Multikine™ “First In Class Immunotherapy” Cancer Therapy

First Indication: Head & Neck Cancer Neoadjuvant Immunotherapy

August 2024

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 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 in our public filings, and in the documents incorporated or deemed to be incorporated by reference therein. The forward-looking statements 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 CELSCI'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.

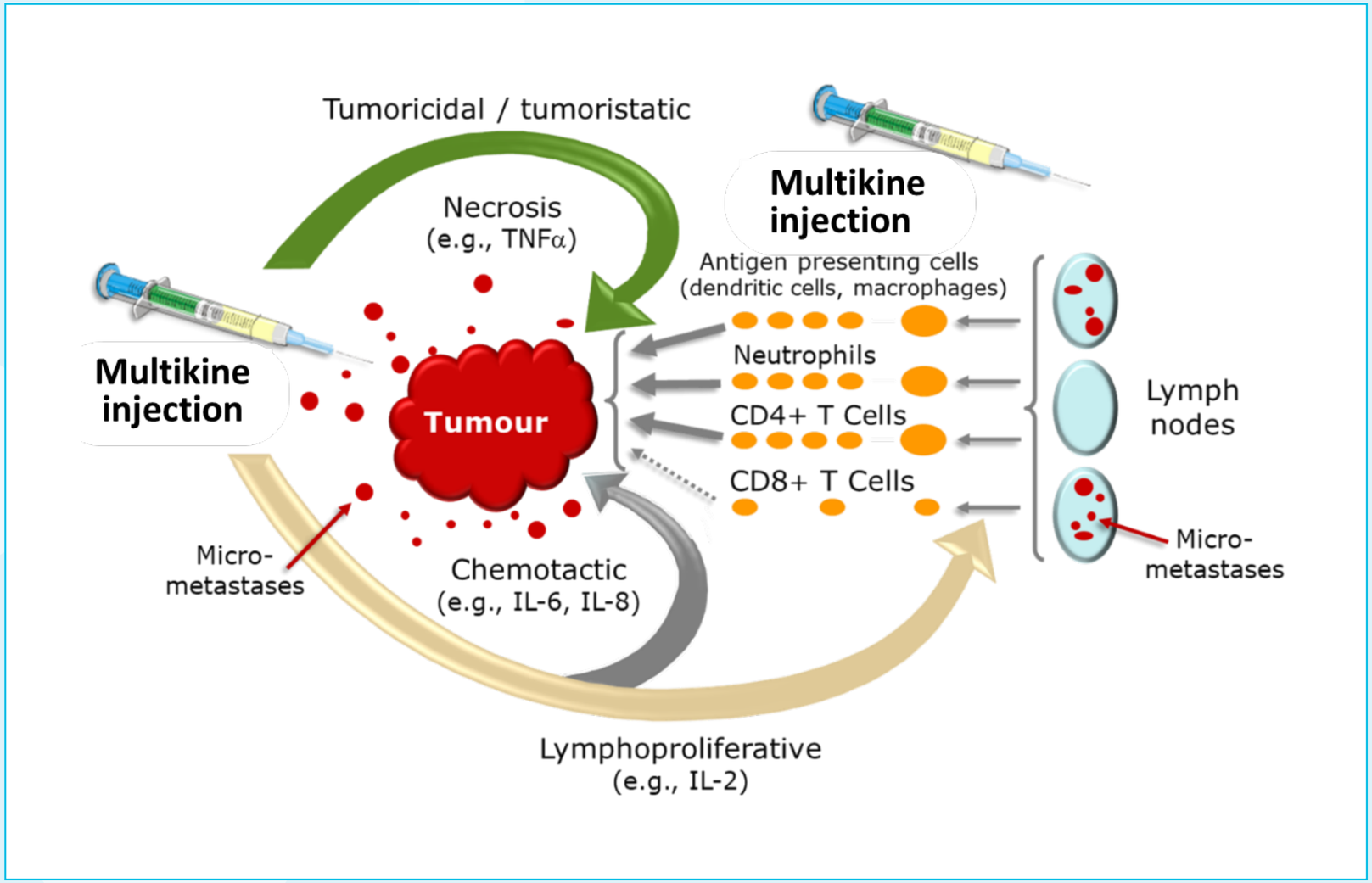
Company Overview

- → Multikine is a pre-surgical (neo-adjuvant) cancer immunotherapy initially focused on newly diagnosed stage 3 and 4 head and neck cancer patients, later on other cancers too.
- → Tested in a 928 patient randomized controlled Phase 3 study. Patients treated with Multikine followed by surgery and radiotherapy had a 46 month survival benefit compared to control; however, patients who had chemotherapy added to the treatment did not show survival benefit.
- → FDA required a confirmatory study focusing on those patients who have a good survival benefit with Multikine.
- → The data for the selected new target population shows a 5-year survival 73% vs 45% control and a Hazard ratio of 0.35 (a 65% reduction in chance of death compared to control).
- → FDA agreed to a 212-patient confirmatory registration study for Multikine focused on these patients.
- → Based on the survival data for the target population as previously seen in the Phase 3 study, we expect to be successful in the confirmatory study.
- → The baseline analysis for the target population showed no bias in favor of Multikine.
- → At the end CEL-SCI will either be sold or partnered to enable the development of Multikine for many different cancers.

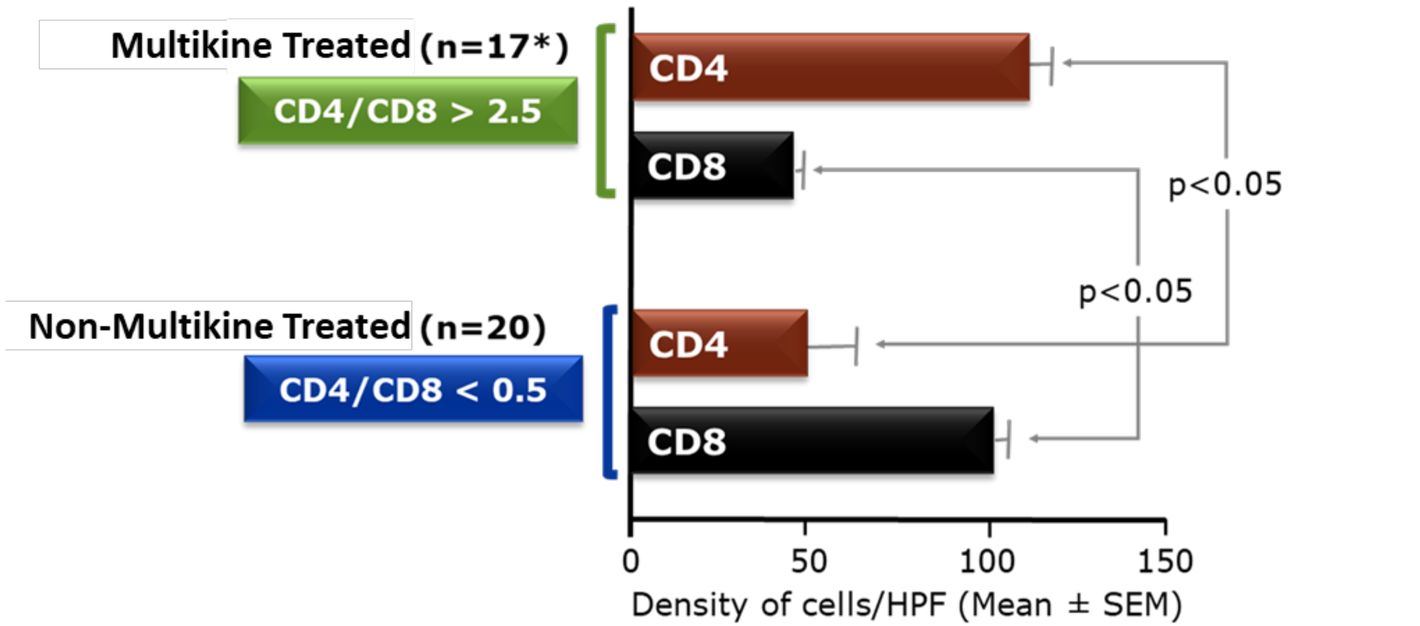
What is unique about Multikine?

- → Multikine is a **cancer immunotherapy**. It is a controlled mixture of natural cytokines and biological molecules that is given right after diagnosis, **before** surgery, radiation and chemotherapy have damaged the immune system.
- → This **approach is unique** compared to normal cancer drug development, which focuses on late-stage patients with metastasized or recurrent tumors.
- → Only a 3-week treatment is permitted to avoid delay of surgery. Other drugs require months of treatment. Also, the drug needs to be very safe and non-toxic since the patients are newly diagnosed. Multikine fulfilled those requirements.
- → **Head and neck cancer** is a devastating very hard to treat cancer (high unmet medical need) with a prevalence of 900,000 cases per year. The target population for Multikine has an estimated 100,000 cases per year. We believe success with Multikine would create a new standard of care.

Multikine Mechanism of Action



CD4 Increased In Multikine Treated Patients (Phase 2, Tímár 2005)

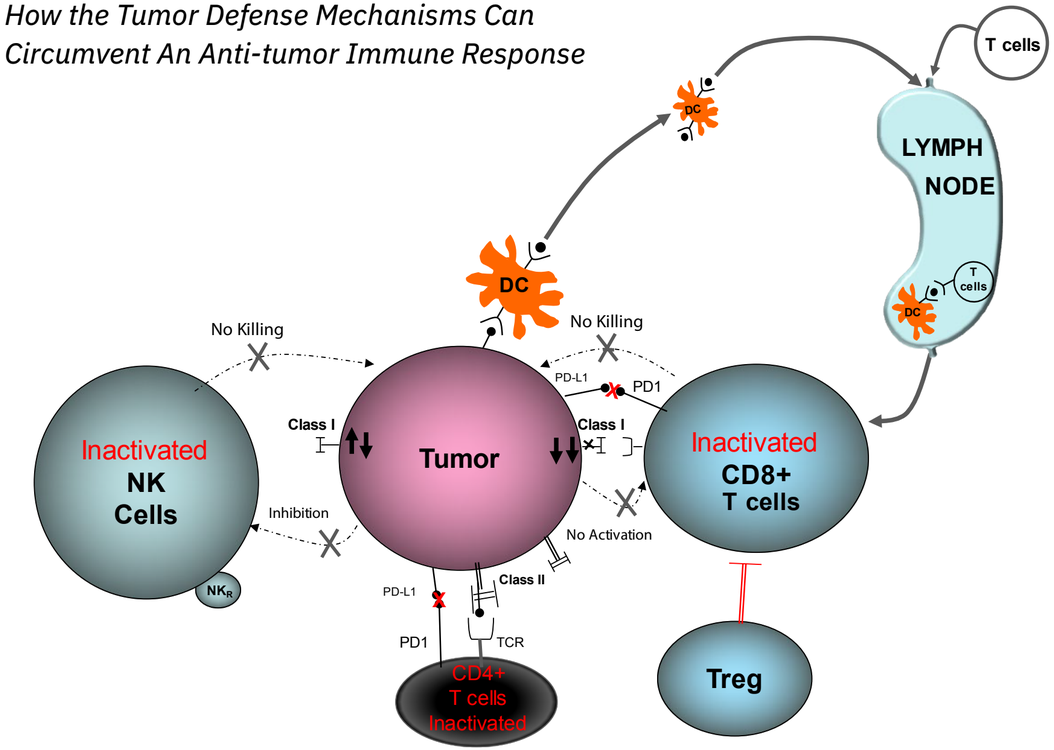


* Two Multikine-treated subjects had complete tumor responses before surgery

Tumor Cell Death Without And With Multikine

Without Multikine

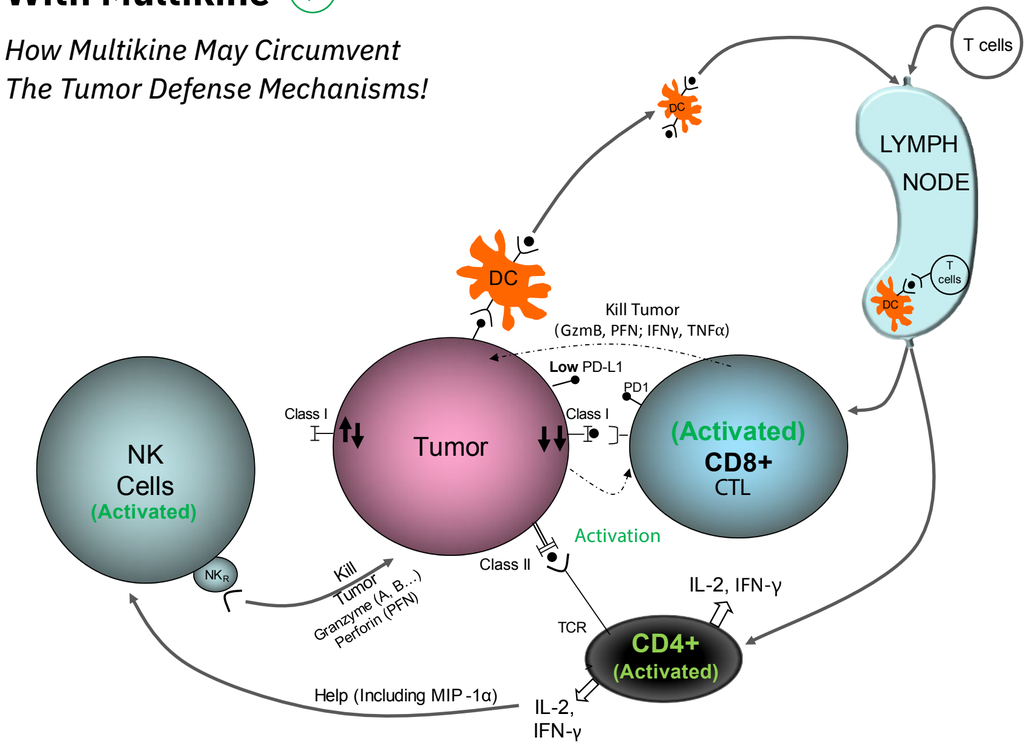
How the Tumor Defense Mechanisms Can Circumvent An Anti-tumor Immune Response



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

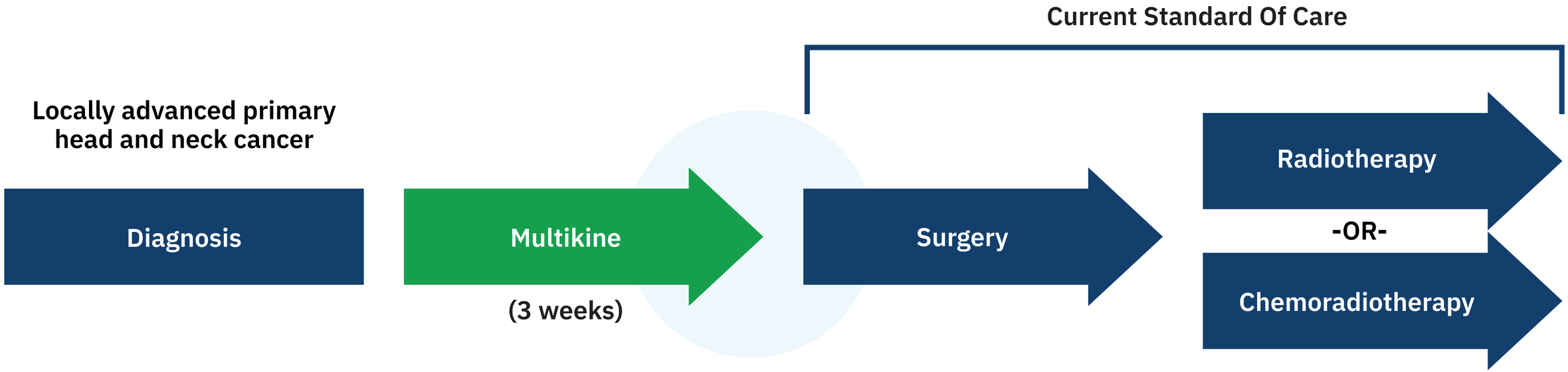
How Multikine May Circumvent The Tumor Defense Mechanisms!



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.

The Multikine Treatment Regimen

Multikine would be added to the current standard of care, delivered locally via injections around the tumor and adjacent lymph nodes for three weeks, 5 days per week before surgery:



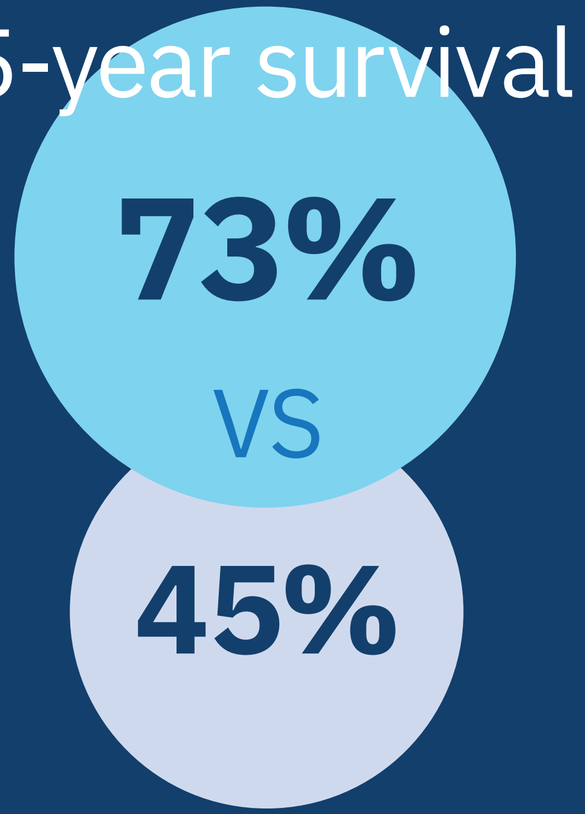
What is the Target Population?

The 212 patient confirmatory study will focus on these patients:

→ Newly diagnosed **locally advanced primary head and neck cancer patients** with **no lymph node involvement** (determined via PET scan) and with **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. If approved as a pre-surgical treatment, we believe Multikine should become part of a new standard of care for the target population.

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



Why N0, PET Scan, and Low PD-L1?

Why N0 (no cancer found in the regional lymph nodes)**?**

↪ The immune system needs the lymph nodes to work. If nodes are damaged by disease, then the immune system is less effective. Patients with “N0” can mount the strongest immune attack.

Why PET scan?

↪ PET Scan provides greater sensitivity than standard techniques. This ensures that patients are truly “N0,” which means the disease has not spread to the lymph nodes.

Why low PD-L1 tumor expression?

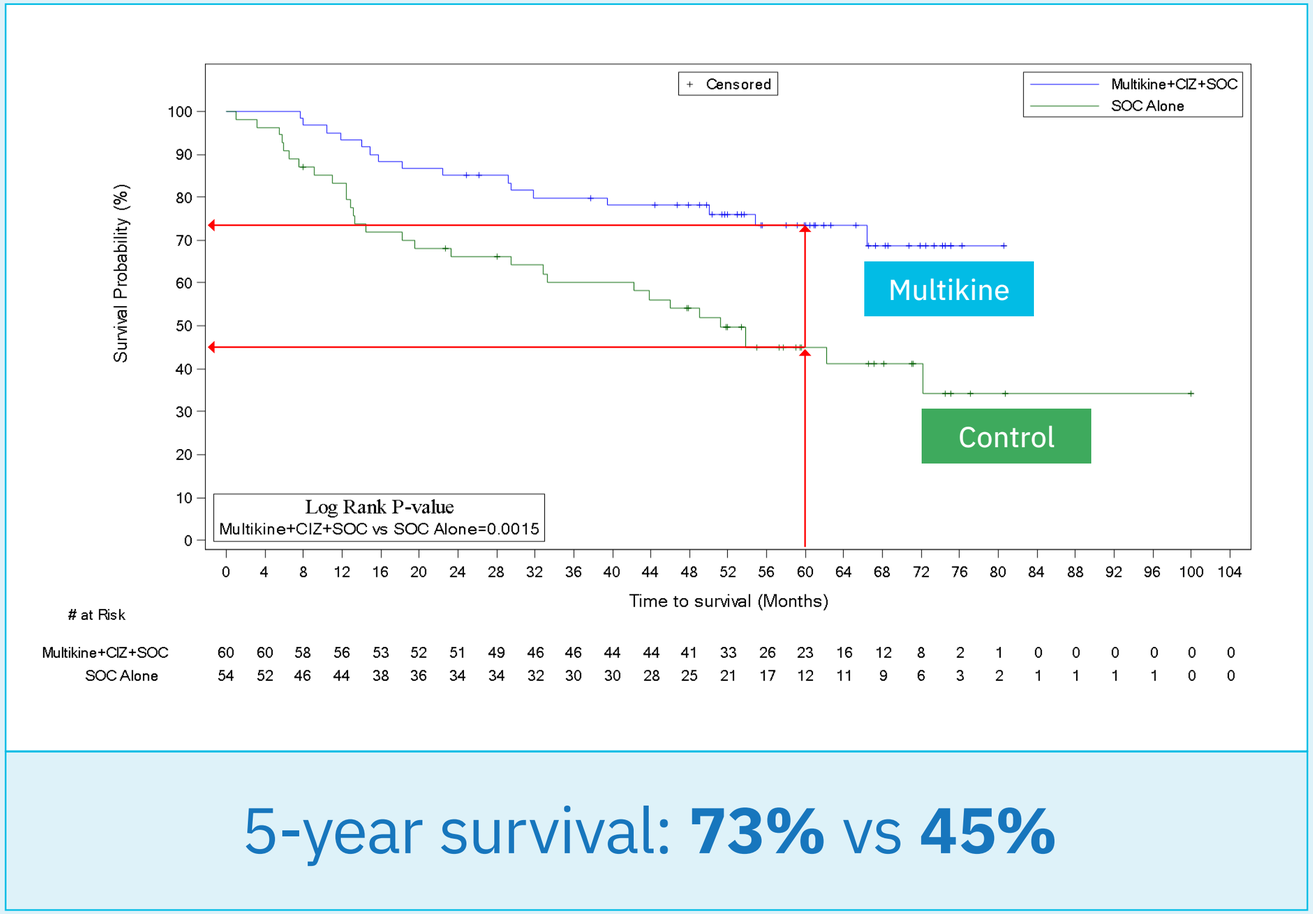
↪ PD-L1 is a protein on the tumor surface that acts as a kind of “brake” to keep the body’s immune responses under control. When PD-L1 binds to another protein called PD-1 (a protein found on immune T cells), it keeps T cells from killing the PD-L1-containing tumor cells. Tumors with low PD-L1 expression do not have much of a brake on the immune response and are therefore more susceptible to an immune attack incited by Multikine. It is estimated that about 70% of these head and neck cancer patients have low PD-L1 tumor expression.

In the Target Population: Improved Survival In Patients

Data Presented at European Society for Medical Oncology in October 2023

- **No safety signals** or toxicities vs standard of care
- **73% survival** for Multikine vs 45% in the control
- Statistically significant (log rank **p = 0.0015**)
- **Hazard ratio = 0.35** (95% CIs [0.19, 0.66])

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



5-year survival: **73%** vs **45%**

Bias Analysis Results

- → Conducting a bias analysis is a standard process used to identify, assess, and address potential sources of bias that could influence the outcomes and interpretations of study results. The goal of a bias analysis is to ensure that the trial's findings are reliable, the conclusions are valid, and to minimize the risk that bias has distorted the results.
- → The bias analysis was conducted for the entire Phase 3 study population of 923 patients with newly diagnosed resectable, locally advanced primary head and neck cancer, as well as the subgroup of 114 patients who had no lymph node involvement and had low PD-L1 tumor expression (determined via biopsy), the target population for our upcoming confirmatory registration study.
- → The bias analysis concluded that the treatment group demographics and baseline characteristics were comparable for the Multikine treated and control arms of the Phase 3 study. No bias was present in the study and none was detected in favor of the investigational product, Multikine.
- → As such, the study data are reliably interpretable, statistically significant and have been shown to support the clinical effect of neoadjuvant (pre-surgery) Multikine immunotherapy in extending the life of these patients in the Phase 3 study.

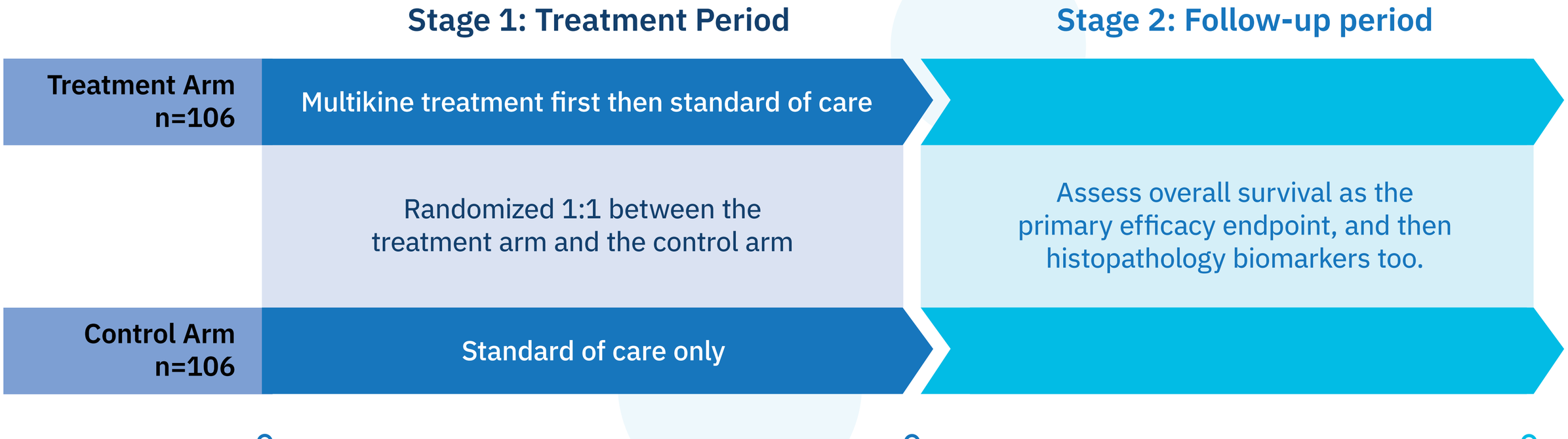
Data From the Bias Analysis

Phase 3 Study Population N0, TPDL1 <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 treatment groups demographics and baseline characteristic were comparable for MK+CIZ+SOC vs SOC Only (Control)

Our Registration Study Design



Q4 2024 / Q1 2025

Enrollment Begins

Q2 2026

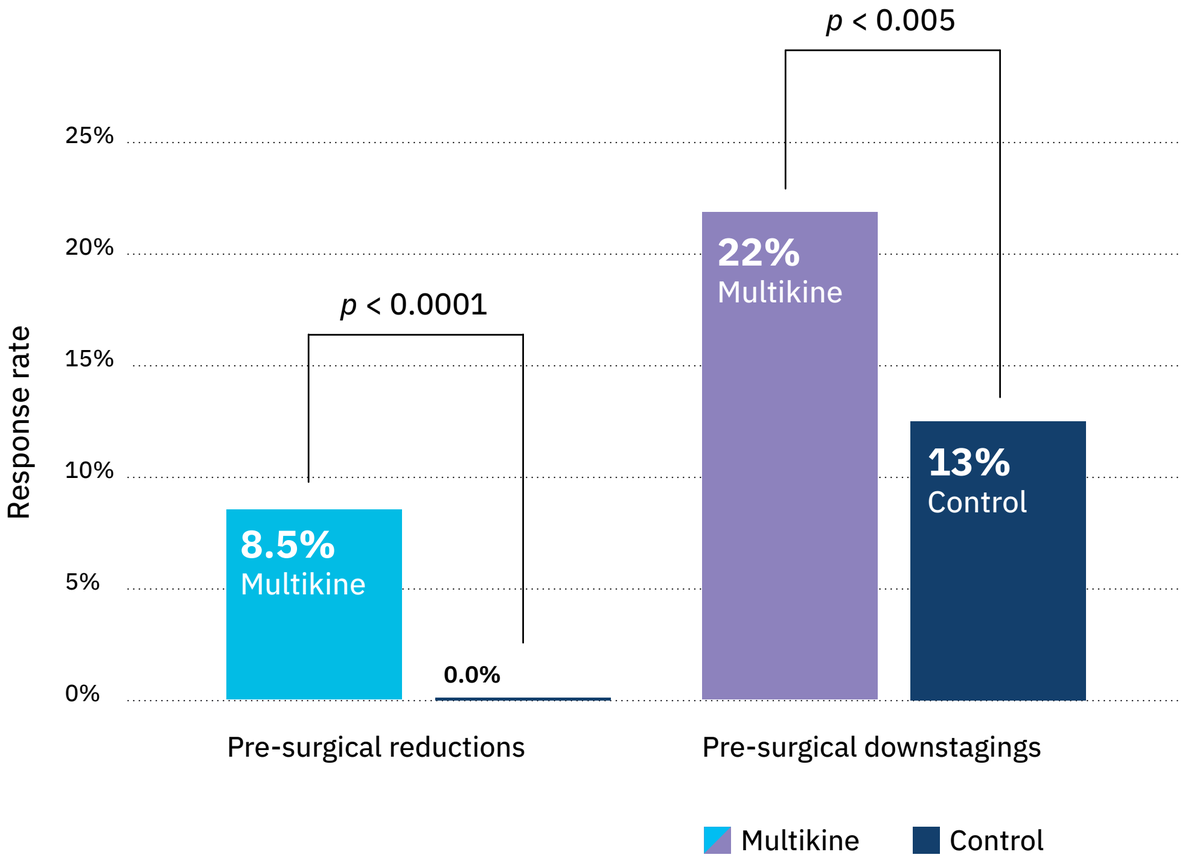
Full Enrollment

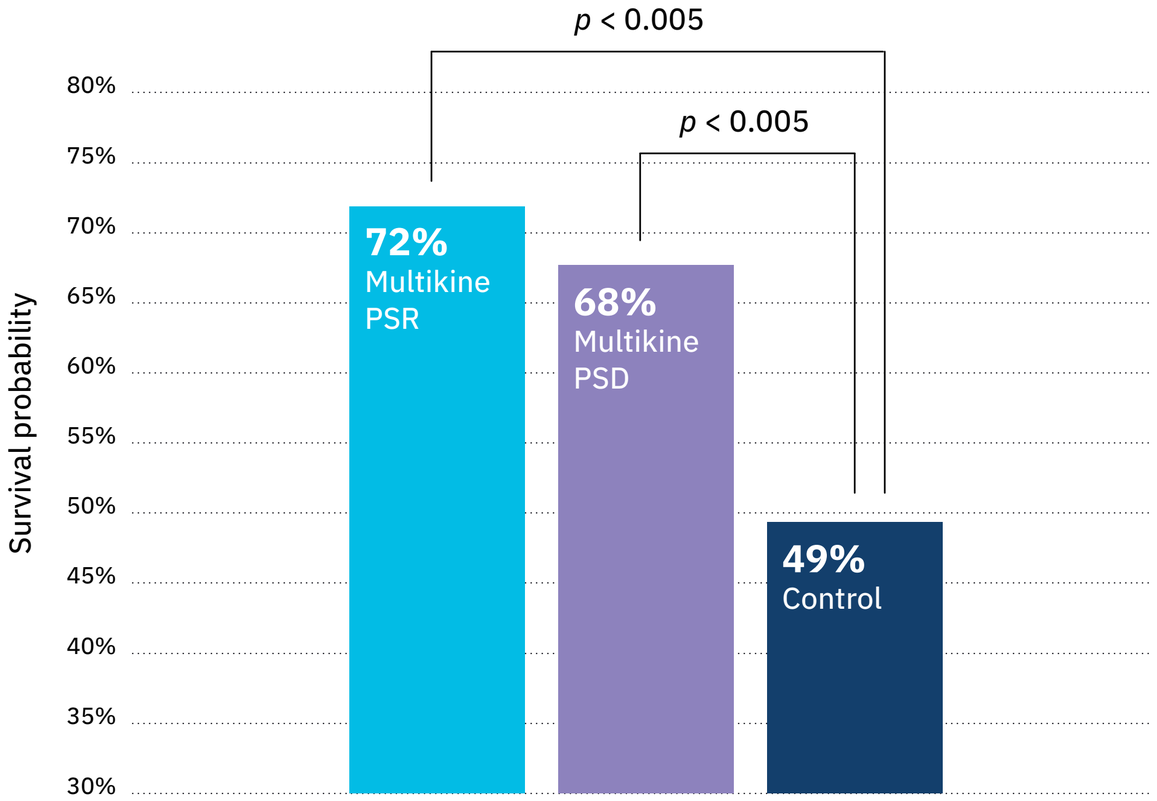
Pre-surgical response rates can be determined almost immediately after full enrollment is completed. Potential to seek early approval at this time.

Conclusion

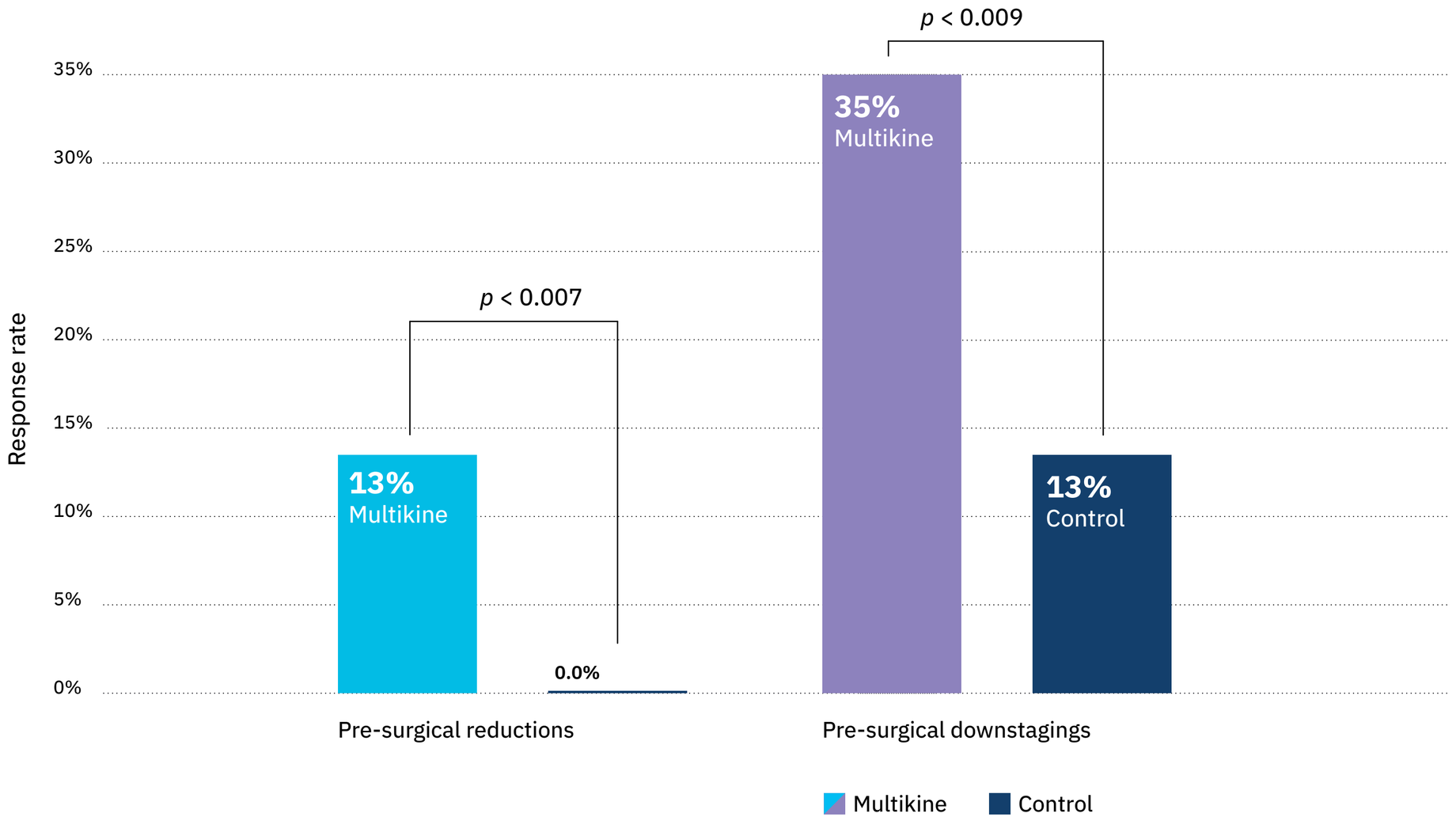
Timing is dependent on 65 patient deaths

Increased Pre-Surgical Tumor Responses Appear to Lead to Increased Survival Across All Patients in the Phase 3 Trial





Higher PSR/PSD Rates in the Target Population



Safety Observed Across the Entire 750 Patient Population

- No Multikine-related systemic AEs (Adverse Effects) or SAEs (Serious Adverse Effects).
- No Multikine-related delays of surgery.
- No Multikine-related interference with post-surgical treatment.
- No Multikine-related deaths.

Why Do We Believe Our Confirmatory Study Will Be Successful?

- → 73% survival for Multikine in the target population vs 45% in the control, at 5 years. Statistically significant (log rank p = 0.0015).
- → Hazard ratio = 0.35 in the target population, (95% CIs [0.19, 0.66]). This means we observed that patients who took our drug experience a 65% reduction in the risk of death compared to those not receiving our treatment.
- → No safety signals or toxicities vs standard of care.

Multikine Partners[1]

Teva Pharmaceuticals
International pharmaceutical company

Orient EuroPharma
Taiwan based pharmaceutical company

Ergomed
Leading Clinical Research Organization (CRO) for head and neck cancer

MD Anderson
for radiation qualification

1 Represents partners from our previously completed Phase 3 trial, and there is no guarantee they will continue to partner with us in our confirmatory registration trial.

Dedicated State-of-the-Art Manufacturing Facility

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
- → Commissioning was achieved in Feb 2024, and validation expected to be completed in Summer 2024.

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)

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.

The CEL-SCI Team

Geert Kersten, Esq.

Chief Executive Officer & Director since 1995

Experience in investment banking 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 Medical Advisor 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

Senior VP of Operations since 1992

Former Manager of Quality and Productivity for the NASD

BA from the University of Bridgeport

Board of Directors

Robert Watson

Chairman of the Board of Directors

Mr. Watson has been a director of CEL-SCI since December 2017. He is an accomplished business leader with over four decades of experience across various healthcare markets.

Geert R. Kersten, Esq.

Director and Chief Executive Officer

Geert Kersten has served in his current leadership role at CEL-SCI since 1995. Mr. Kersten has been with CEL-SCI from the early days of its inception since 1987.

Bruno Baillavoine

Director

Mr. Baillavoine has been a Director of CEL-SCI since June 2015. Since 2017 Mr. Baillavoine has been the Director, Head of Pericles Group UK the subsidiary of the Paris based leading French consulting firm.

Mario Gobbo

Director

Mr. Gobbo has been a Director of CEL-SCI since April 2024. He has nearly 40 years of banking and corporate finance experience in healthcare and energy.

Top-Tier Physician Consultants

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

Opinion of a Key Opinion Leader in Head and Neck Cancer?

Multikine in the curative setting is unique. The confirmatory study is an opportunity to improve overall survival in the eligible patient population without increasing toxicity. ***It is a potential game changer in the management of oral cavity cancers.***

— Dr. Mehmet Sen

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)

Opinion of a Key Opinion Leader in Head and Neck Cancer?

As a surgical oncologist who has treated oropharyngeal cancer for 45 years, and witnessed the results of our often failure to control the disease (whether by surgery, radiation, chemotherapy or any combination of all three), I was impressed by the positive results of this local treatment without the often severe systemic effects of chemotherapy. This treatment is virtually symptom free. The local injections are extremely well tolerated and easily administered. A treatment this simple with results this good should be available to appropriate patients and may replace adjuvant chemotherapy (with all the benefits or patients and the health care system that would achieve). My guess is that this treatment in other head and neck cancer sites may prove to be equally efficacious.

— Dr. J. E. M. Young

Clinical Professor of Surgery, McMaster University
Hamilton, Ontario, Canada

Investment Highlights and Milestones

Strong survival data

The goal of the confirmatory study is to show an absolute **10%** survival benefit. The analysis of these patients in the completed Phase 3 study showed a much higher survival benefit of **28%**.

Addressing an unmet medical need

No drug is approved as a pre-surgical treatment in head & neck cancer. In addition, **Multikine focuses on the 70% of patients** not well served by the two leading approved drugs for head and neck cancer, *Keytruda* and *Opdivo*, both of which are also not approved as pre-surgical treatments, the proposed Multikine indication.

FDA approval pathway

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

Enrollment commences

Enrollment expected to commence in **Q4 2024 / 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 N0 and low PDL1).

Our belief on the clinical trial

Given the results of the prior Phase 3 study, we believe the confirmatory registration study will be successful.

Thank you!

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