



Multikine (Leukocyte Interleukin, Inj.) Cancer Immunotherapy

Activating the immune system of cancer patients before the ravages of surgery and radiation

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CEL-SCI Corporation

Geert Kersten
Chief Executive
Officer

8229 Boone Boulevard, Suite 802
Vienna, VA 22182, USA
Phone: **(703) 506-9460**

NYSE American: **CVM**

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safety profile and related adverse events of our product candidates; our ability to manufacture sufficient amounts of Multikine or our other product candidates for use in our clinical studies or, if approved, for commercialization activities following such regulatory approvals; our plans with respect to collaborations and licenses related to the development, manufacture or sale of our product candidates; our expectations as to future financial performance, expense levels and liquidity sources; our ability to compete with other companies that are or may be developing or selling products that are competitive with our product candidates; anticipated trends and challenges in our potential markets; and our ability to attract, retain and motivate key personnel.

All forward-looking statements contained herein are expressly qualified in their entirety by this cautionary statement, the risk factors set forth under the heading “Risk Factors” and elsewhere in our public filings, and in the documents incorporated or deemed to be incorporated by reference therein. The forward-looking statement contained in this presentation speak only as of their respective dates. Except to the extent required by applicable laws and regulations, we undertake no obligation to update these forward-looking statements to reflect new information, events or circumstances after the date of this presentation. In light of these risks

and uncertainties, the forward-looking events and circumstances described in this presentation may not occur and actual results could differ materially from those anticipated or implied in such forward-looking statements. Accordingly, you are cautioned not to place undue reliance on these forward-looking statements.

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. 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.

Our Goal is to Create a Novel Non-Toxic Cancer Drug

- We believe that
 - 1) the immune system is key to our fight against cancer and that
 - 2) the immune system must be activated to fight cancer BEFORE surgery and radiation have damaged the immune system. Typically cancer immunotherapy drugs are given after those first treatments
- Our immunotherapy is called Multikine®*
- Multikine is a copy of the pro-inflammatory cytokine immune response our bodies produce every day
- Phase 3 results from the largest head and neck cancer study in the world show very significant survival benefit with no safety issues for head and neck cancer patients receiving our Multikine followed by surgery and radiation

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Multikine Supplies The Cytokines Needed for Tumor Rejection

- Multikine is a consistent mixture of cytokines. The cytokines listed to the right are those known to be present in Multikine
- Research at the US National Institutes of Health (NIH) has shown that the cytokines (shown in **red**) are the ones that are required to mount a rejection episode including tumor rejection
- Multikine is 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 cell antigens
- 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
- The goal is to kill the tumor micrometastases thought to be responsible for recurrence, thereby reducing cancer recurrence and increasing survival.

Major Cytokine(s) and other Cellular Products in Multikine

IL-1 α

IL-6

IL-1 β

IL-8

IL-2

TNF- β

IL-3

G-CSF

TNF- α

RANTES

IFN- γ

MIP-1 α

GM-CSF

MIP-1 β

State-of-the-Art Facility & Proprietary Manufacturing Process: Potential Barriers to Competition

- cGMP and BSL-1 facility near Washington, DC, USA
 - Built specifically for Multikine
 - State-of-the art facility
 - Over 73,000 ft² of Manufacturing and R&D space available
 - About 45,000 ft² fully developed
 - Proprietary automated cold fill to ensure no loss of biological activity during fill
- Well over \$100 million was spent on manufacturing related items. Facility was built before the Phase 3 trial started and the capacity was recently doubled in preparation for commercialization
- Inspected several times by European Qualified Person (QP)
 - Inspected by the QP for the manufacture and release of Sterile Medicinal Products (per ICH and EU Directives)
- Significant “know how” developed to manufacture Multikine – Method of Manufacture
 - Trade-secret

Topline Results: Large 5-Year Survival Benefit - CEL-SCI to File for FDA Approval

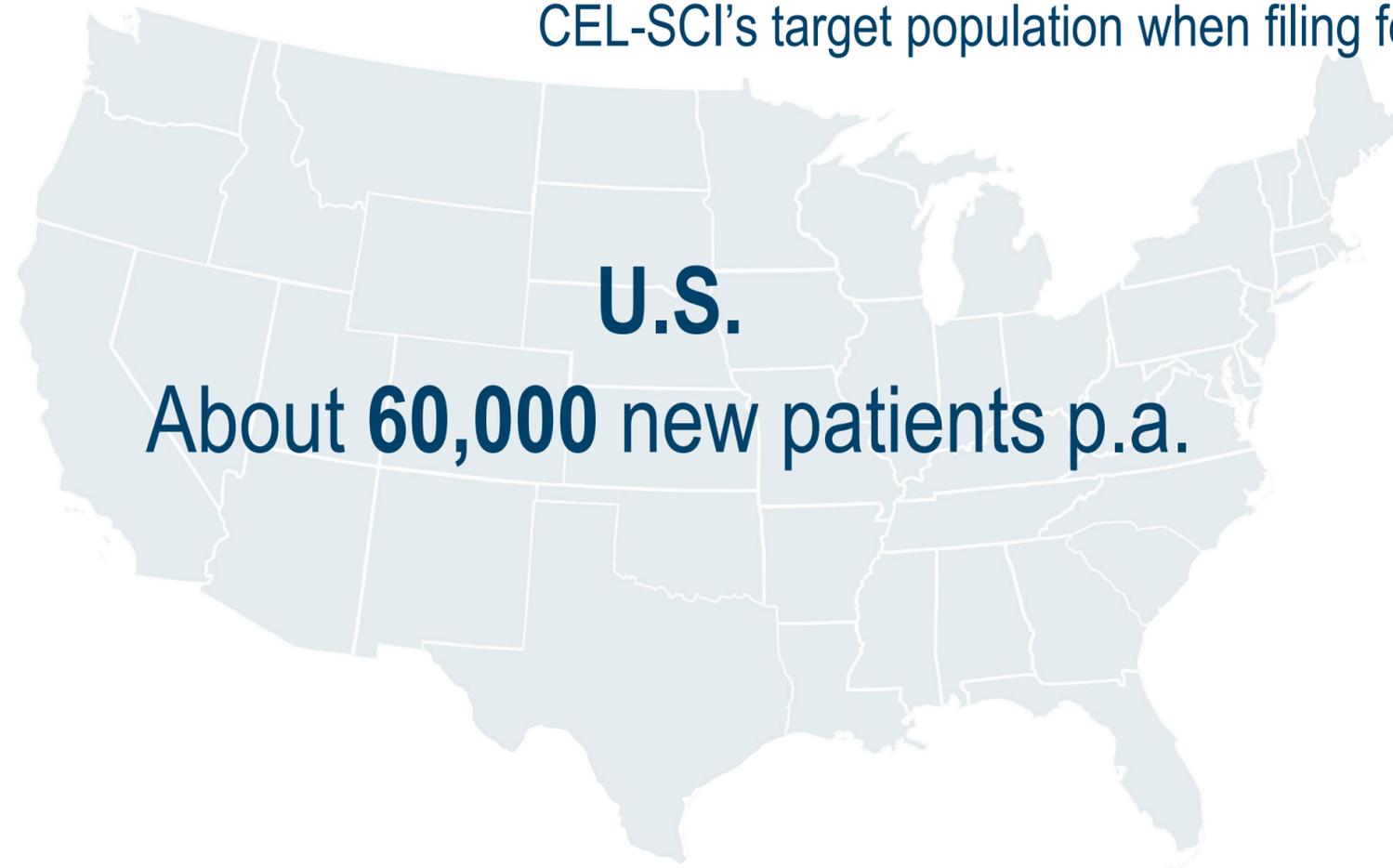
- Almost 10-year 928 patient advanced primary head and neck cancer study
- Multikine immunotherapy was given following cancer diagnosis for 3 weeks prior to the current standard of care
- Multikine produced a very significant 14.1% 5-year survival benefit (62.7% vs 48.6%) in the treatment arm receiving surgery plus radiotherapy (n=380), but not in the treatment arm that had chemotherapy added to the same treatment
- The analysis of this treatment arm was pre-specified in the study protocol, included in the study's statistical analysis plan, and concluded prior to unblinding. It is therefore expected to meet regulatory requirements for FDA submission
- No safety issues were found for the entire Multikine treated population of the study
- CEL-SCI plans to file for FDA approval in patients receiving Multikine followed by surgery and radiotherapy (standard of care) and the data relevant to this group is discussed herein

Why Head and Neck Cancer as a First Target?

- Advanced (stages III and IV) primary (not yet treated) head and neck cancer was selected as the first indication because:
 - It represents a severe **unmet medical need**
 - Last FDA approval of a therapy for advanced primary head and neck cancer was over 50 years ago
 - Multikine was awarded **Orphan Drug Status** in the US
 - Head and neck cancer represents a very large cancer
 - Only one standard of care throughout the world
 - If approved Multikine should become the first treatment for the treatment arm of surgery and radiotherapy

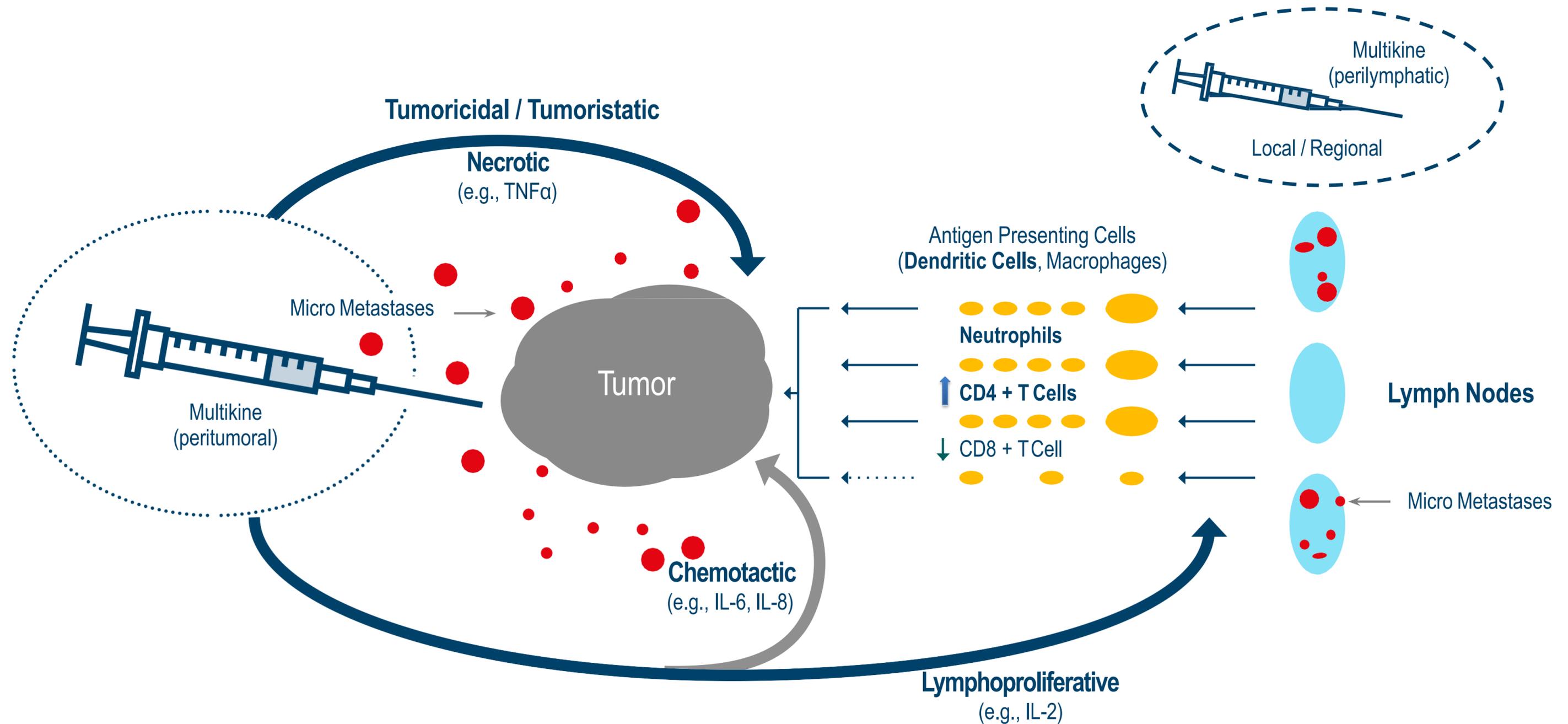
Head and Neck Cancer Market

Worldwide about **890,000** new head and neck cancer patients are diagnosed per year.
CEL-SCI's target population when filing for FDA approval is about **210,000** patients



- 90% of head and neck cancers are squamous cell carcinomas
- About 66% of those are advanced primary
- Of the advanced primary about 40% are prescribed surgery and radiation therapy as standard of care
- We plan to apply for FDA approval for that market of about 210,000 annual cases globally
- Our global study spanned 20 countries; FDA approval expected to lead to approval in many countries

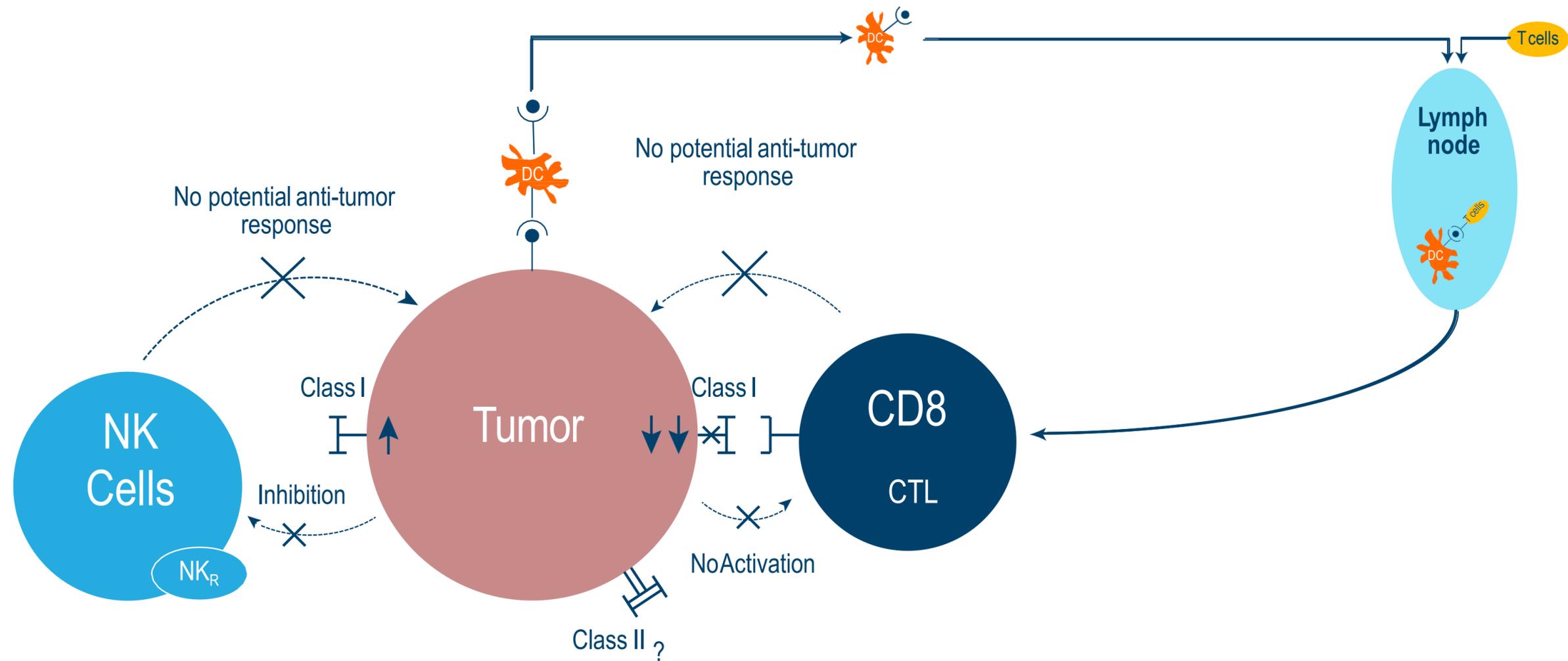
Mechanism of Action Stimulates an Immune Response at the Injection Site



Multikine – How it Helps the Immune System Kill Cancer Cells

How Multikine is Designed to Circumvent the Tumor Defense Mechanisms

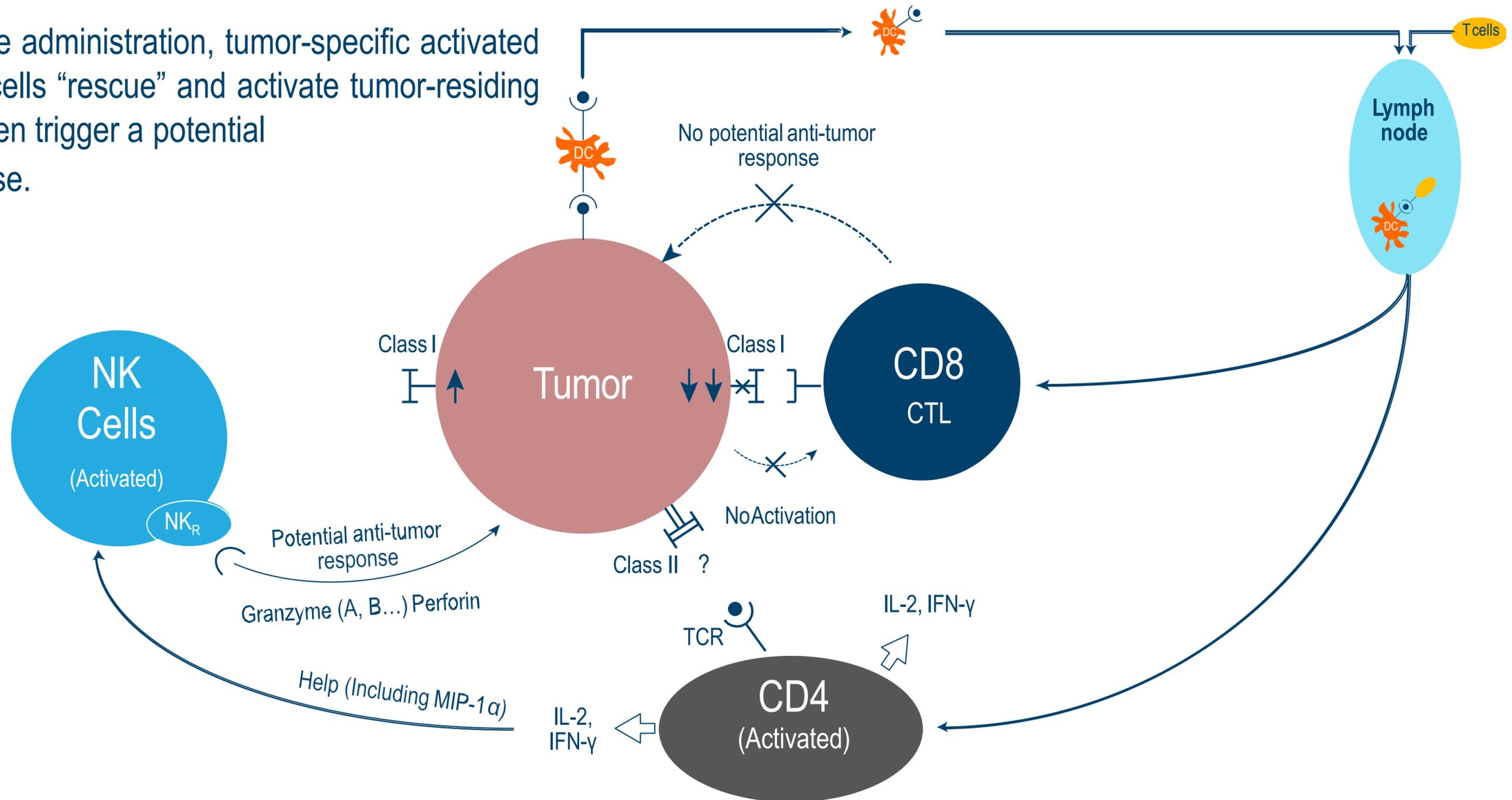
In patients not treated with Multikine, CD8+ T-cells and NK cells are “blocked” by the tumor. Therefore they are unable to trigger a potential anti-tumor immune response.



Multikine – How it Helps the Immune System Kill Cancer Cells

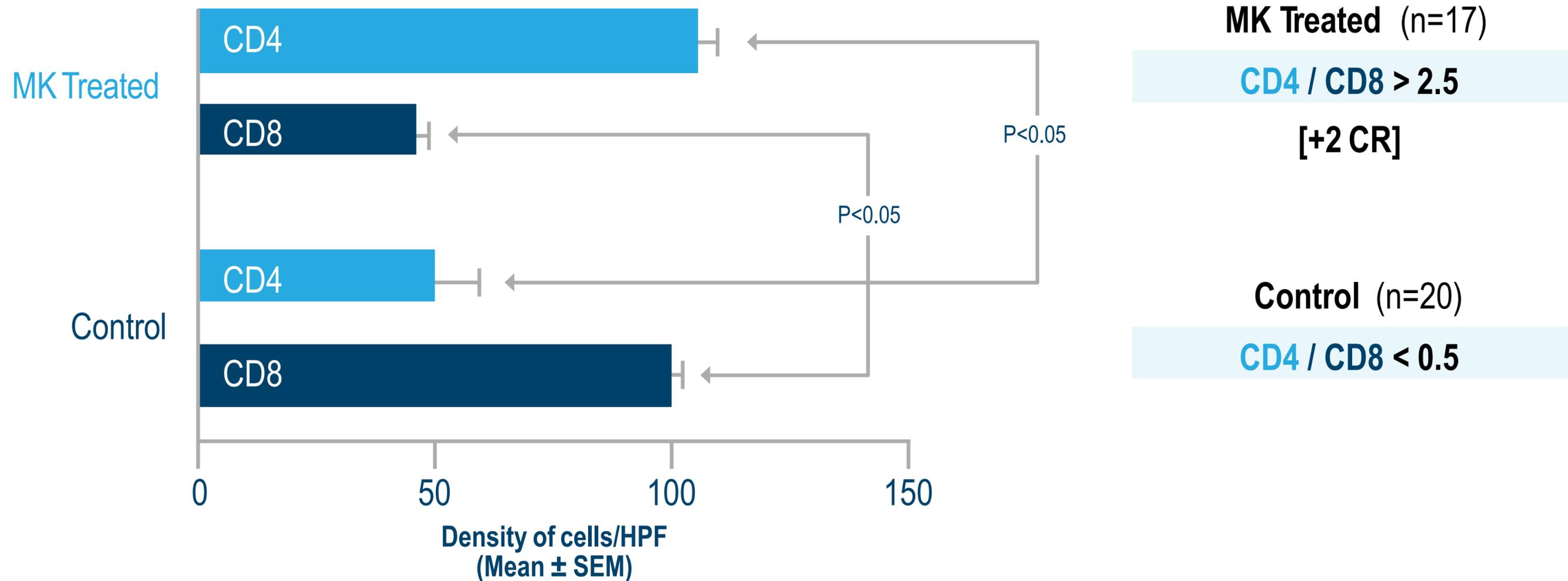
How Multikine is Designed to Circumvent the Tumor Defense Mechanisms

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.



Observed Effects Following Multikine Treatment Regimen – Phase 2

An Apparent Shift in Tumor Microenvironment



Multikine Treatment Effect on Host CD4 and CD8 Tumor Infiltrating Cell Density in OSCC
(Locally Advanced Primary H&N Cancer)

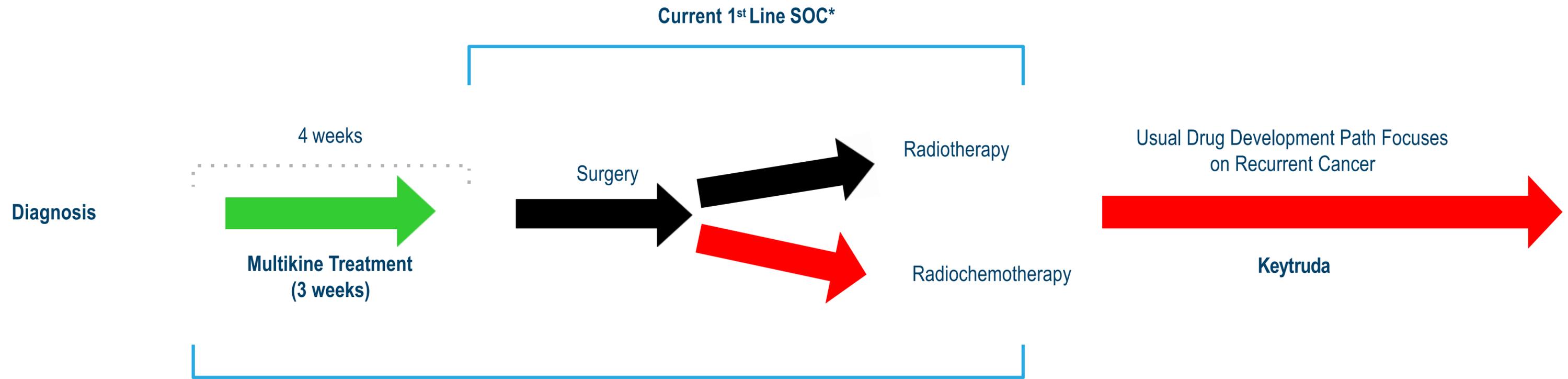
* Talor et al., ASCO Annual Meeting Proceedings 22(14S): 189S, 2004
Adapted from: Timar et al., Journal of Clinical Oncology 23(15) May 20, 2005

CEL-SCI Phase 3 Study Trial Design & Summary Study Results

As one physician wrote: "Head and neck cancer is possibly the most horrific of all cancers. Not only does it take your life, but it takes your beauty, your voice and your dignity."

Phase 3 Study Design -Timing of Multikine Treatment Regimen

Advanced Primary Head and Neck Cancer



Proposed New 1st Line SOC* for patients receiving Surgery and Radiotherapy only

* Standard of Care

Patients fall into one of two Treatment Arms per NCCN Guidelines

- 928 patients randomized
- Intent to Treat (ITT) group was 923 patients, 99.5% of the 928 randomized
- 2 treatment arms determined by risk of recurrence post-surgery following National Cancer Comprehensive Network (NCCN) guidelines
 - n=380 (41.2%) of patients prescribed surgery + radiation because they were at lower risk of recurrence (NCCN guidelines)
 - n=467 (50.6%) of patients prescribed surgery + chemoradiation (chemotherapy and radiation concurrently) because they were at higher risk of recurrence (NCCN guidelines)
 - Total exclusions: n=76 (8.2%) did not receive radiation or chemoradiation (exclusions reflect investigator, family, and patient decisions)

Phase 3 Topline Results

- The survival benefit in the ITT population increased over time and at 5-years the overall survival benefit reached an absolute 14.1% advantage for the Multikine treated arm over the control arm (n=380, total study patients treated with surgery plus radiation), control arm 48.6%, Multikine arm 62.7%
- The overall survival benefit was robust and durable
- No safety issues throughout the study

Filing for FDA Approval for Patients in the Treatment Arm Receiving Surgery and Radiation

- The analysis for the successful treatment arm of Multikine followed by surgery and radiotherapy was pre-specified in the protocol and conducted per the Statistical Analysis Plan before unblinding. This means the data from the successful treatment arm can be used in seeking FDA approval. The treatment arm was determined by the treatment the physicians chose to give. No patients were excluded from the analysis. The number of patients in this group (n=380) is significant and the number of patients who would benefit each year is large (about 210,000). When we apply the statistical parameters of the protocol to this patient group, the results of this treatment arm meet and exceed them:
 - The 5-year overall survival benefit was **14.1% in absolute terms exceeding the protocol required 10% or better**
 - The study result's p-value was **0.0236 exceeding the protocol required p-value of <0.05**
 - The study result's Hazard Ratio was **0.68 exceeding the protocol required 0.721**
 - There were **no safety issues** involving the whole study population

Summary: Phase 3 Clinical Trial in Advanced Primary Head and Neck Cancer

- We have run the largest and longest study ever in head and neck cancer
- We are the first in the world to show that neoadjuvant cancer immunotherapy, used BEFORE surgery and radiation, increases overall survival
- No safety issues were reported
- The disease represents both a severe unmet medical need and has orphan drug designation from FDA

Key lessons from the study:

- It is possible to have a cancer drug with no safety issues
- Survival benefit with Multikine appears to increase over time
- Since survival increases over time, we may be able to alter the course of the disease
- Chemotherapy given about 6 – 8 weeks after our cancer immunotherapy appears to negate the benefit from our the Multikine immunotherapy

Steps in the process for approval:

- We have identified, and validated with the study data, a way to determine what patient is supposed to receive radiotherapy as opposed to radiochemotherapy following surgery
- File data package for pre-Biologics License Application (BLA) meeting with FDA
- Submit data for peer review in top scientific journals
- Finalize clinical report and submit to FDA

Equity Summary

CEL-SCI Corporation

NYSE American: CVM

Clinical Trial Stage

Completed Phase 3 cancer immunotherapy study

Market Capitalization

~\$450 million

Trading Volume

~ 1 million shares per day (last 90 days)

Shares Outstanding

~ 43 million shares

Share Price

~ \$11

Cash on Hand

\$47.1 million (June 30, '21)



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