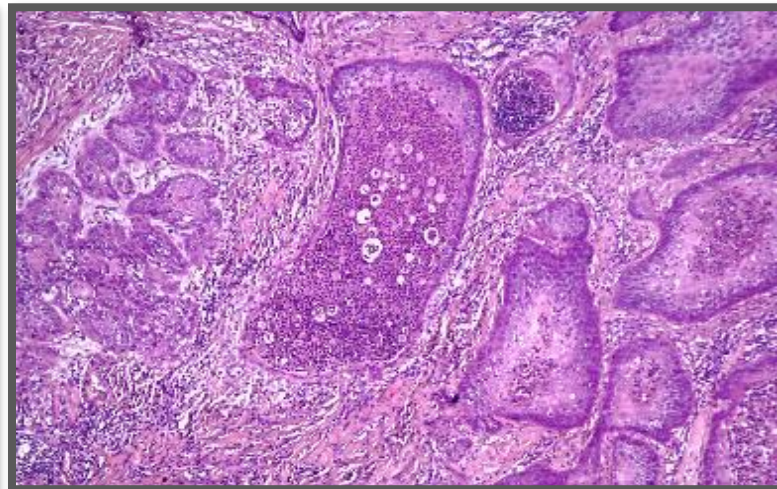
## Pathology: Multikine Treated – vs. – Non-Treated (Final Phase II)

### 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**

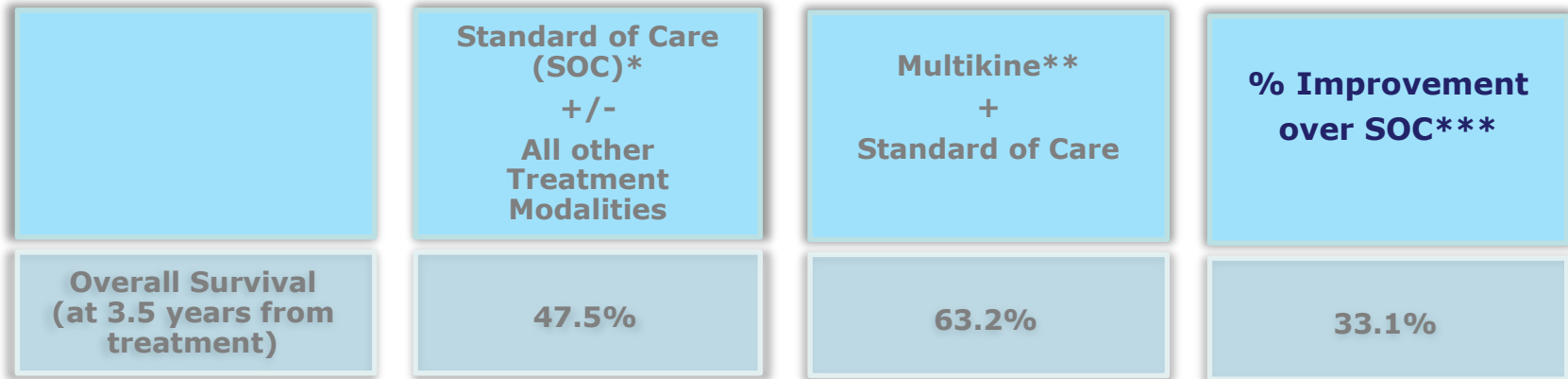


**Multikine treated**

**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

## Multikine Increased Overall Survival by 33%



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

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

\*\*\* Talor et al, Oral Oncology Supplement (2) No. 1, May 2007

### Other observations final Phase II (Timar et al: Journal of Clinical Oncology 23 (15) May 20, 2005):

- 12% of patients had no remaining cancer cells (by pathology) and the overall response rate in this study was 42%, following 3 weeks of Multikine alone.
- 50% average reduction in the number of cancer cells (by pathology) in the remaining patients following 3 weeks of Multikine alone.

### Anecdotal and general observations from Phase II Studies reported by Investigators:

- 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.
- Many patients gain weight.

### Largest Phase III Trial in World for Indication

Phase III open-label, randomized, controlled, multi-center study, with U.S. FDA Orphan Drug designation, to gain “worldwide” approval.

- Enroll about 880 patients to have about 780 evaluable patients in over 20 countries, 100 clinical centers ( <http://clinicaltrials.gov> , search for Multikine).
- Current enrollment is about 330 patients. Aiming for full enrollment by December 2015.
- Reference Therapy: Standard of Care = Surgery + Radiation +/- Chemotherapy.
- Multikine therapy: Three (3) week administration of Multikine first, then standard of care.
- Primary end point: 10% Improvement in Overall Survival over Standard of Care control group (event-driven).

## Presentation of Phase III data, April 2014

- European Head and Neck Cancer Conference, Liverpool, UK, April 24-26, 2014.
- Dr. Feinmesser, Chairman H&N and Autolaryngology Department of the Rabin Medical Center Petach Tikva and Professor of Medicine Tel-Aviv Medical University, Israel, presented data on his four patients treated to date as part of the global Phase III trial.
  - 4 patients
  - 2 randomized to treatment, 2 patients to control group
  - Tolerated injections well
  - No adverse effects
  - No dropouts
  - Both completed treatment regiments
  - General feeling – better
  - Trismus (lockjaw) – improved
  - Weight – gained weight

*Ref. European Head and Neck Cancer Conference, Liverpool, UK, April 24-26, 2014.*

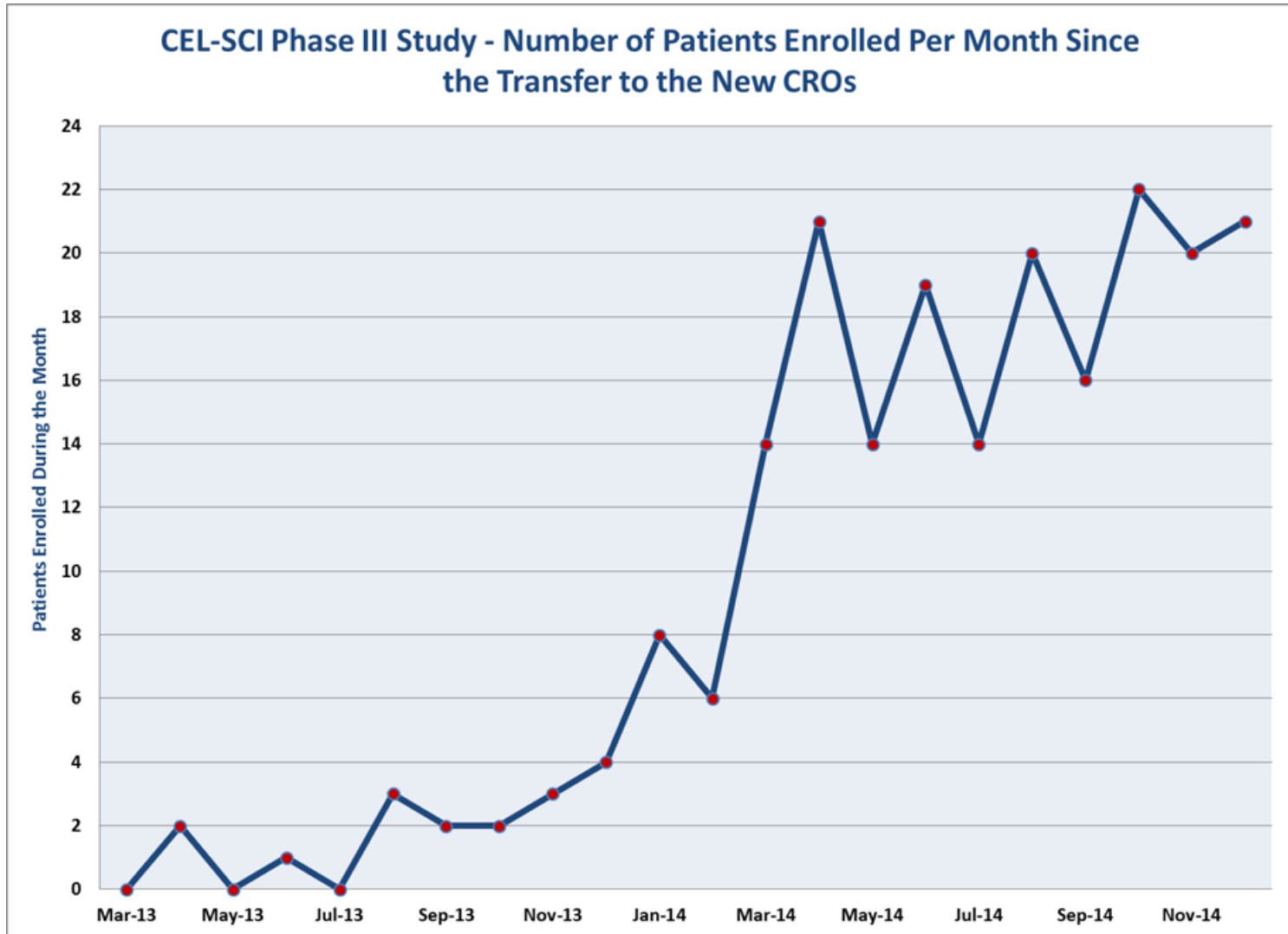


## **Prior CRO Dismissed from Phase III Trial**

Our prior CRO running our Phase III clinical trial was purchased by another CRO during the Phase III trial. Key personnel running our study at the CRO left after the acquisition.

- In April 2013 we dismissed the CRO because, among other things, they did not enroll patients as contractually agreed.
- In October 2013 we filed a \$50 million arbitration against the CRO.
- On December 20, 2013, the CRO moved to dismiss certain claims.
- On June 24, 2014, the arbitrator denied the CRO's motion to dismiss.

## The Phase III Study is Now Enrolling Well Under the New CROs



## **A New Indication for Multikine – Diseases Caused by Human Papillomavirus (HPV)**

- The CDC (US Center for Disease Control and Prevention) designated HPV as the 4<sup>th</sup> biggest threat to health care in the US in 2014.
- Human Papillomavirus (HPV) is the most common sexually transmitted disease. It can lead to cancer of the cervix, penis, anus, esophagus and head and neck.
- HPV is a very significant health problem in immune suppressed people such as HIV-infected population and organ transplant patients.
- HPV is rapidly growing problem among the HIV-infected as they are living longer due to greatly improved HIV medications. Since the HIV patients' immune systems are weakened, they cannot kill HPV and recurrence rates are very high.
- Multikine is the only drug to have killed HPV in an HIV-infected patient.
- We know of no drugs that are currently being developed for the HIV/HPV co-infected patients. Current treatments are at best suboptimal.

### U.S. Navy as Phase I Study Development Partner for HPV induced anal warts

- Cooperative Research and Development Agreement (CRADA) with the U.S. Navy. U.S. government to pay for and run studies. CEL-SCI to supply Multikine and commercialize following successful studies.
- Naval Medical Center in San Diego is currently enrolling patients in a Phase I, 15 patient, dose escalation safety study of Multikine in HIV/HPV co-infected men and women with peri-anal warts.
- Goal of study is to evaluate safety and assess clinical impact on peri-anal warts and on anal intraepithelial neoplasia (AIN).
- Treatment regimen given in this study is identical to the one used in the Phase I study with HIV/HPV co-infected women with cervical dysplasia where promising results were seen.
- Treatment period about 6 weeks, follow-up about 6 months.
- Expected end of study, fall 2015.

## Competition and Market Size

### Current therapies:

- No approved therapies for HIV/HPV co-infected.
- Current therapies are not effective - recurrence is the norm.

### Market size:

- About 25% of HIV-infected patients are thought to have anal warts.
- US has 1.2 m HIV-infected patients. Europe has 2.3 m HIV-infected patients.
- Therefore US and Europe have about 875,000 HIV-infected patients (25% of HIV-infected population) with anal warts.

## Anticipated Upcoming Milestones

<b>Expected Timeline</b>	<b>Event</b>
Q1 2015	Leading HIV/HPV Clinician to Join Anal Wart Study
Q2 2015	50% Patient Recruitment in Phase III Head & Neck Cancer Trial
Q2 2015	Complete Patient Recruitment for HIV/HPV Anal Warts Study
H2 2015	Final Results from HIV/HPV Anal Warts Study
H2 2015	Start of Phase IIb Study for HIV/HPV in Anal Warts
Q4 2015	Completion of Patient Recruitment for Phase III Head & Neck Cancer Trial

### CVM is Priced Like a Phase I Company Due to Enrollment Problems (now fixed) with Prior CRO

Company	Ticker	Market Cap	Indication - Study Phase
Juno Therapeutics Inc.	JUNO	\$4.3B	End of Phase 1, autologous
Celldex Therapeutics	CLDX	\$1.68B	Glioblastoma - Phase III
NewLink Genetics	NLNK	\$1.15B	Pancreatic Cancer – Phase III
Inovio Pharmaceuticals	INO	\$562M	Cervical Dysplasia – end of Phase II
Peregrine Pharmaceuticals	PPHM	\$262M	Non-small Cell Lung Cancer - Phase III
Northwest Biotherapeutics	NWBO	\$334M	Brain Cancer - Phase III, autologous
<b>CEL-SCI Corporation</b>	<b>CVM</b>	<b>\$65M</b>	<b>Head and Neck Cancer - Phase III</b>