Multikine™ "First In Class Cancer Immunotherapy"

First Indication: Head & Neck Cancer Neoadjuvant (Pre-surgery) Immunotherapy

January 2025

NYSE American: CVM

Forward Looking Statements

This presentation 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 licensesrelatedtothedevelopment, manufactureorsale 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.

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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 CEL-SCI’s 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 concerning the Company in its public filings.

Why is CEL-SCI so Valuable for Cancer Patients and Investors?

We all know people who were treated for their cancer, but then the cancer came back. Most recurrences end in death. Therefore, **we seek to make the first treatment more successful and stop cancer recurrences**.

We do this by activating the immune system to fight cancer BEFORE surgery, radiotherapy and chemotherapy have destroyed it.

We have completed the largest ever Phase 3 study in Head and Neck cancer. This cancer is our initial focus because it is a huge unmet medical need and a multi-billion market. Our study showed that our immunotherapy Multikine is basically non-toxic and extends survival by almost 4-years in the target population.

The FDA agreed with us and gave the go-ahead on a small confirmatory study to bring Multikine to market, to start Q1 2025, with potential approval in 2026. Statistically this study has an over 95% chance of success because it repeats our Phase 3 study but includes only the target population of patients who benefitted most from Multikine.

All cancer drugs that have shown **overall survival** benefit have **historically been worth billions of dollars**.

Our drug manufacturing facility is ready to produce over $2 billion worth of Multikine.

Unique De-Risked Opportunity in Cancer Immunotherapy

- Multikine has been **extensively tested in clinical studies**, including a 928-patient Phase 3 study in newly diagnosed head and neck cancer:
  - 46.5-month (nearly 4 years) survival benefit over control when patients were treated with Multikine followed by surgery and radiotherapy (not chemotherapy)
  - 5-year survival rate increased to 73% vs 45% for control when patients were treated with Multikine followed by surgery and radiotherapy (not chemotherapy)
  - No survival benefit in patients who had chemotherapy added to the treatment
  - Multikine was safe and well tolerated
- FDA asked us to do a **small final confirmatory study** for approval focusing on the patients with the 4-year survival benefit (i.e., those who did not receive chemotherapy)
- Focus on patients who are PD-L1 low/negative (70% of patients) who are **not addressed by current blockbuster drugs Keytruda and Opdivo**
- No new drug approved by FDA for the specific indication in decades
- Potential for development to treat other solid tumor cancers

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About $35 M Market Cap

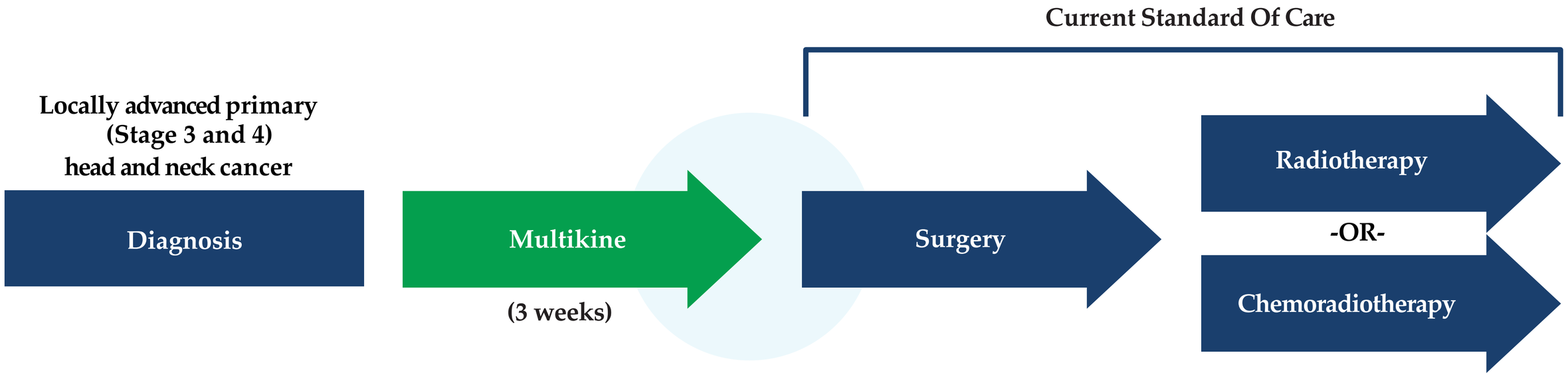
$24 M Raised in 2024

Multi-Billion $ Head & Neck Cancer Market

Potential to be THE CANCER DRUG for Low PD-L1 Patients, Not Currently Addressed by Blockbuster Checkpoint Inhibitors

This is the Current Standard of Care for These Very Sick Patients

Multikine would be added to the current standard of care, delivered locally via injections around the tumor and adjacent to the draining lymphatic chain area before surgery:

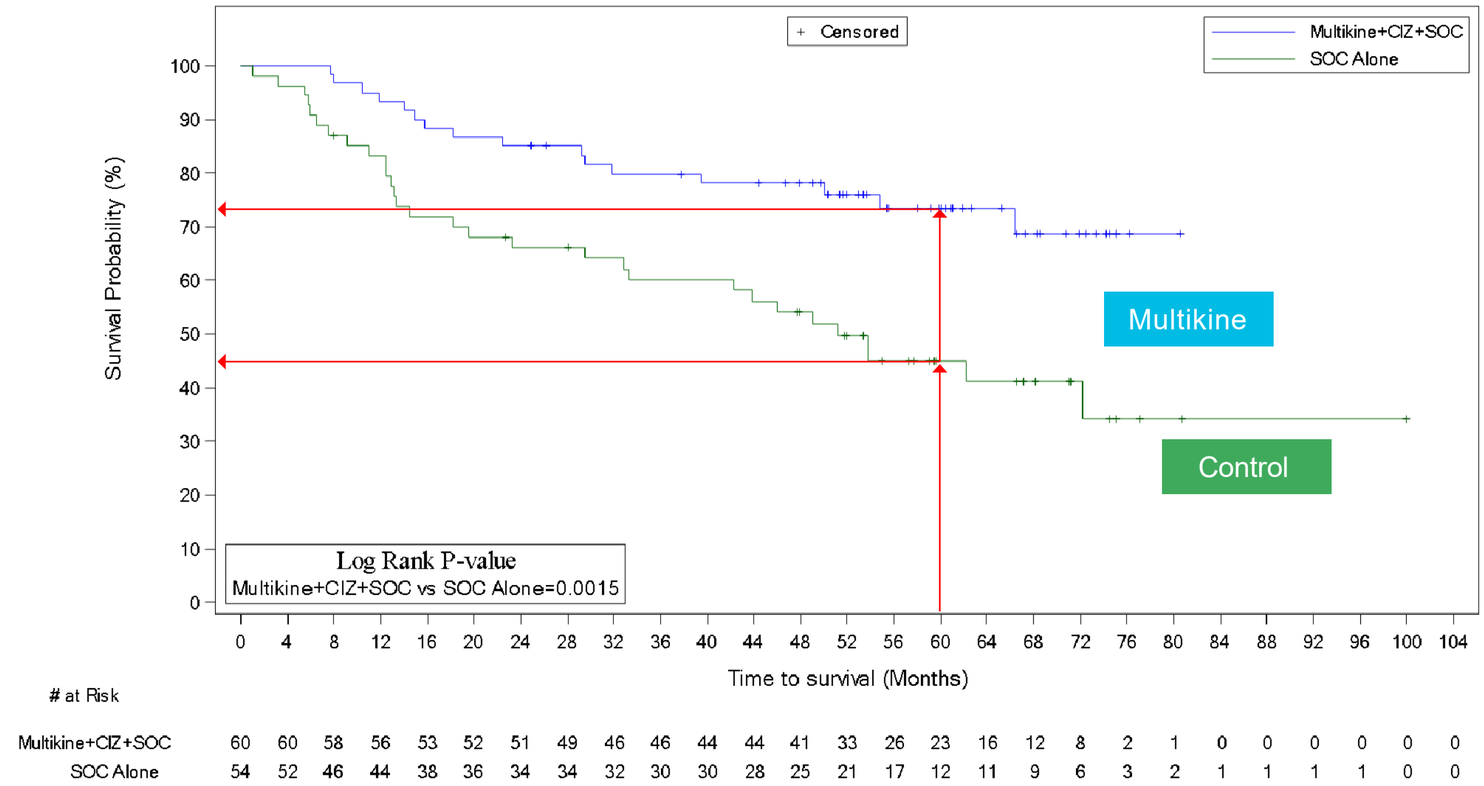


Multikine Improved Survival in the Completed Phase 3 Study

Target Population (No lymph node involvement & PD-L1 low) for Confirmatory Study

Data Presented at ESMO 2023

- **No safety signals** or toxicities vs standard of care
- Statistically significant (log rank **p = 0.0015**)
- **Hazard ratio = 0.35** (95% CIs [0.19, 0.66])
- Curves separate early and plateau with a tail typical of immuno-oncology drugs as in the Multikine arm



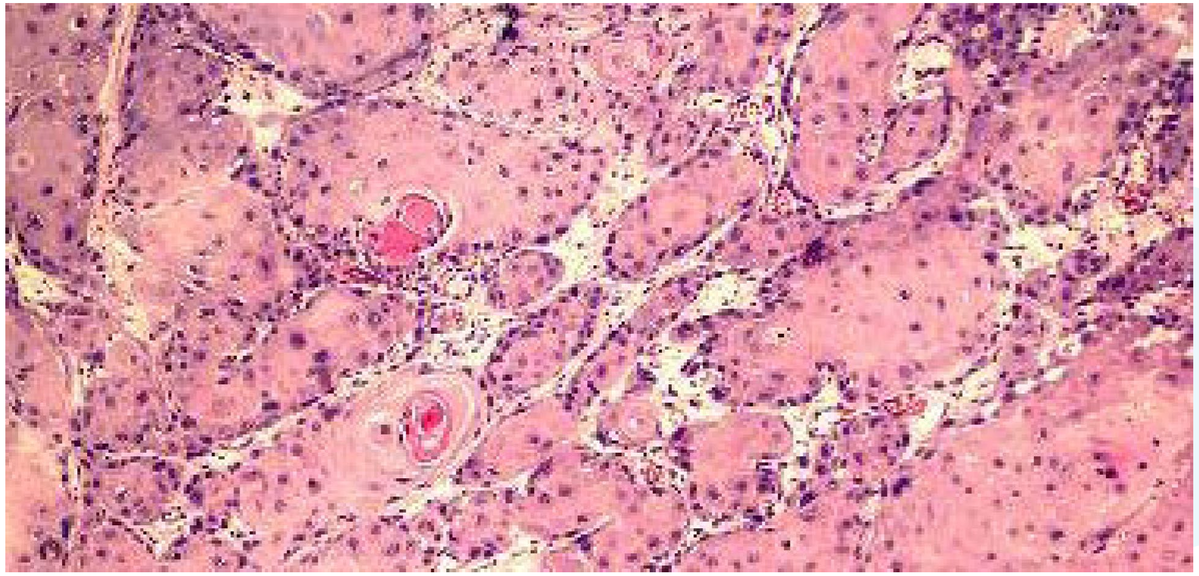
5-year Overall Survival: **73%** vs **45%**

Kaplan-Meier Overall Survival for Multikine target population (n=114)

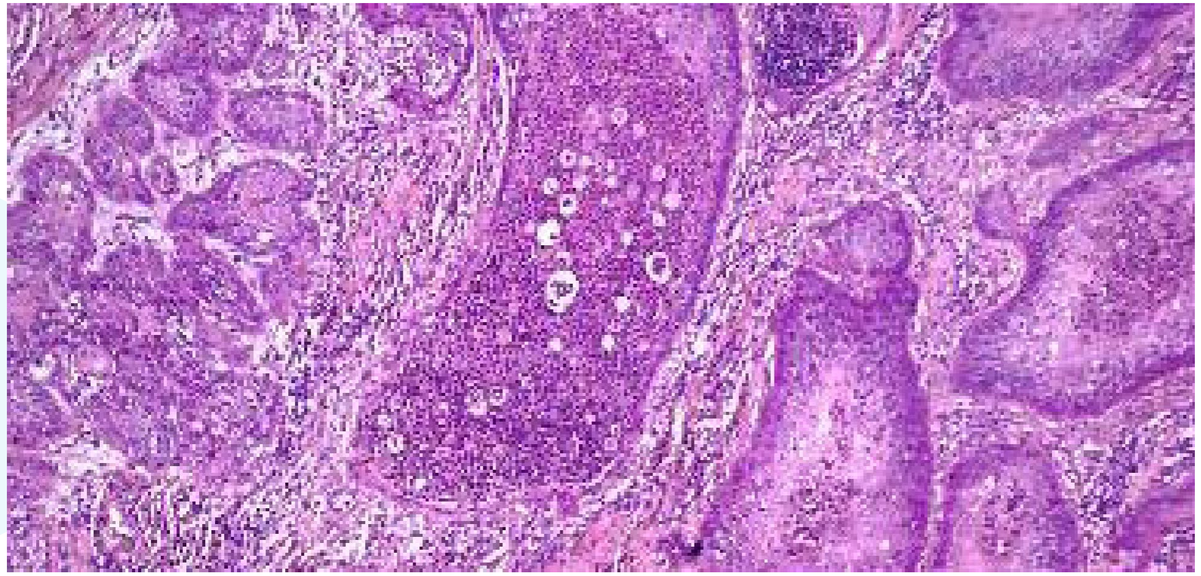
Some Patients Have Complete Tumor Responses in Just 3 Weeks

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
Lack of necrosis in the epithelial nests of OSCC



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

Highly De-Risked Confirmatory Study With Potential Approval by 2026

- Statistically the chance of success in the confirmatory study is estimated at over **95%.**
- Potential accelerated/conditional approval by 2026, based on tumor responses predictive of survival.
- Better overall survival (OS) benefit than needed for approval—We showed a 28% absolute survival benefit at 5-years, but we only need to show 10% survival benefit to succeed with the study.
- Tumors disappear and shrink in just 3 weeks of Multikine treatment; zero such responses reported in the control group.
- OS is the 'gold standard' for approval.
- Approval would create a new standard of care in the treatment of PD-L1 low newly diagnosed head and neck cancer patients (about 70%).
- This should create a multi-billion $ market with no competitor. We also have the FDA's Orphan Drug Designation allowing multi-year market exclusivity.

The Value of Cancer Drugs That Increase OS is Very High

Acquisition Price	Date	Deal Description
$10 Billion	2024	**AbbVie acquired ImmunoGen** for its antibody-drug conjugate (ADC) for ovarian cancer; ImmunoGen had one FDA approved drug with a few others in Phase 1 and 2 at the time of acquisition
$21 Billion	2020	**Gilead Sciences acquired Immunomedics** for its ADC Trodelvy, approved for triple negative breast cancer and investigated to potentially treat other cancers
$11.4 Billion	2019	**Pfizer acquired Array BioPharma** which had 2 approved small molecule cancer drugs to treat melanoma; These drugs were being investigated to treat other cancers at the time of acquisition
$9 Billion	2018	**Celgene acquired Juno Therapeutics**, focused on immunotherapy and CAR-T cell therapies, to expand its cancer treatment portfolio; Juno had no approved drugs at the time of the acquisition though its lead candidate was expected to receive approval and subsequently did in 2021
$11.9 Billion	2017	**Gilead Sciences acquired Kite Pharma** for its CAR-T cell therapies, particularly Yescarta for certain types of blood cancers; At the time of acquisition, Kite had no FDA approved drugs, though Yescarta was under FDA priority review and got approval within a few months of the acquisition
$14 Billion	2016	**Pfizer acquired Medivation**, known for its blockbuster approved prostate cancer drug Xtandi
$21 Billion	2015	**AbbVie acquired Pharmacyclics** primarily for its blockbuster drug Imbruvica, used to treat blood cancers like chronic lymphocytic leukemia

Investment Catalysts: Head & Neck Caner is Multi-Billion Market

Strong Survival Data for Unmet Medical Need

The goal of the confirmatory study is to show an absolute **10% or better** survival benefit. The analysis of these patients in the completed Phase 3 study showed a much higher absolute survival benefit of **28% over control**. No other drug has been approved in Multikine's indication focused on PD-L1 low (70% of patients).

FDA Approval Pathway: As Early as 2026

Confirmatory study of **212 patients**. FDA found the proposed study design acceptable and gave the go-ahead.

Study Starts Q1 2025

Study expected to start in **Q1 2025**. This study will enroll the same type of patient that showed excellent long-term survival benefit in the completed Phase 3 study (those with no lymph node involvement and low PD-L1).

Plan to Request Accelerated/ Conditional Approval

Expected to complete enrollment in **Q2 2026**. Response to 3-week Multikine treatment confirmed at surgery would lead to submission for potential accelerated approval (FDA) and/or conditional approval (rest of world).

Statistically, 95% Chance of Success for Confirmatory Study

Given the results of the prior Phase 3 study, statistically the **chance of success is 95%.** We believe the confirmatory registration study will be successful.

More on CEL-SCI, Multikine and Pathway to Approval

What is Multikine?

Multikine is an investigational cancer immunotherapy with *little to no toxicity* that activates the immune system of cancer patients. It is given before surgery, radiotherapy and chemotherapy have compromised or destroyed the immune system.

Normally cancer drugs are developed for recurrent cancer patients, those patients who have already failed other treatments.

Our goal is to establish a new Standard of Care (SOC) for newly diagnosed head and neck cancer patients which would add Multikine treatment before surgery etc.

Multikine is not tumor specific. Therefore, it should also be developed against other solid tumors such as cervical, anal, melanoma, bladder and breast cancer.

How Does Multikine Work?

Multikine is a mixture of natural cytokines (regulators of our immune system).

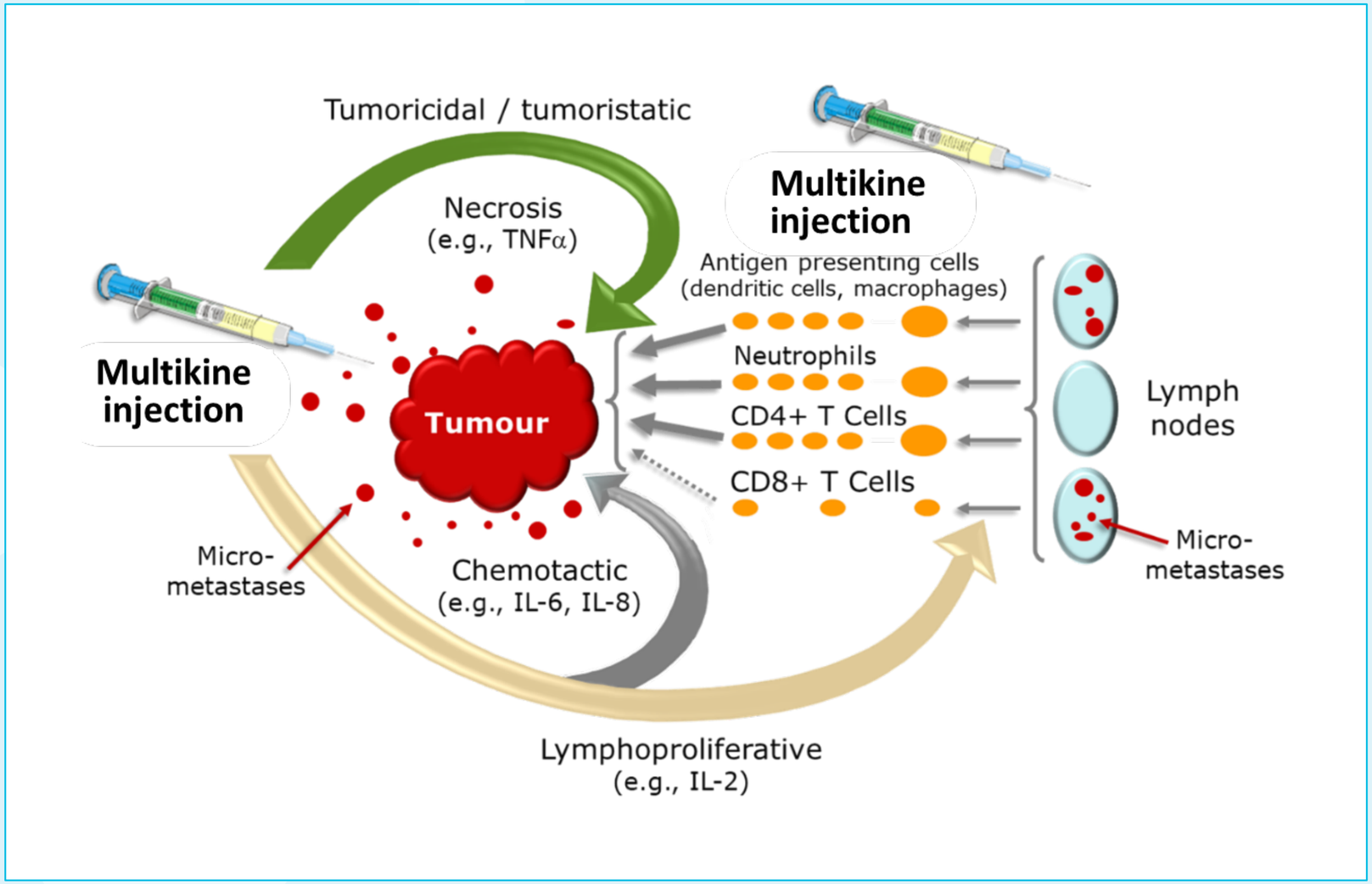
It helps the body's immune cells recognize a tumor when the immune system is strongest, before surgery, radiotherapy and chemotherapy.

Published studies of cancer patients have shown anti-tumor immune cells infiltrating the tumor, but not able to destroy the tumor because the tumor's defense mechanisms blocks them.

Treating with Multikine helps the body's natural immune cells overcome the tumor's defense mechanisms, enabling the immune cells to kill the tumor cells.

It is a non-toxic, mass-produced (off-the-shelf) product, which becomes specific to a person's own tumor when injected near that person's tumor and adjacent draining lymph nodes.

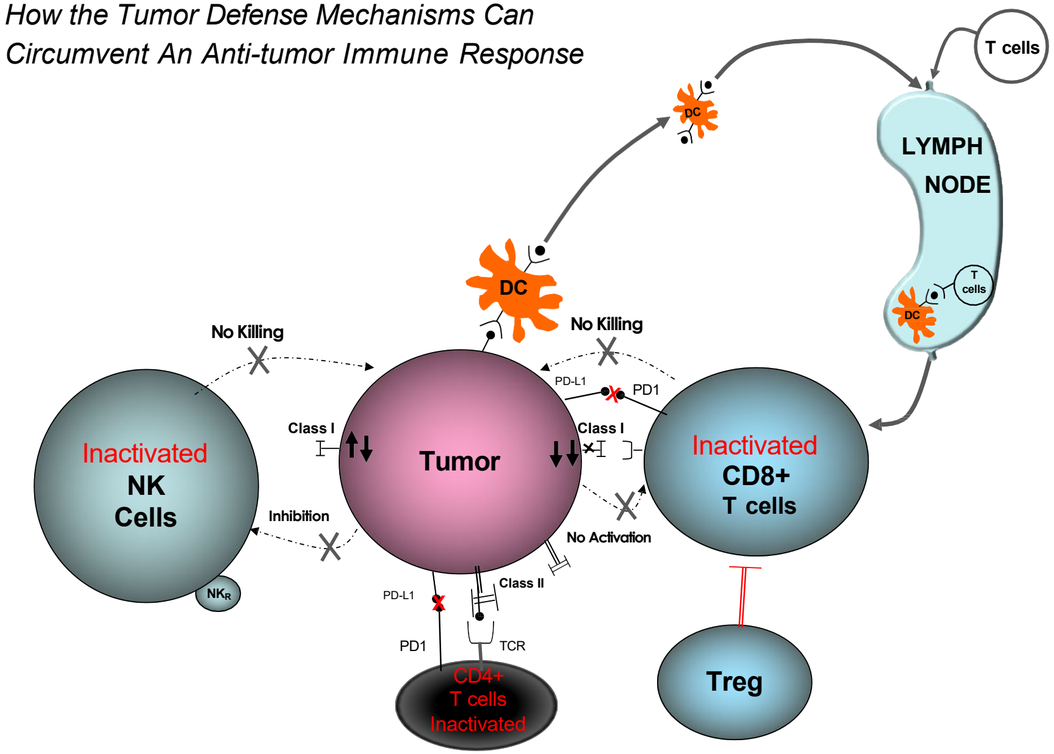
Multikine Mechanism of Action



Tumor Cell Death Without and With Multikine

Without Multikine

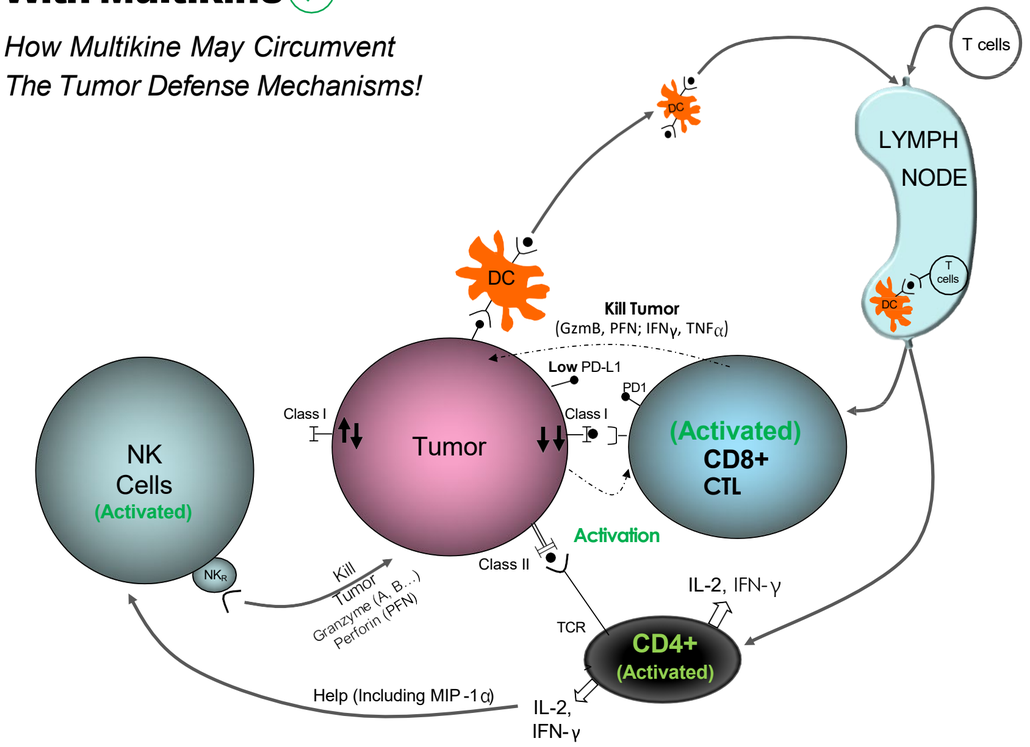
How the Tumor Defense Mechanisms Can Circumvent An Anti-tumor Immune Response



CD4+, CD8+ T-cells and NK cells and “blocked” by the tumor (PD-L1-x-PD1 interaction, HLA Class I and II modulation, etc.). Decreasing Immune cells’ ability to kill the tumor.

With Multikine

How Multikine May Circumvent The Tumor Defense Mechanisms!



Administration, tumor-specific activated CD4+ helper T cells “rescue” and activate tumor residing CD8 and NK cells, which then kill the tumor. Tumor low (no) expression of PD-L1 reduces tumor defenses making it more susceptible to immune attack.

Multikine's Target Population for the Confirmatory Registration Study

Target Population for Confirmatory Study

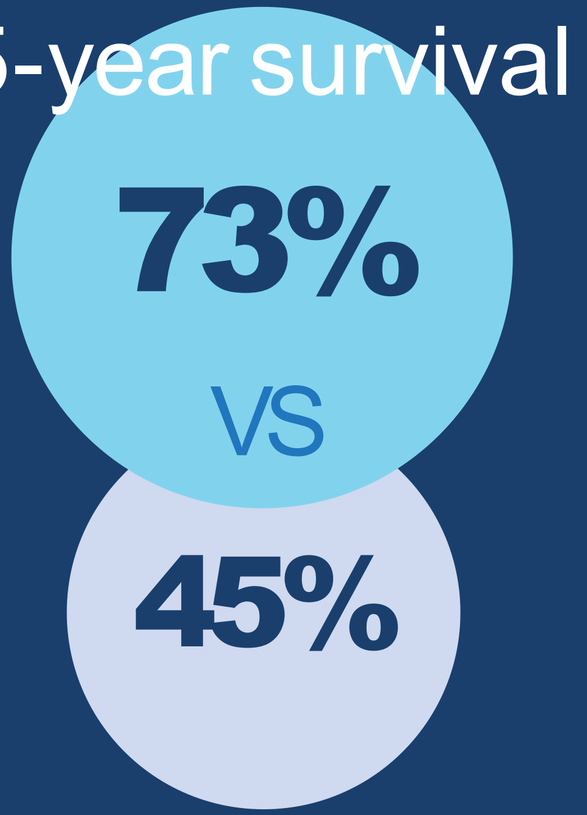
The 212-patient confirmatory study will focus on these patients:

→ Newly diagnosed **locally advanced primary (stage 3 and 4) head and neck cancer patients** with:

- **no lymph node involvement ("N0")** (determined via PET scan) and
- **low PD-L1 tumor expression** (determined via biopsy).

- Physicians routinely assess these features at baseline as part of standard practice.
- This population represents approximately 100,000 patients globally per year.

Kaplan-Meier Overall Survival
for Multikine target population (n=114)
in the Phase 3 study



Why "*N0*" (No Cancer in the Lymph Nodes)?

These stage 3 and 4 very sick cancer patients are the ones who have the best survival with Multikine and also the best tumor responses and tumor elimination as shown in the prior study. Why?

- ***"N0"***, no cancer in the lymph nodes, means a more functional immune system, which, in turn, produces better anti-tumor immune response. That makes sense since Multikine activates the immune system.

- ***"N0"*** also means unlikely to have chemotherapy added to treatments following surgery. That also makes sense since our data shows that we should avoid chemotherapy.

- This group alone had a hazard ratio a bit over 0.5, already very good and below (below is good) the 0.7 needed for approval in oncology studies.

Why Low PD-L1 Tumor Expression?

70% of the patients treated in our Phase 3 study had low or zero levels of PD-L1 expressed by their tumors. These patients had both the best tumor responses and the best survival with Multikine.

PD-L1 is a brake on the immune system. Multikine works better if there is no brake on the immune system since it activates the immune system to fight cancer. Therefore, Multikine works better in patients with little to no PD-L1 (no brake on immune system).

This selection criteria (i.e., having tumors with low PD-L1 expression) lowered the hazard ratio to an even better 0.35 (the lower the better) and lowered the upper limit of the 95% confidence interval to 0.66, thereby giving us an excellent chance of success in the study and for approval since both are below 0.70.

FDA started focusing on the distinction in the level of PD-L1 expression in cancer patients in its first Oncologic Drugs Advisory Committee meeting on this subject on September 24, 2024.

We Focus on Those Cancer Patients Checkpoint Inhibitors Cannot Help

We are not competing with checkpoint inhibitors Keytruda and Opdivo, the most successful cancer drugs in the world, selling over $40 billion per year.

- They extend survival in patients who have high levels of PD-L1 since they inhibit PD-L1, but do not appear to work well in patients who have low or zero PD-L1.
- We focus on patients who have little to zero PD-L1, which represents 70% of head and neck cancer patients.

Why Is The Chance of Success for the Study so High?

Very strong statistical significance shows likelihood of success in excess of 95%.

CEL-SCI's subgroup is based on a large number of patients (n=114).

"N0" (no cancer in the lymph nodes) selection was pre-specified in the protocol.

The selection for PD-L1, unavailable commercially when we started the study, was pre-specified in the Statistical Analysis Section prior to database lock.

The baseline and demographic characteristics of the two comparator groups in the Phase 3 that led to the selection of patients for the confirmatory registration study are well balanced. See *Bias Analysis* in next slide.

It makes biological sense.

FDA gave the go-ahead for this confirmatory study after review of all data.

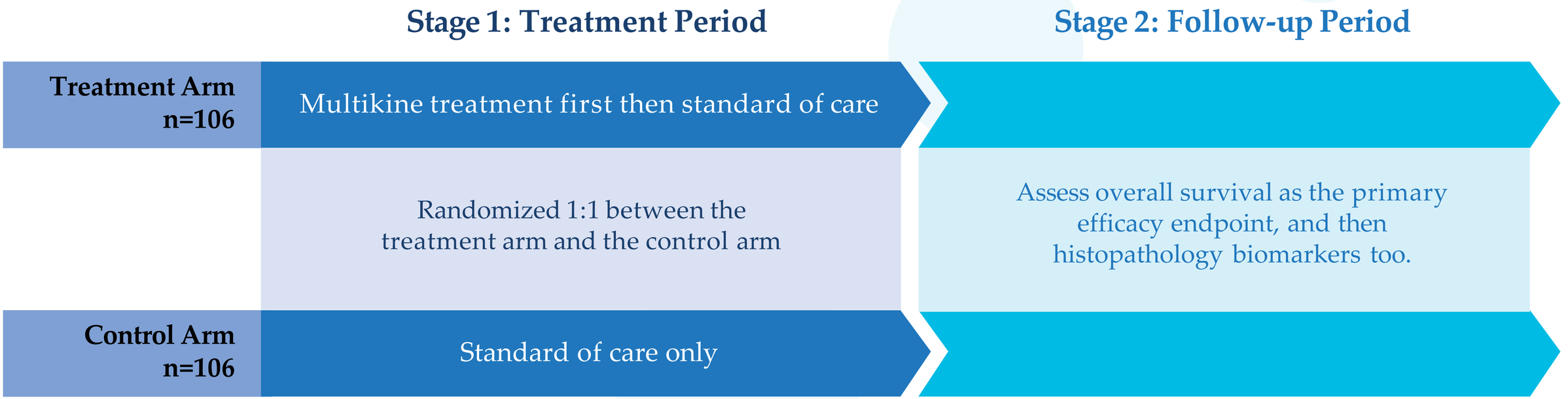
Data From the Bias Analysis

Phase 3 Study Selected Target Population N0, TPD-L1 ≤10 *(n=114, baseline characteristics, demographics)*

Baseline Covariate	Covariate Level	MK+CIZ+SOC (n=60)	SOC Only (n=54)
		Percents	Percents
Age	Mean (Range)	56.9 (33-76)	58.0 (35-80)
Sex	% Male	76.7	88.9
Race	% Asian % Black/AA % White/Caucasian	0.0 3.3 96.7	7.4 0.0 92.6
Ethnicity	% Not Hispanic/Latino % Not Reported	46.7 53.3	46.3 53.7
BMI	Mean (Range)	24.9 (17.4-33.4)	23.9 (18.2-36.1)
Tumor Location	% Oral Tongue % Floor of Mouth % Cheek (buccal mucosa) % Soft Palate	26.7 55.0 6.7 11.7	33.3 44.4 7.4 14.8
Baseline Stage	% Stage III % Stage IVa	65.0 35.0	74.1 25.9

Conclusion: The Target Population treatment groups demographics and baseline characteristic were comparable for MK+CIZ+SOC vs SOC Only (Control)

Tell Me About the Design of the Confirmatory Study



Q1 2025
Enrollment Begins

Q2 2026
Targeting Full Enrollment

Pre-surgical response rates can be determined almost immediately after full enrollment is completed.

Plan to seek early approval at this time in U.S. and other countries.

Conclusion

Timing is dependent on 65 patient deaths in the combined arms of the study

Who Will Lead the Confirmatory Registration Study?

Nabil F. Saba, MD, FACP

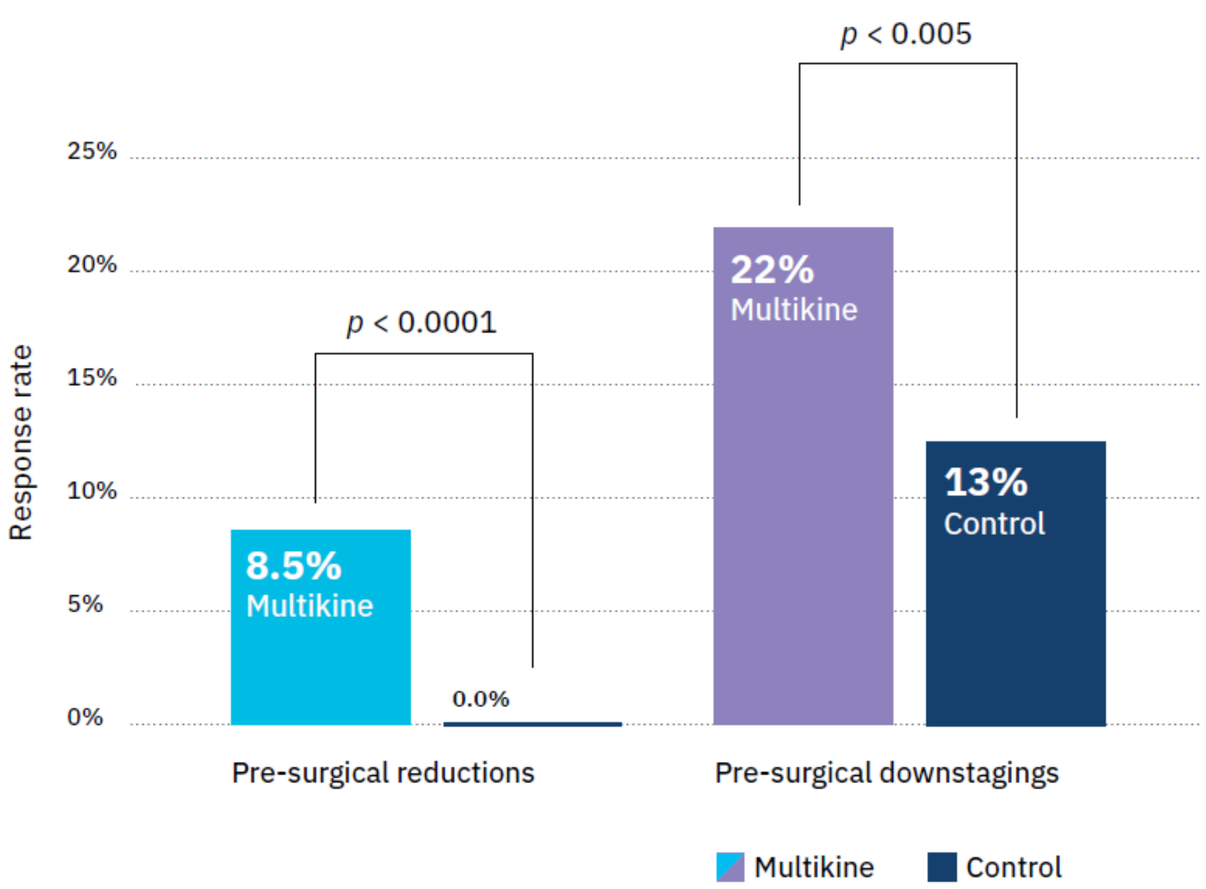
- Dr. Nabil F. Saba, MD, FACP will serve as the global clinical trial Lead for CEL-SCI's upcoming confirmatory registration study.
- Nationally and internationally recognized expert in head and neck cancer and is professor. Director of the Head and Neck Cancer Medical Oncology at Winship Cancer Institute of Emory University.
- Principal investigator in more than 50 clinical trials and chairs national as well as investigator initiated multi-institution studies focusing on novel approaches for treating head and neck and esophageal cancer.
- He is an active member of the NRG Oncology and Eastern Cooperative Oncology Group Head and Neck Cancer Core Committees, and chairs two NCI cooperative group trials in the field of head and neck oncology under the ECOG-ACRIN group.
- Published more than 290 peer reviewed manuscripts and textbook chapters and is editor of two textbooks and is a member of the ASCO Guidelines Committee.

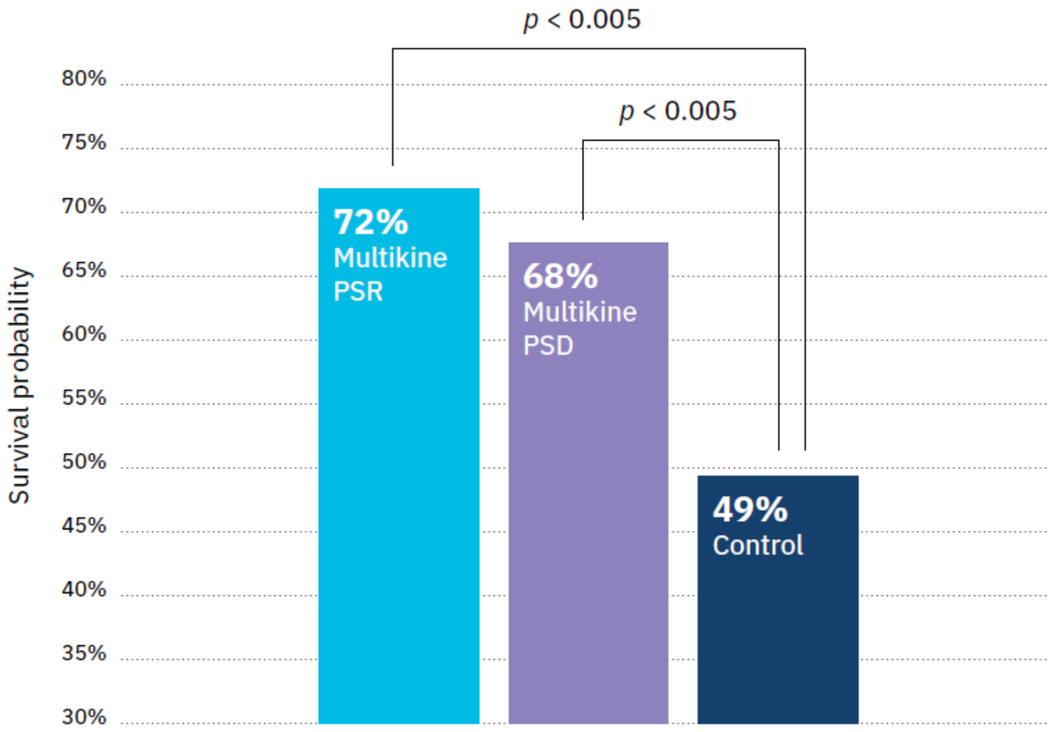
When Can the Study Lead to an Approval?

Per the FDA, we will be allowed to see the tumor response data after full enrollment, which we expect by Q2 2026. At that time, we plan to discuss with the FDA and other countries' regulators an early approval based on pre-surgical tumor responses shown to predict survival.

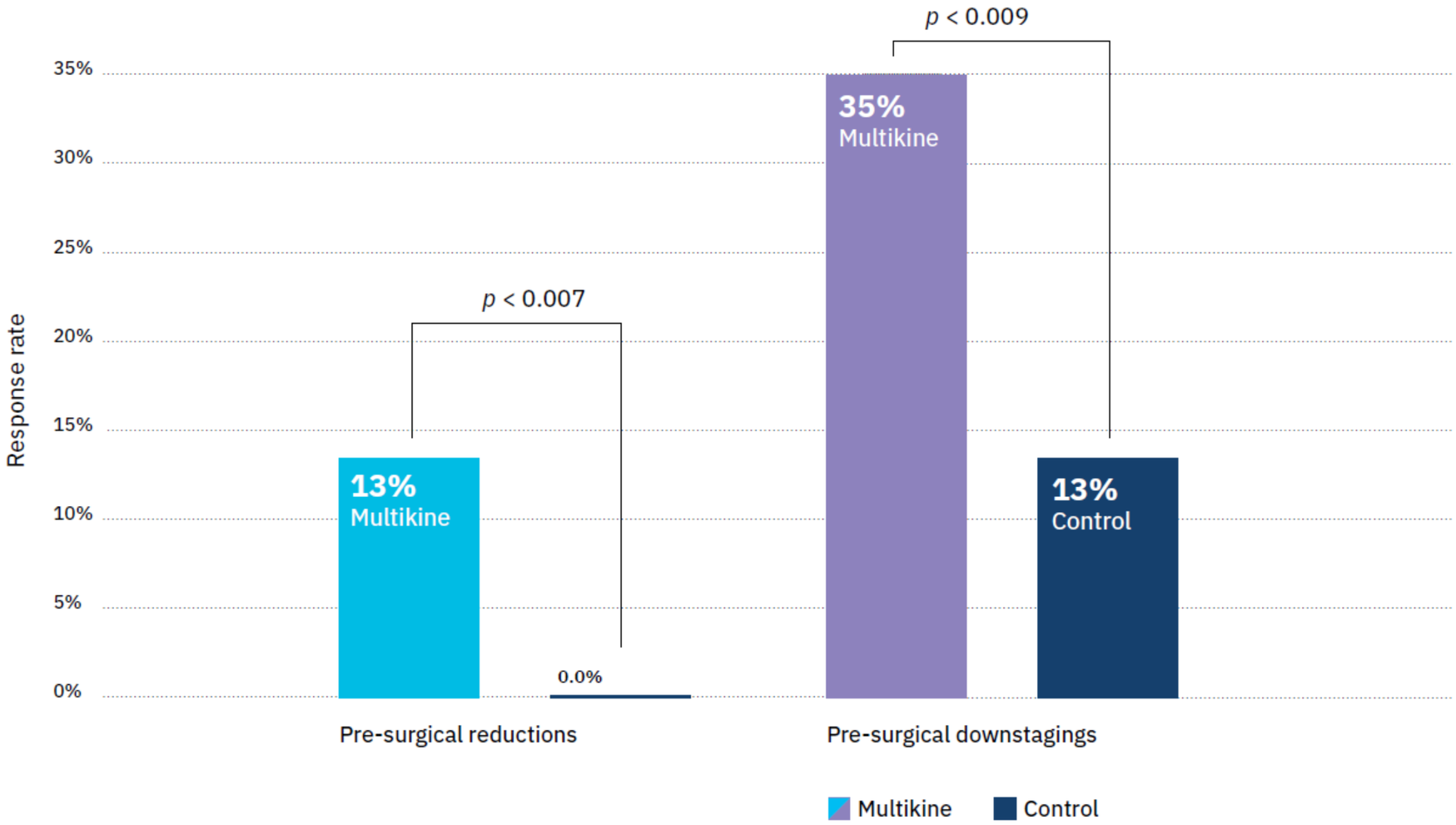
The very end of the study will occur when 65 patient deaths have occurred in the total population (the combined groups) of the study. At that time, we will analyze the survival benefit of Multikine over control and, if successful, the early approval will become a full approval.

Increased Pre-Surgical Tumor Responses Predict for Survival Across <u>All</u> Patients (n=928) in the Phase 3 Trial





Higher PSR/PSD Rates in the Target Population (n=114)



Manufacturing Facility Ready for Commercial-Scale Production of Multikine

Dedicated State-of-the-Art Manufacturing Facility as Requested by FDA

c GMP 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
→ Commissioning was achieved in February 2024. We are currently making drug for the new study

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/Regulations)

Barriers to competition – Process of manufacture

→ In house manufacturing process for complex biologic with initial capacity 12,000+ treatments per year

Over $200 million invested in drug manufacturing.

Dedicated facility was built before the Phase 3 trial started and the capacity was recently doubled in preparation for commercialization.

Stellar Management & Medical Advisory Team

Experienced Management Team

Geert Kersten, Esq.

Chief Executive Officer & Director since 1995

Experience in finance and law

Accounting, MBA and JD degrees

Eyal Talor, PhD

Chief Scientific Officer since 2009

Inventor / developer of Multikine®

30 years at CEL-SCI in R&D, Manufacturing and Clinical development

Author of over 30 peer-reviewed publications

Adjunct Faculty at Johns Hopkins University

Giovanni Selvaggi, MD

CEL-SCI Acting Chief Medical Officer since 2024

CMO at Xcovery (ongoing NDA for ensartinib, ALK TKI)

Clinical strategy consultant for Tubulis for first in class ADC program in solid tumors

Prior experience:

20 years in academia in Italy as clinician

GSK: Director in Cancer Immunotherapy

Novartis Oncology: led ceritinib (ALK inhibitor) to AA.

Oncolytics: VP of Clinical Development

BMS: Lung cancer Program Lead (multiple NDAs for nivolumab/ ipilimumab)

John Cipriano

Senior VP of Regulatory Affairs since 2004

Former FDA Deputy Director, Division of Biologics Investigational New Drug

Former FDA Deputy Director, IND Branch, Division of Biologics Evaluation, Office of Biologics

Degrees in pharmacy and pharmaceutical chemistry

Patricia Prichep

Chief Financial & Operations Officer

Previously Senior VP of Operations since 1992

Former Manager of Quality and Productivity for the NASD

BA from the University of Bridgeport

Top-Tier Physician Consultants Who Accompanied Us to Regulators

Barbara Burtness, MD

Anthony N. Brady Professor of Medicine (Medical Oncology) at Yale School of Medicine

Chief Translational Research Officer, Yale Cancer Center

Chief, Head and Neck Cancers/Sarcoma and Co-Leader, Developmental Therapeutics, Yale Cancer Center

Associate Cancer Center Director for Translational Research, Yale Cancer Center

Internationally recognized for her work in head & neck cancer and leads national and international head and neck cancer trials, extensively published

Marshall Posner, MD

Consultant for CEL-SCI since 2005

Principal Investigator and Chair of the IDMC in CEL-SCI's Phase 3 study Director, Head and Neck Oncology, Mt. Sinai NY

Co-Leader, Cancer Clinical Investigation Program, Tisch Cancer Institute More than 250 peer-reviewed publications

Mehmet Sen, MD, FRCR

Practicing head and neck oncologist and radiologist for >30 years in UK and Europe

Consultant Clinical Oncologist & Honorary Senior Lecturer, St. James Institute of Oncology, Leeds, UK

Council Member of the British Association of Head and Neck Oncologists (BAHNO)

Member, EORTC Head and Neck Cancer Group and the EORTC Radiotherapy Group (ROG)

Internationally recognized for his work in head & neck cancer and leads national and international head and neck cancer trials, extensively published

J. Edward M. Young, MD

Clinical Professor of Surgery, McMaster University 45+ years managing head and neck cancer

Former President of Society of Head and Neck Surgeons

Former head Surgical Oncology, Hamilton Regional Oncology Center, Canada

Principal Investigator in CEL-SCI's Phase 2 and 3 studies

Thank you!

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