CEL-SCI
Empowering Immune Defenses

Multikine (Leukocyte Interleukin, Inj.) Cancer Immunotherapy

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

September 2021

CEL-SCI Corporation

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Forward Looking Statements

This presentations contains “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995, Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. You can generally identify these forward-looking statements by forward-looking words such as “anticipates,” “believes,” “expects,” “intends,” “future,” “could,” “estimates,” “plans,” “would,” “should,” “potential,” “continues” and similar words or expressions (as well as other words or expressions referencing future events, conditions or circumstances). These forward-looking statements involve risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by such forward-looking statements, including, but not limited to: the progress and timing of, and the amount of expenses associated with, our research, development and commercialization activities for our product candidates, including Multikine; the success of our clinical studies for our product candidates; our ability to obtain U.S. and foreign regulatory approval for our product candidates and the ability of our product candidates to meet existing or future regulatory standards; our expectations regarding federal, state and foreign regulatory requirements; the therapeutic benefits and effectiveness of our product candidates; the 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.

FDA Disclaimer Statement

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 Bring our Novel Non-Toxic Cancer Drug to Patients in Need

- We believe the immune system is key to our fight against cancer
- We further believe 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 large survival benefit with no safety issues

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Topline Results: 14.1% 5-Year Survival Benefit - CEL-SCI to File for FDA Approval

- Multikine immunotherapy 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 overall survival benefit imparted by Multikine increased over time as compared to overall survival in the control. This is different from other cancer drugs that may initially give some survival benefit (in other cancers), but then survival drops off
- There are 2 treatment arms. Physicians select the treatment arms, not CEL-SCI. The successful treatment arm represents 40% of people diagnosed with advanced primary head and neck cancer or about 210,000 new cases per year
- Results in this treatment arm were robust and durable, and statistically significant (ITT, p=0.0236, HR= 0.68)
- 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)
- 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

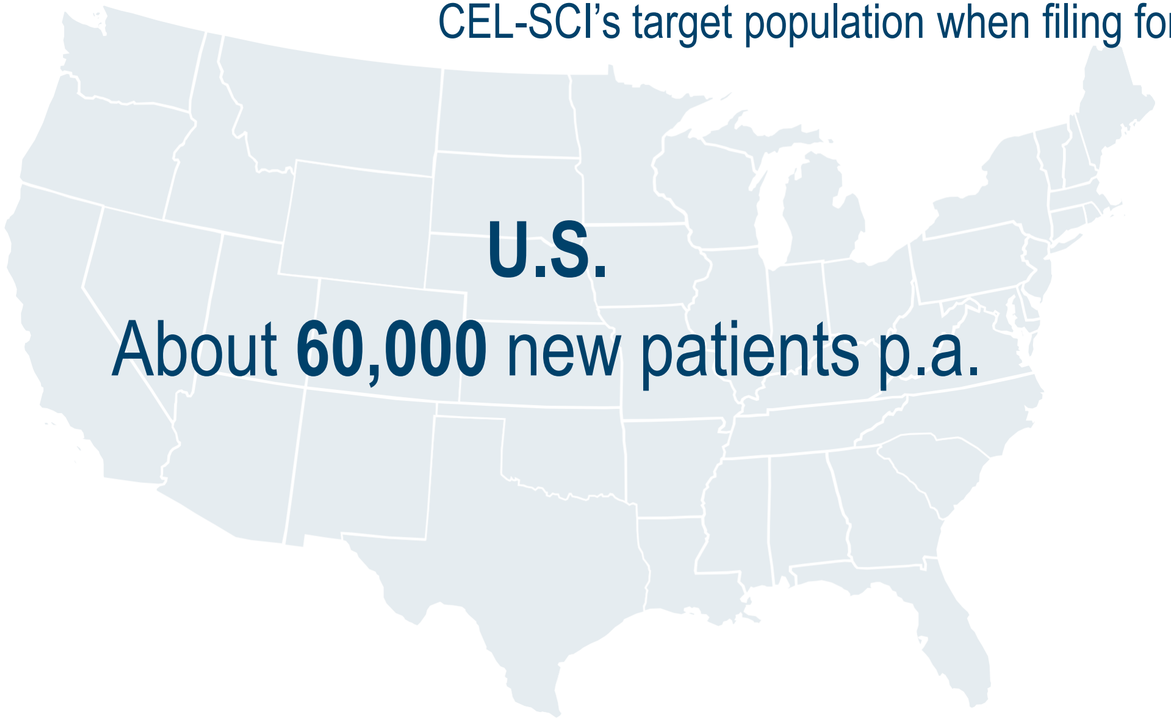
Why Head and Neck Cancer as a First Target?

- Advanced (stages III and IV) primary (not yet treated) head and neck cancer was selected as the first indication because:
  - It represents an **unmet medical need** and everyone agrees that the current treatments are horrible
  - 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 with 890,000 cases p.a. worldwide; approximately 210,000 of these are CEL-SCI's target population in its FDA filing
  - Only one standard of care throughout the world
  - If approved Multikine should become the first treatment for the treatment arm of surgery and radiotherapy
  - CEL-SCI's Phase 3 positive results believed to mark the first-ever success of a neoadjuvant cancer immunotherapy in advanced primary head and neck cancer

- Regulators historically have been more likely to approve drugs that help patients with **unmet medical needs** and/or **orphan drug** diseases. This is very important.

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



U.S.

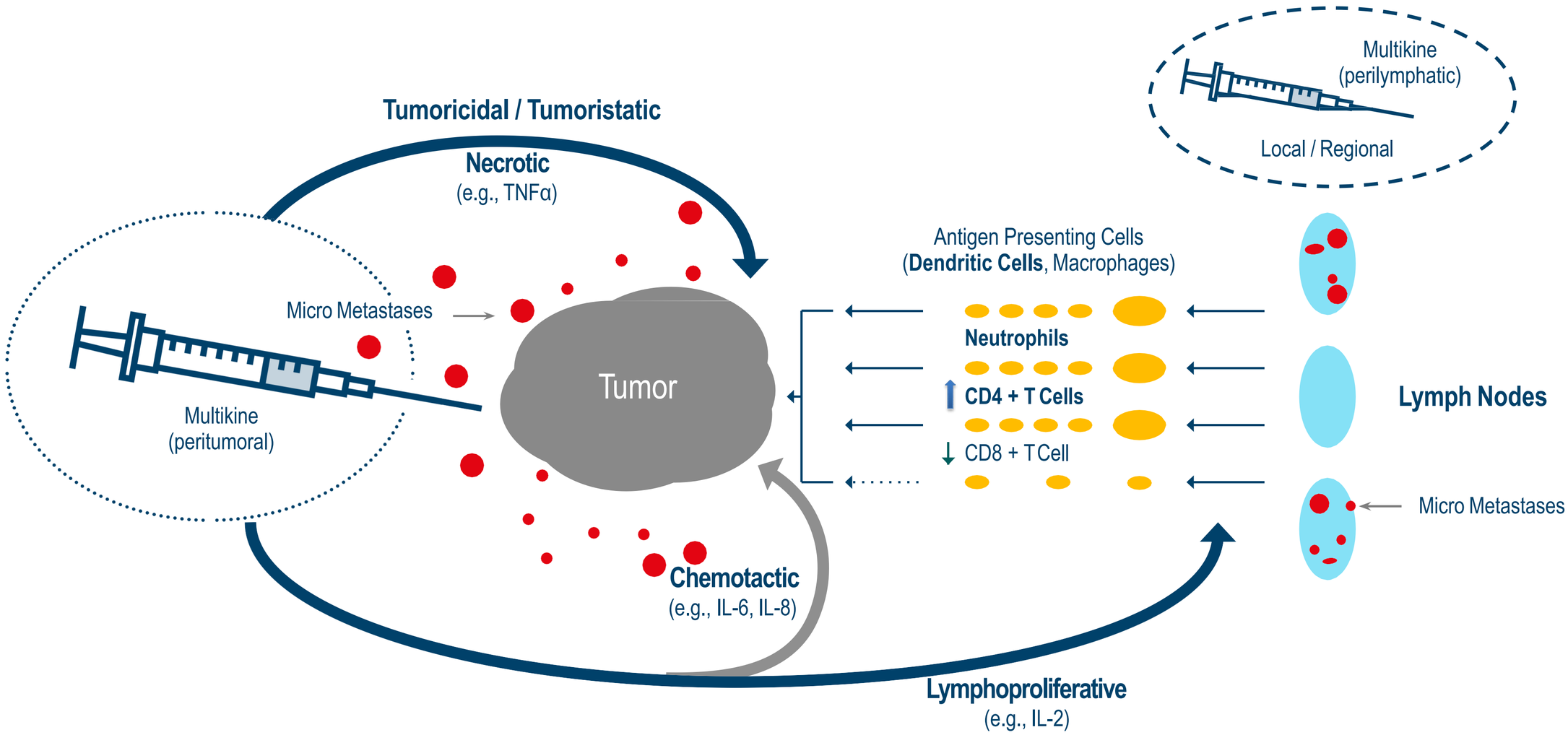
About **60,000** new patients p.a.

Europe

About **105,000** new patients p.a.

- 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

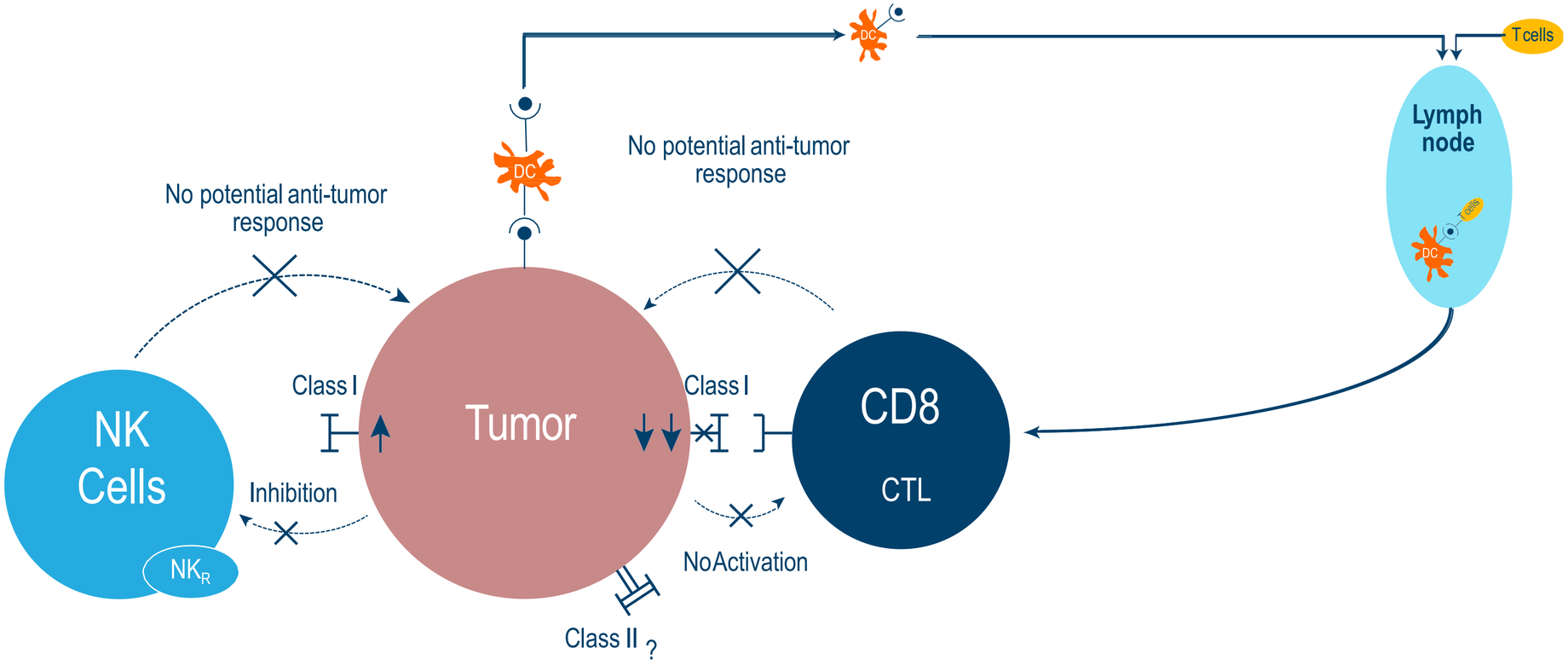


Source: Timar et al., Journal of Clinical Oncology 23(15) May 20, 2005

Multikine – How it Helps the Immune System Kill Cancer Cells

How Multikine is Designed to Circumvent the Tumor Defense Mechanisms

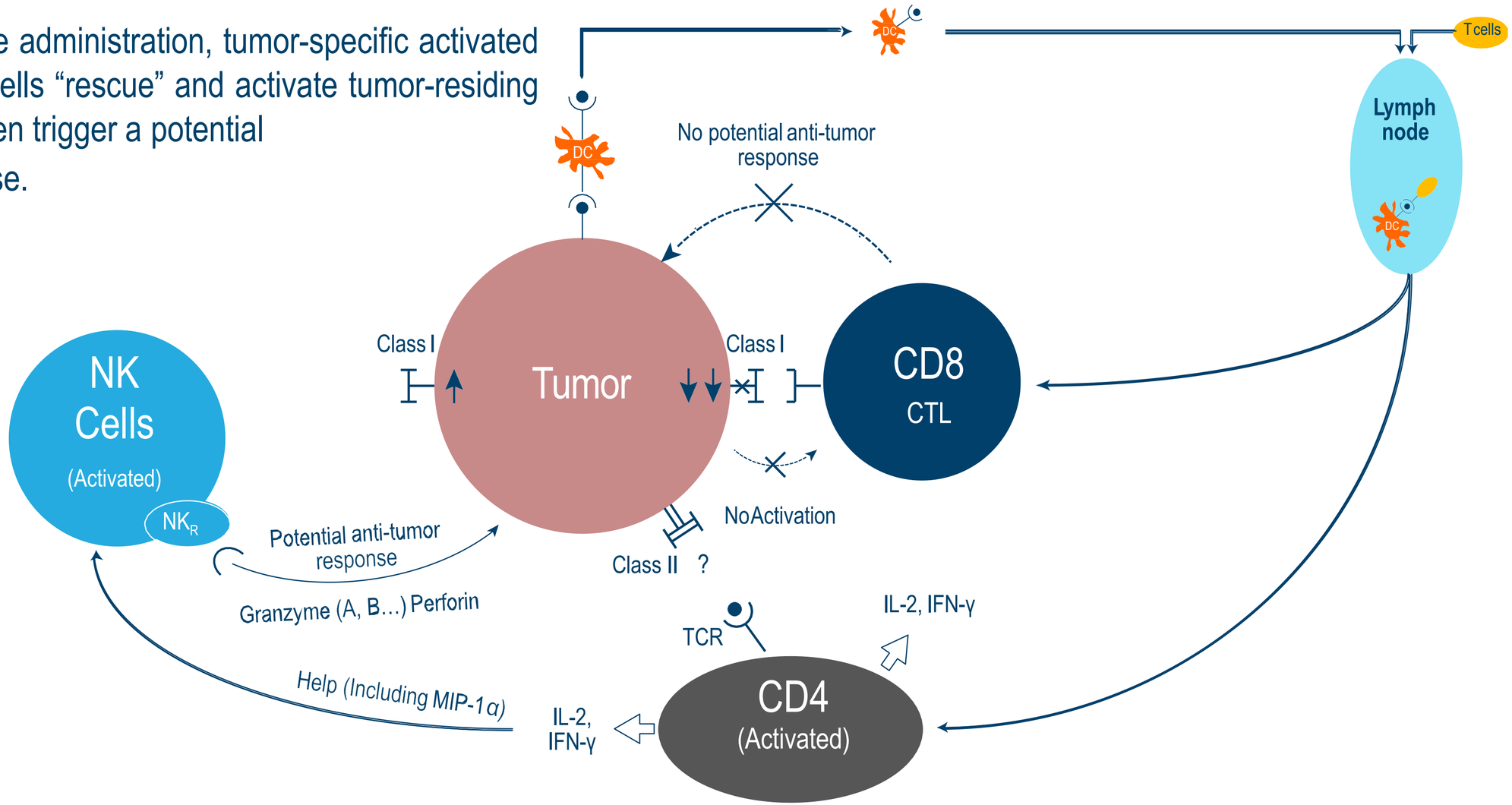
In patients not treated with Multikine, CD8+ T-cells and NK cells are “blocked” by the tumor. Therefore they are unable to trigger a potential anti-tumor immune response.



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.

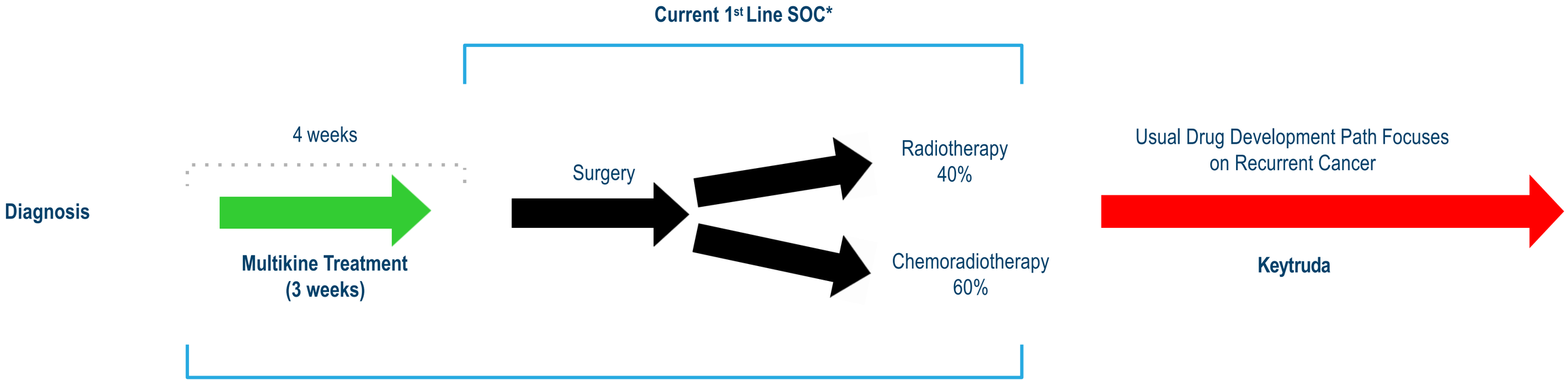


CEL-SCI Phase 3 Study
Trial Design &
Summary Study Results

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

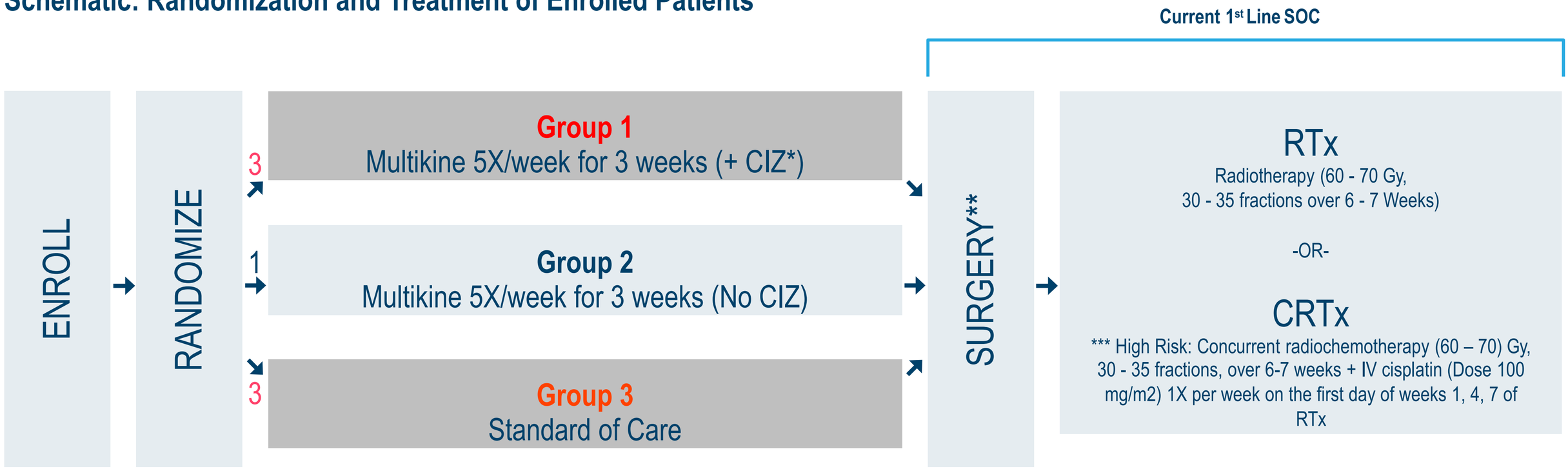


Proposed New 1st Line SOC* for patients receiving Surgery and Radiotherapy only

* Standard of Care

Multikine Phase 3 Trial Design

Schematic: Randomization and Treatment of Enrolled Patients



Note: The **overall survival comparison is made between groups 1 and 3**. The primary purpose of the smaller Group 2 is to gain additional information on the mechanism of action and toxicity of Multikine. CIZ is added to decrease tumor suppressor mechanisms and thereby is thought to increase Multikine's effectiveness.

* CIZ: Cyclophosphamide 300 mg/m^2 (x1,IV, day -3); Indomethacin 25mg tid, po (day 1 to 24 hrs prior to surgery) + 15 - 45mg Zinc (as Multivitamin) i.d., p.o.

** Surgery: complete surgical resection of primary tumor and any positive lymph nodes.

*** High risk patients are defined as those with: positive surgical margins, 2 or more clinically positive nodes, or extra capsular nodal spread, perinural invasion, etc (any or all of the above).

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)

Multikine Phase 3 Study Endpoints

- **Primary Endpoint:**
  - Overall Survival
- **Secondary Endpoints:**
  - Progression Free Survival
  - Local/Regional Control
  - Safety
  - Histopathology of Tumor infiltrate
  - Quality of Life
- **Tertiary Endpoint:**
  - Tumor Response

Phase 3 Topline Results

- The treatment arm receiving Multikine (plus CIZ) followed by surgery and radiation showed a **long-term 5-year overall survival (OS) benefit that was robust and durable, with no safety issues**. The **survival benefit 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), which is about a 29% improvement, control arm 48.6%, Multikine arm 62.7%
- 3-year survival advantage was 4.9% (72.4% vs 67.5%) for the treatment arm receiving no chemotherapy
- 5-year survival advantage was 14.1% (62.7% vs 48.6%) for the treatment arm receiving no chemotherapy
- Median follow up time was greater than 7 years for those last alive for the treatment arm receiving no chemotherapy
- Patients treated with the same Multikine treatment regimen prior to surgery and radiotherapy, but who also received chemotherapy as part of the other treatment arm, did not exhibit this survival advantage
- The chemotherapy, cisplatin, appears to have negated the survival benefit imparted by Multikine immunotherapy
- Therefore when combined, the two treatment arms did not reach 10% improvement in survival

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

- The analysis for the successful treatment arm of Multikine (plus CIZ) 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 cancer immunotherapy used BEFORE surgery and radiation increases survival
- No safety issues were reported
- The disease represents both an 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
- Since survival increases over time, we may be able to alter the course of the disease
- Chemotherapy given after our cancer immunotherapy appears to negate the benefit from our the Multikine immunotherapy

Next steps:

- 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
- We have expanded our full scale GMP manufacturing facility in Maryland. We are waiting for the occupancy permit to conclude the final manufacturing work for FDA submission

Equity Summary

CEL-SCI Corporation	NYSE American: CVM
Clinical Trial Stage	Completed huge Phase 3 cancer immunotherapy study
Market Capitalization	~$500 million
Trading Volume	~ 1.7 million shares per day (last 90 days)
Shares Outstanding	~ 43 million shares
Share Price	~ $12
Cash on Hand	$47.1 million (June 30, ‘21)

Share based information as of September 7, 2021

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