Multikine™ "First In Class Immunotherapy" Cancer Therapy

First Indication: Head & Neck Cancer Neoadjuvant Immunotherapy

November 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 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.

The CEL-SCI 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

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

Key Facts About CEL-SCI Corporation

→ NYSE American, stock symbol CVM.

→ We believe cancer immunotherapy should be administered before surgery, radio and chemotherapy have destroyed the immune system. The goal is to make the first cancer treatment more successful so that the tumor does not kill the patient.

→ Completed a 928 patient head and neck cancer Phase 3 study.

- 46 month (nearly 4 years) survival benefit over control when our cancer immunotherapy drug Multikine was followed by surgery and radiotherapy
- but no survival benefit in patients who had chemotherapy added to the treatment.

→ We identified the patients who have the best survival and FDA gave go-ahead for a confirmatory study of 212 patients.

→ The confirmatory study is being designed with FDA input to be the sole registration study. EU and UK regulators agreed that no pediatric studies are needed.

Key Facts About CEL-SCI Corporation

→ Expects to initiate the confirmatory registration study in Q1 2025.

→ By Q2 2026, we expect full enrollment, data on pre-surgical response rates (indicative of overall survival results), and we plan to seek early approval in the U.S. and other countries based on these results.

→ This study is designed to do two things:

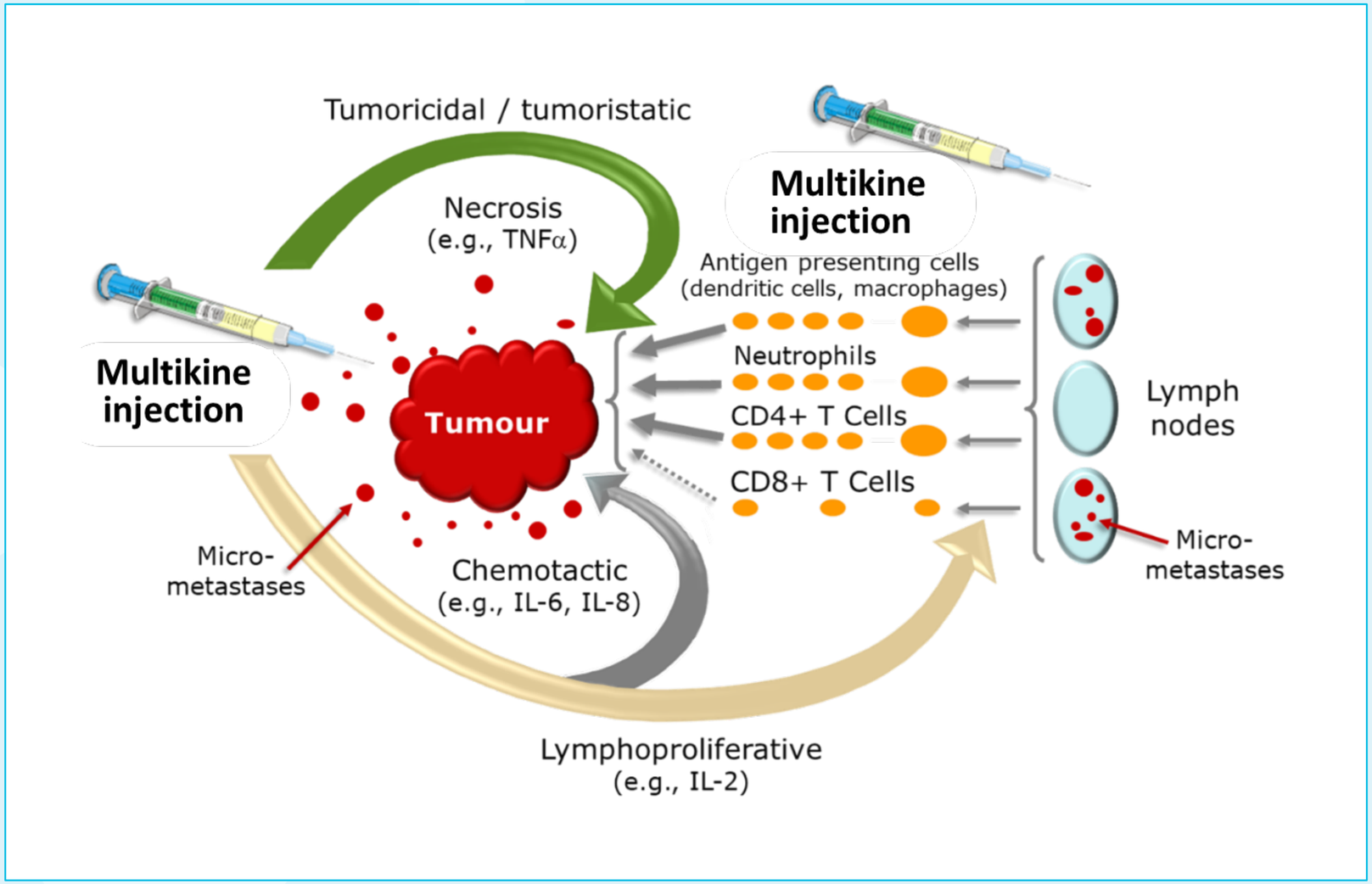
1) create a new standard of care for newly diagnosed treatment naïve head and neck cancer patients and
2) provide a survival benefit for the type of patient that have historically not responded well to checkpoint inhibitors (e.g., Keytruda, Opdivo).

Development in other cancer types is planned.

What is Multikine?

- Multikine is a consistent mixture of cytokines. Research at the US National Institutes of Health (NIH) has shown that the cytokines (shown in yellow) are the ones that are required to reject a tumor.
- Multikine is a non-toxic mass-produced immunotherapy that becomes specific to a person's tumor when injected near the tumor.

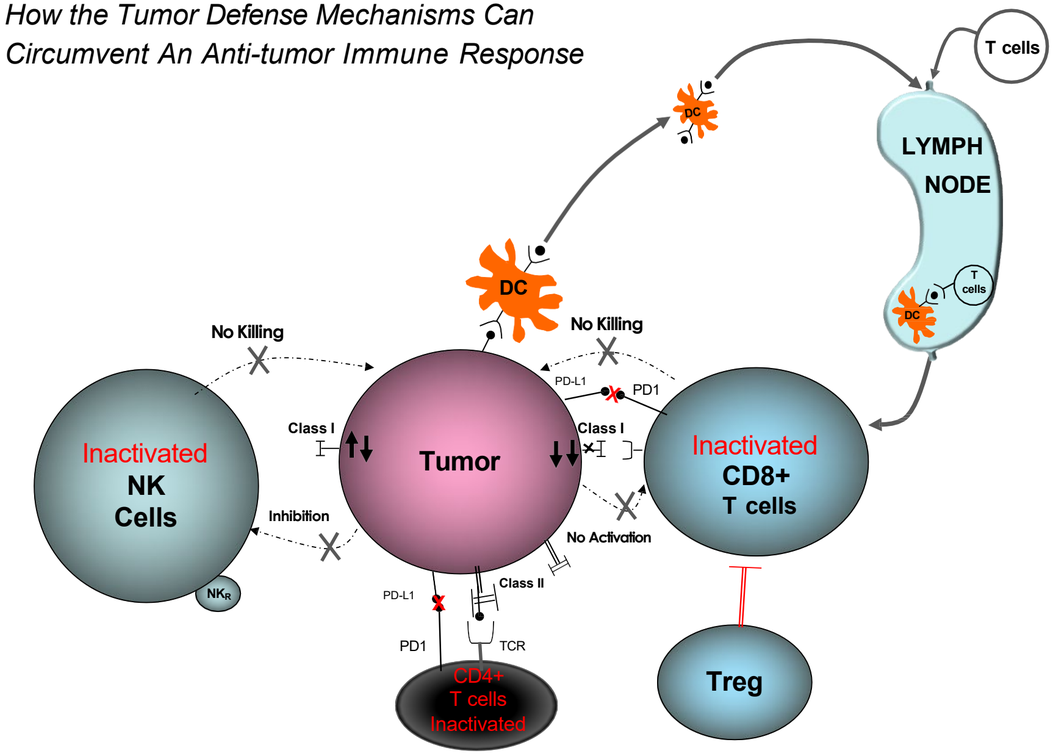
Multikine Mechanism of Action



Tumor Cell Death Without And With Multikine

Without Multikine

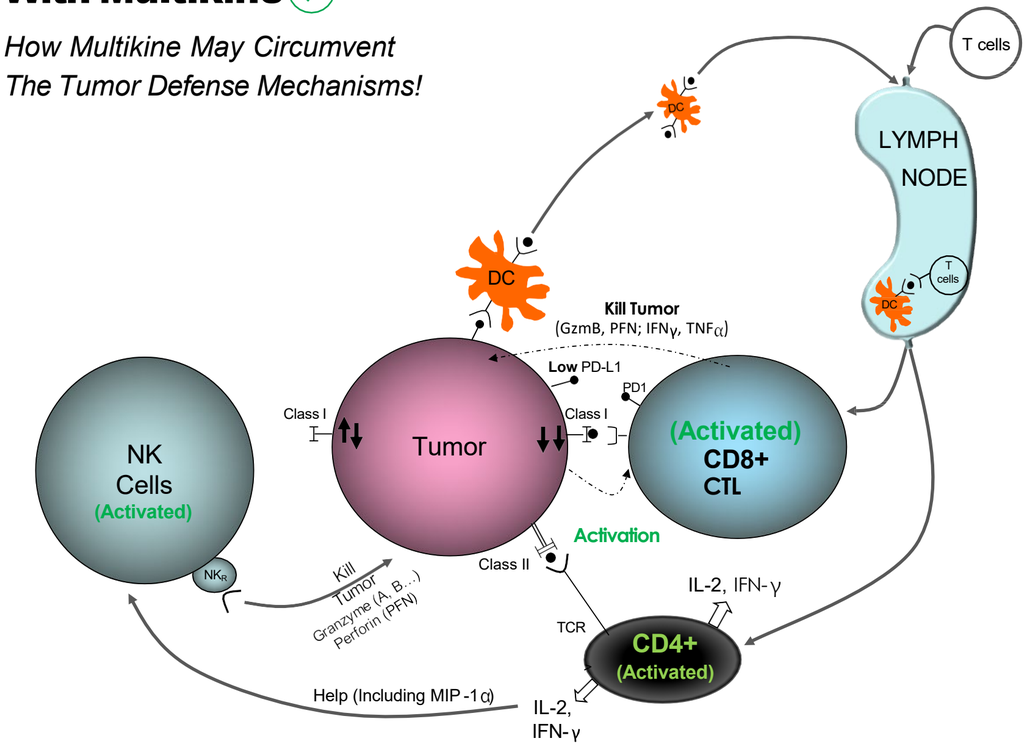
How the Tumor Defense Mechanisms Can Circumvent An Anti-tumor Immune Response



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.

Dedicated State-of-the-Art Manufacturing Facility

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

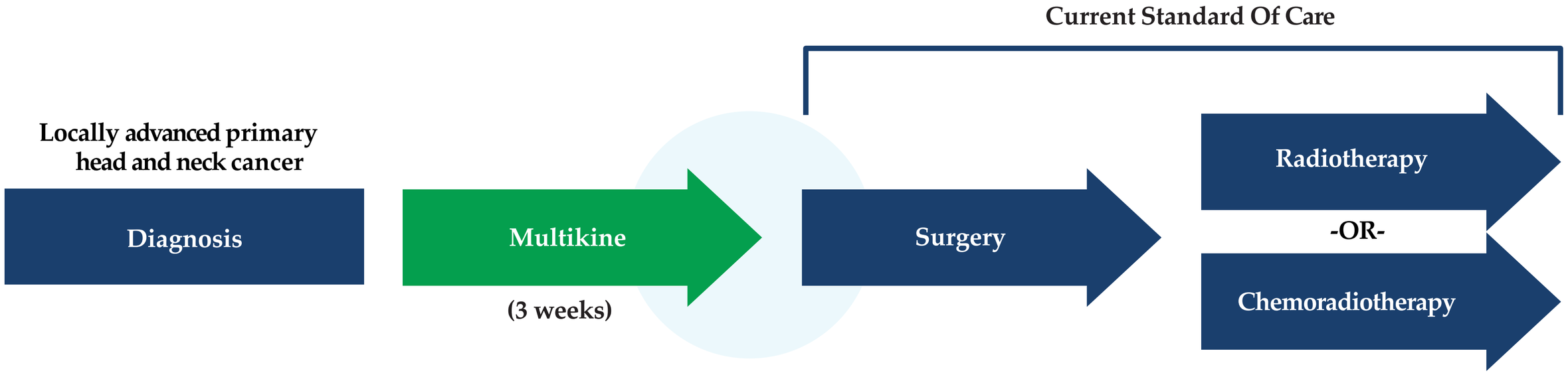
→ In house manufacturing process for complex biologic with initial capacity 12,000+ treatments per year.

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.

The Multikine Treatment Regimen

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:



What is the Target Population?

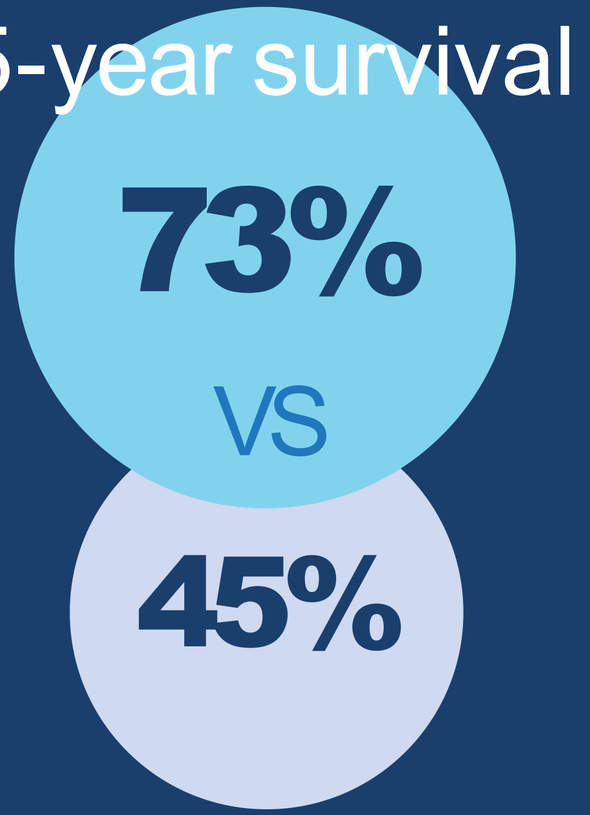
The 212 patient confirmatory study will focus on these patients:

→ 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



What are the Characteristics of the Selected Population?

Why N0?

- Healthier immune system can mount better anti-tumor immune response.
- Less likely to have chemotherapy added following surgery.
- Therefore, the target population for the confirmatory study is mostly composed of patients who receive radiotherapy, but no chemotherapy following surgery.
- What about the small number of patients who have **chemotherapy** added? The Selection Criteria selects those patients who have a strong survival benefit, even if they will receive chemotherapy after surgery.

Are Multikine and Checkpoint Inhibitors in Competition? NO!

- Checkpoint Inhibitors (CI) (e.g., Keytruda, Opdivo) are currently approved in head and neck cancer for use after the first treatments have failed. We are pursuing the treatment of **newly diagnosed** patients.

Why do we use PD-L1 level to select patients?

- PD-L1 is the #1 marker for the selection of patients for the treatment with the most successful class of cancer drugs, checkpoint inhibitors (e.g. Keytruda, Opdivo). These drugs work by blocking the interaction of PD-L1 on the tumor with PD-1 on immune cells and enable an immune response against the tumor.
- HOWEVER, if the tumor does not have overexpression of PD-L1, there tends to be no survival benefit with the treatment of immune checkpoints. In general, only about 30% of patients have tumors with high levels of PD-L1.
- Multikine works differently, it does not block PD-L1. Multikine stimulates the immune system to fight cancer.

Is this PD-L1 Distinction Relevant for the FDA?

Yes, very relevant:

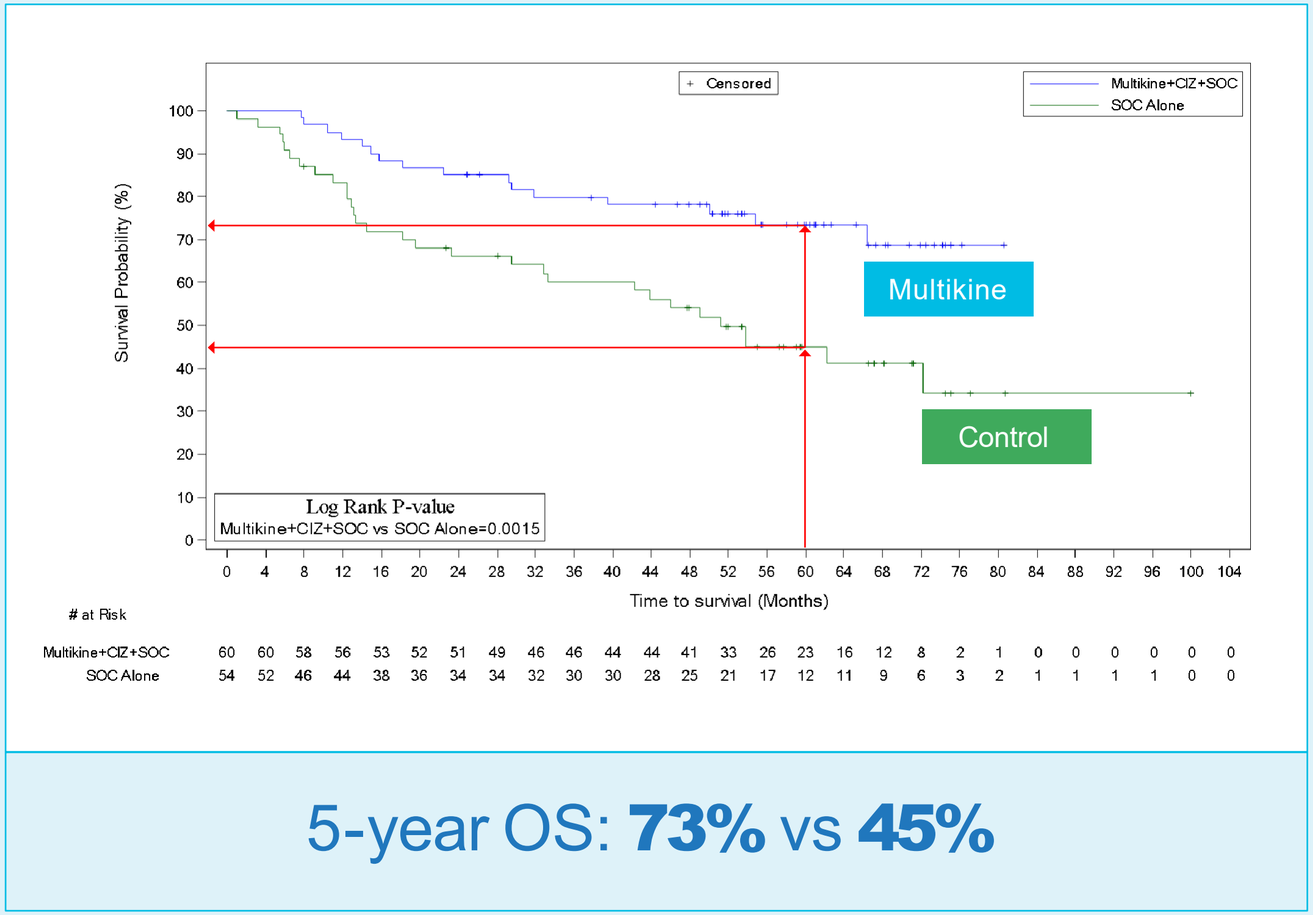
- **September 27, 2024:** FDA Oncologic Drugs Advisory Committee (ODAC) discussed this very issue.
- The title was: "Risks Outweigh Benefits for Checkpoint Inhibitors in Some Cancers".
- A U.S. FDA advisory committee determined that the risks outweigh the benefits for frontline immune checkpoint inhibitors in patients with advanced or metastatic gastric and esophageal cancers **who have low PD- L1 expressions.**
- ***Other than CEL-SCI, we do not know of any company that focuses on an immunotherapy that is effective in the PD-L1 negative (low) population as a single agent.***

Target Population (N0 & PD-L1 low) for Confirmatory Study: Improved Survival In the Completed Phase 3 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 IO for Multikine arm

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



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

Target Population (N0 & PD-L1 low) for Confirmatory Study - Chances of Success -

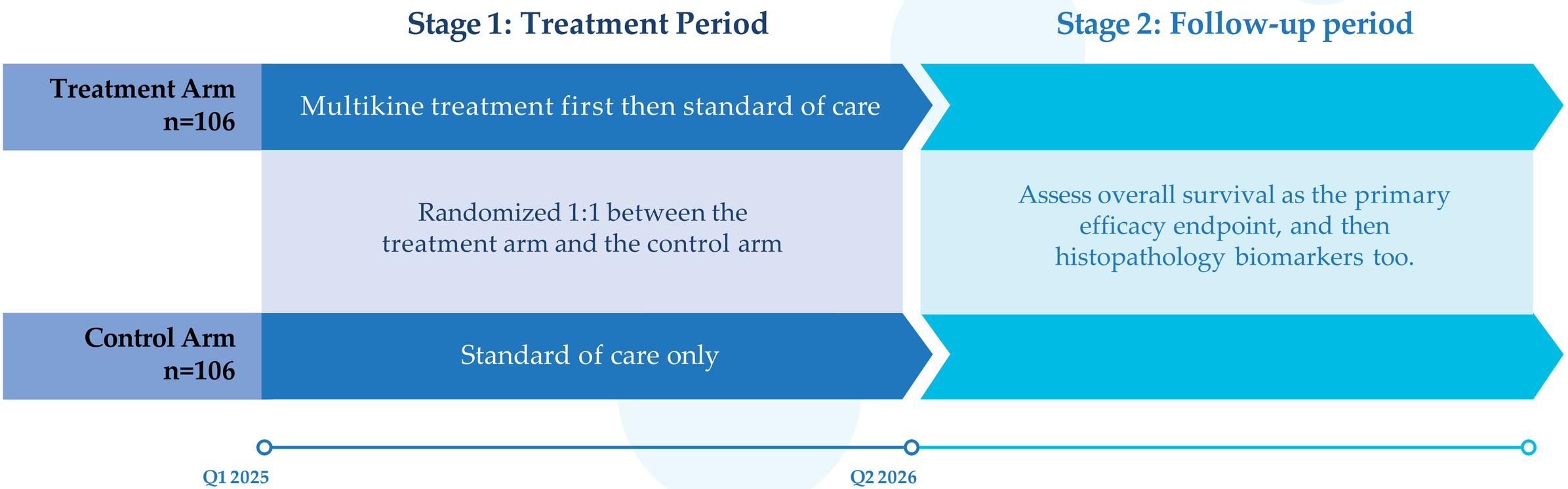
- Subgroup analysis is of a large size of over 100 patients
- Baseline and demographics of the two groups are well balanced
- Analysis was pre-specified in the protocol of the previous Phase 3 study and SAP
- HR CI upper limit is below 0.7 that is considered an approvable threshold for efficacy in oncology
- Patients can be selected with routinely used methods in the clinic (PET and PD-L1 testing)

Leading KOL will lead Confirmatory Registration Study

Nabil F. Saba, MD, FACP

- Dr. Nabil F. Saba, MD, FACP will serve as the confirmatory global Phase III clinical trial Lead, as a member of the Study Steering Committee, 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.

Our Registration Study Design



Enrollment Begins

Full Enrollment

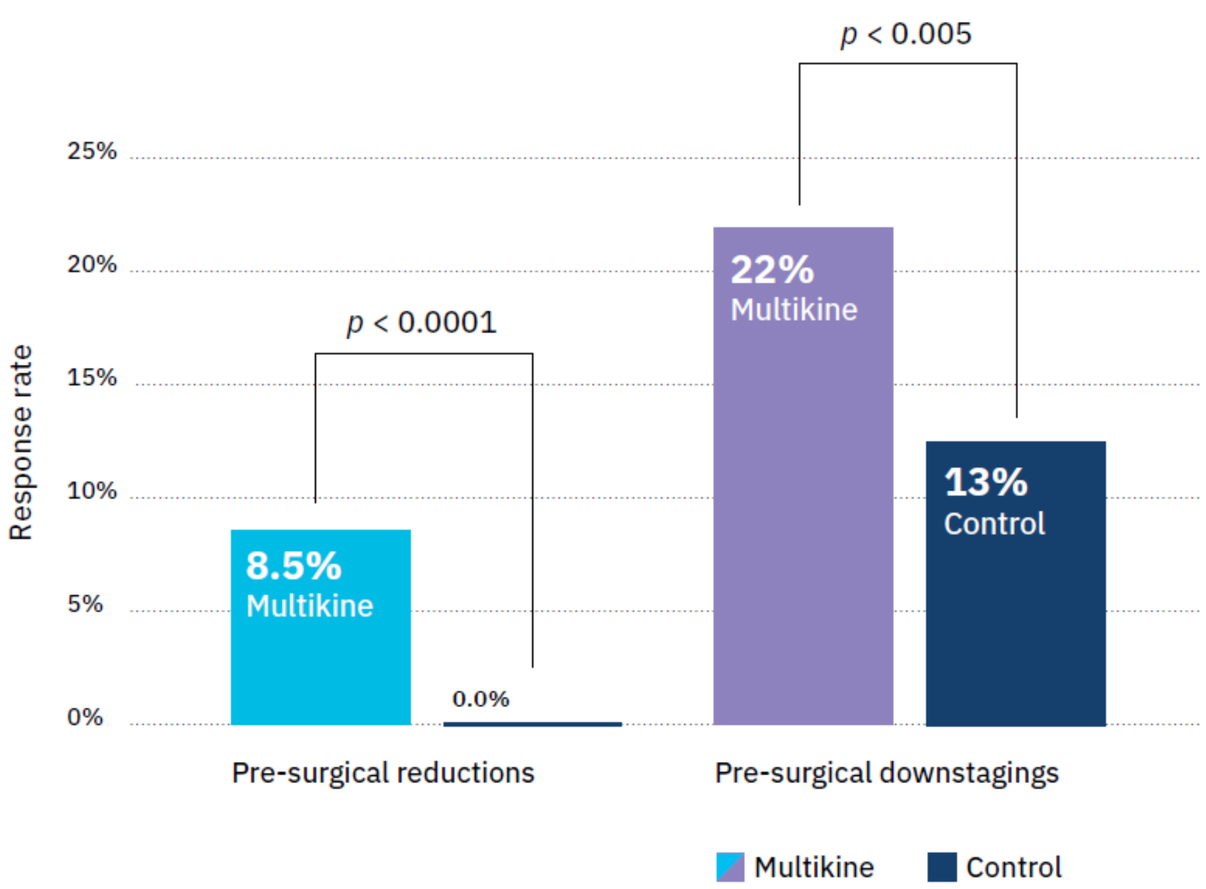
Pre-surgical response rates can be determined almost immediately after full enrollment is completed.

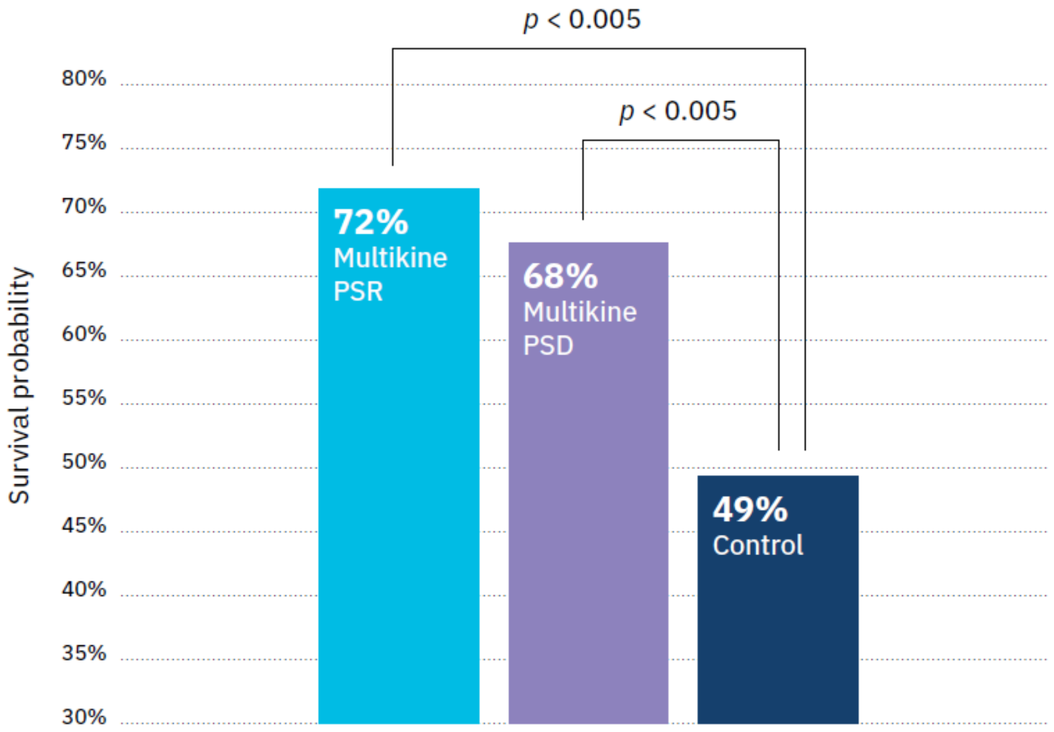
Plan to seek early approval at this time in U.S. and other countries.

Conclusion

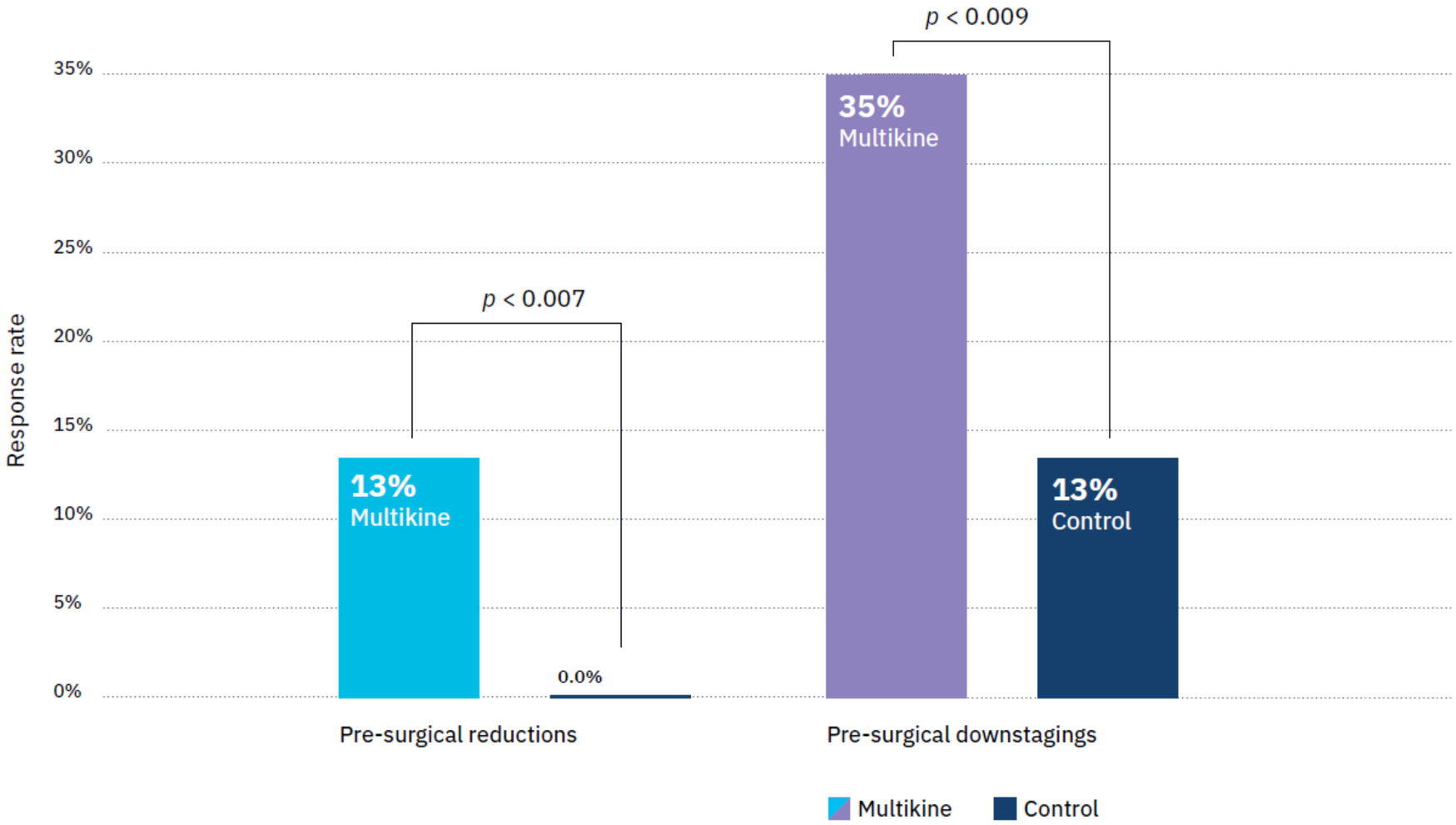
Timing is dependent on 65 patient deaths

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)



Summary: Highlights and Milestones

Strong survival data for unmet medical need

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 absolute survival benefit of 28% over control. No drug approval for Multikine indication is focused on PD-L1 low (70% of patients)

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 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 PD-L1).

Planning 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).

Why we believe in a positive outcome of the confirmatory 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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Appendix

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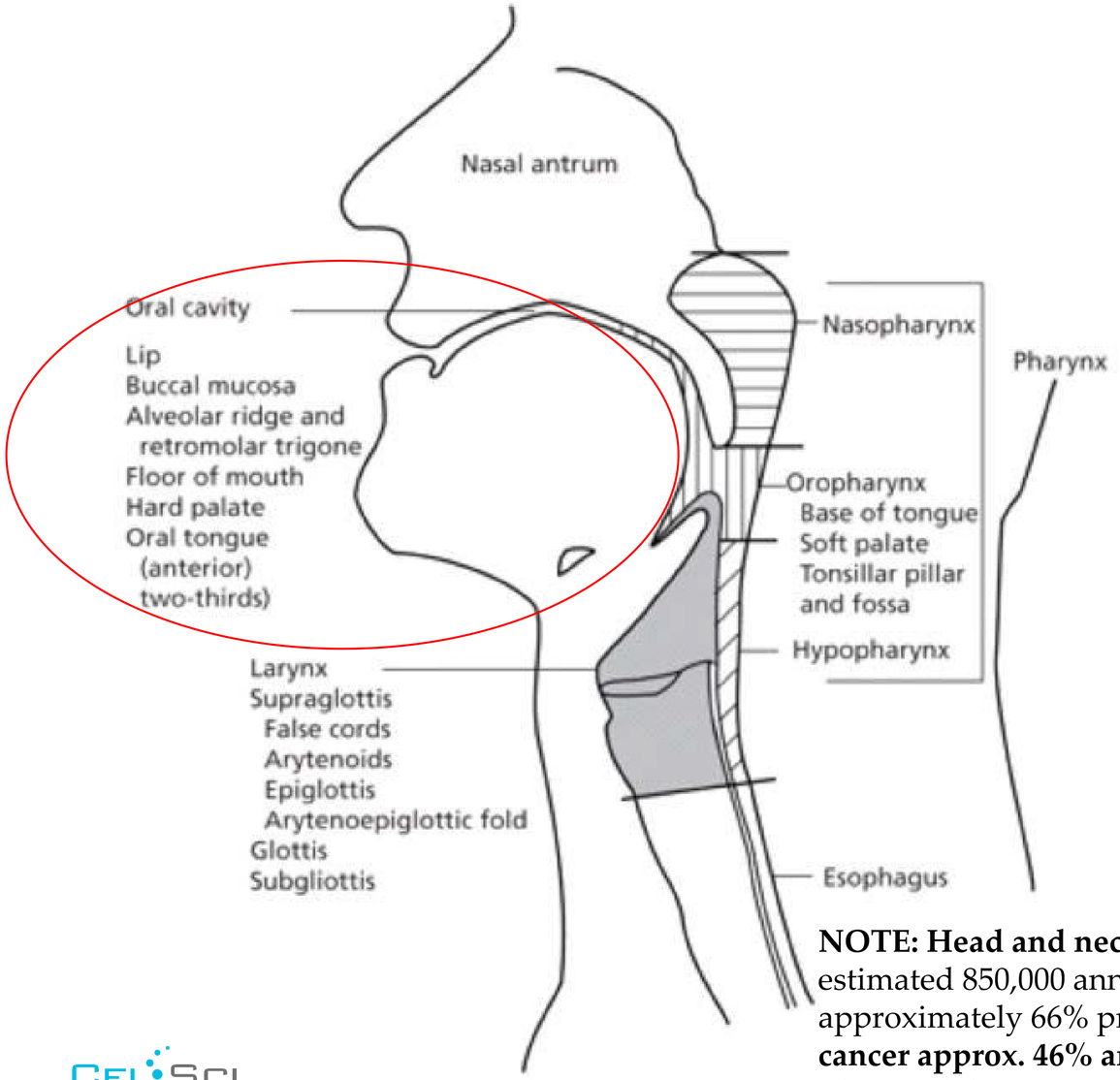
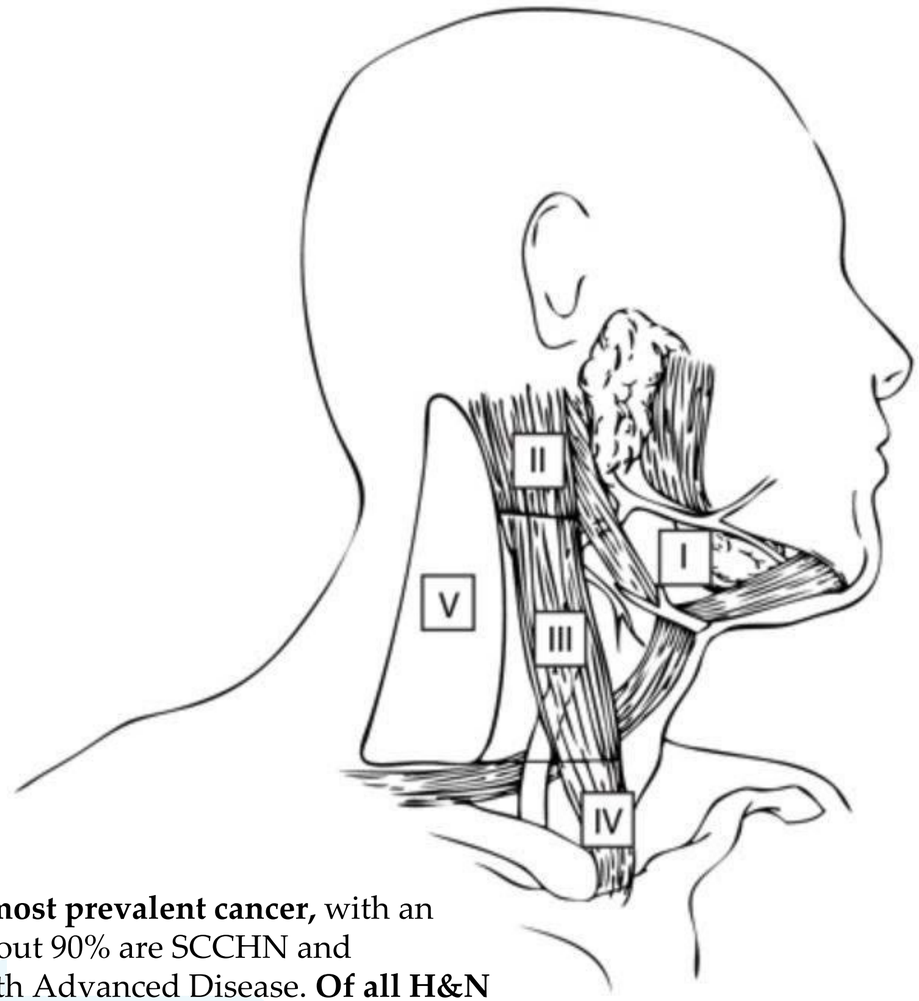
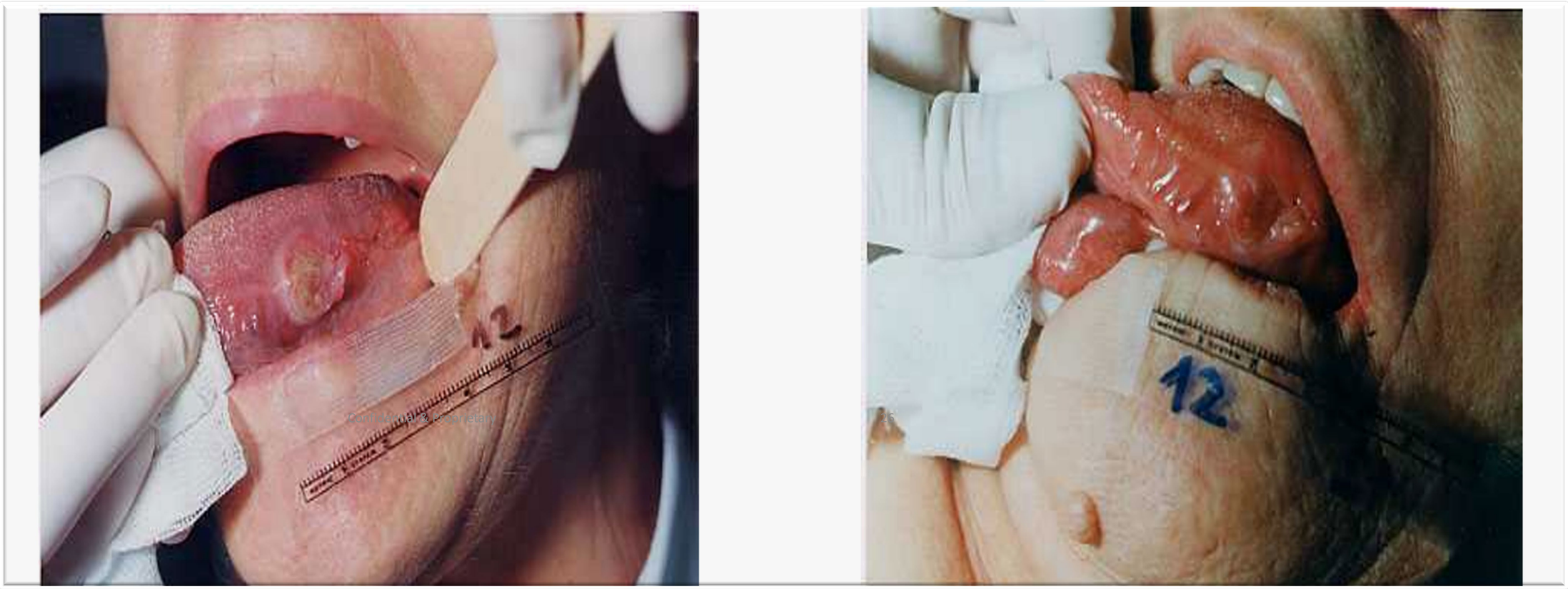
Cartoon Adapted from: NCCN Guidelines – Standard of Care





NOTE: Head and neck cancer world's 6th most prevalent cancer, with an estimated 850,000 annual cases globally; about 90% are SCCHN and approximately 66% present at diagnosis with Advanced Disease. **Of all H&N cancer approx. 46% are Oral Cavity. The 5-yr Overall Survival of locally advanced disease patients is <50% when treated with SOC - a clear unmet medical need.**

Phase 1 / 2 Trial



Screening/Baseline

Post- MK treatment Regimen

- Pre-surgical tumor response and histopathological evidence of MK's mechanism of action
- **pCR** (Determined at surgery: Necrosis)

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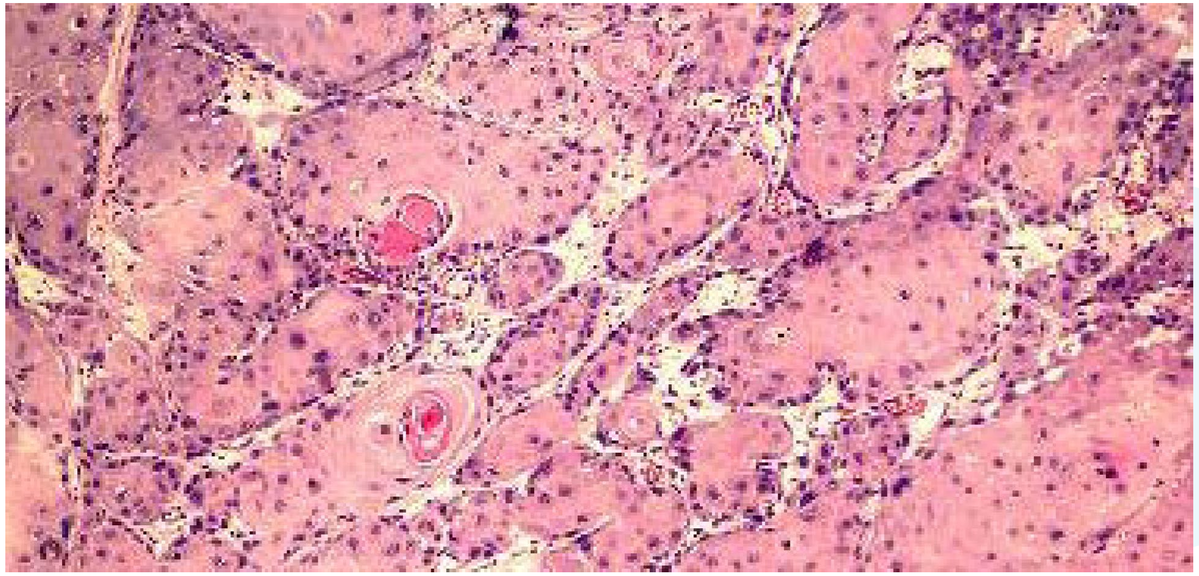
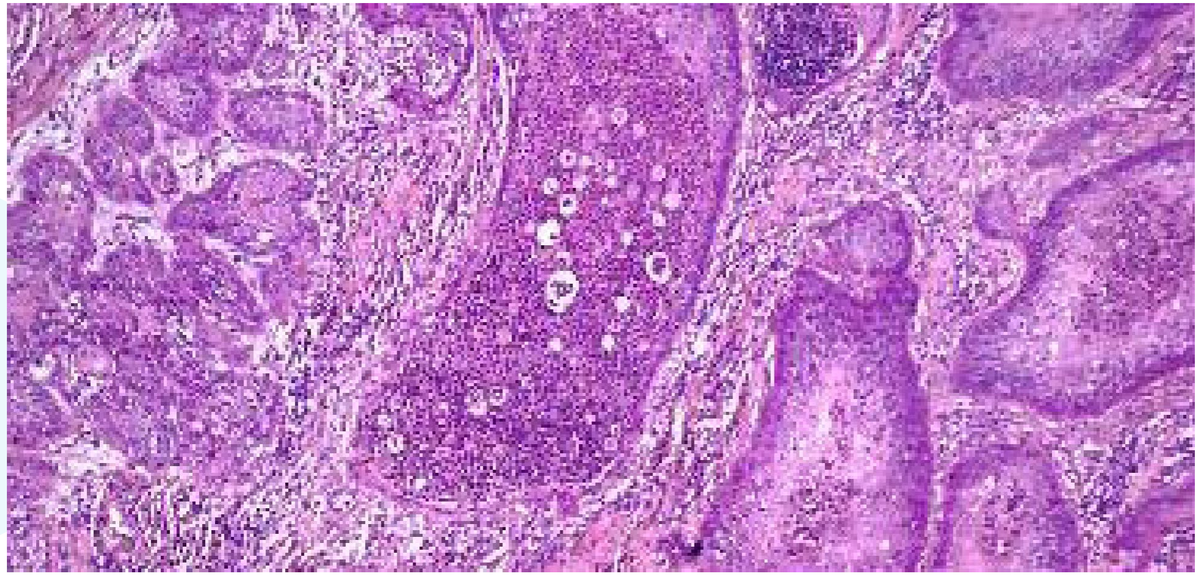
Non-Multikine Treated vs. Multikine Treated

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

RCT Multikine Phase 3 Trial Design

Schematic: Randomization and Treatment of Enrolled Patients with Disease Stage III and IVa

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 per NCCN Guidelines

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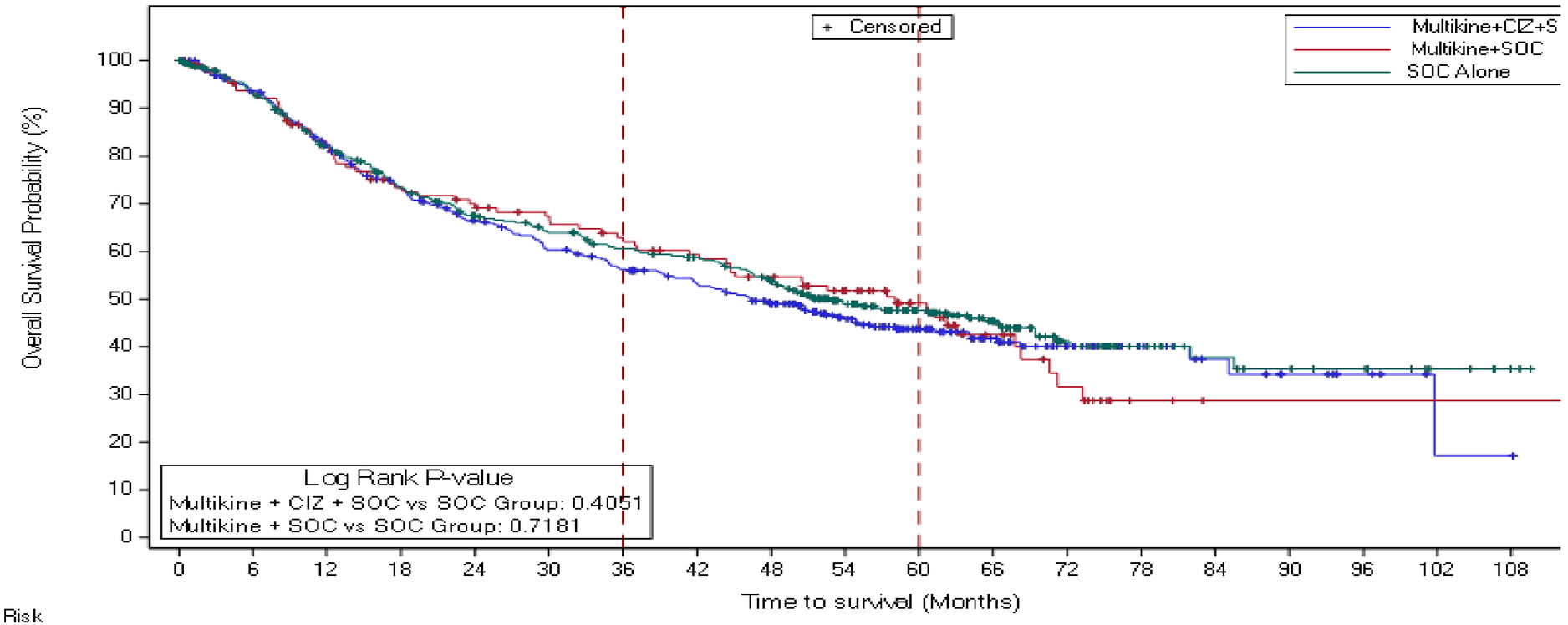
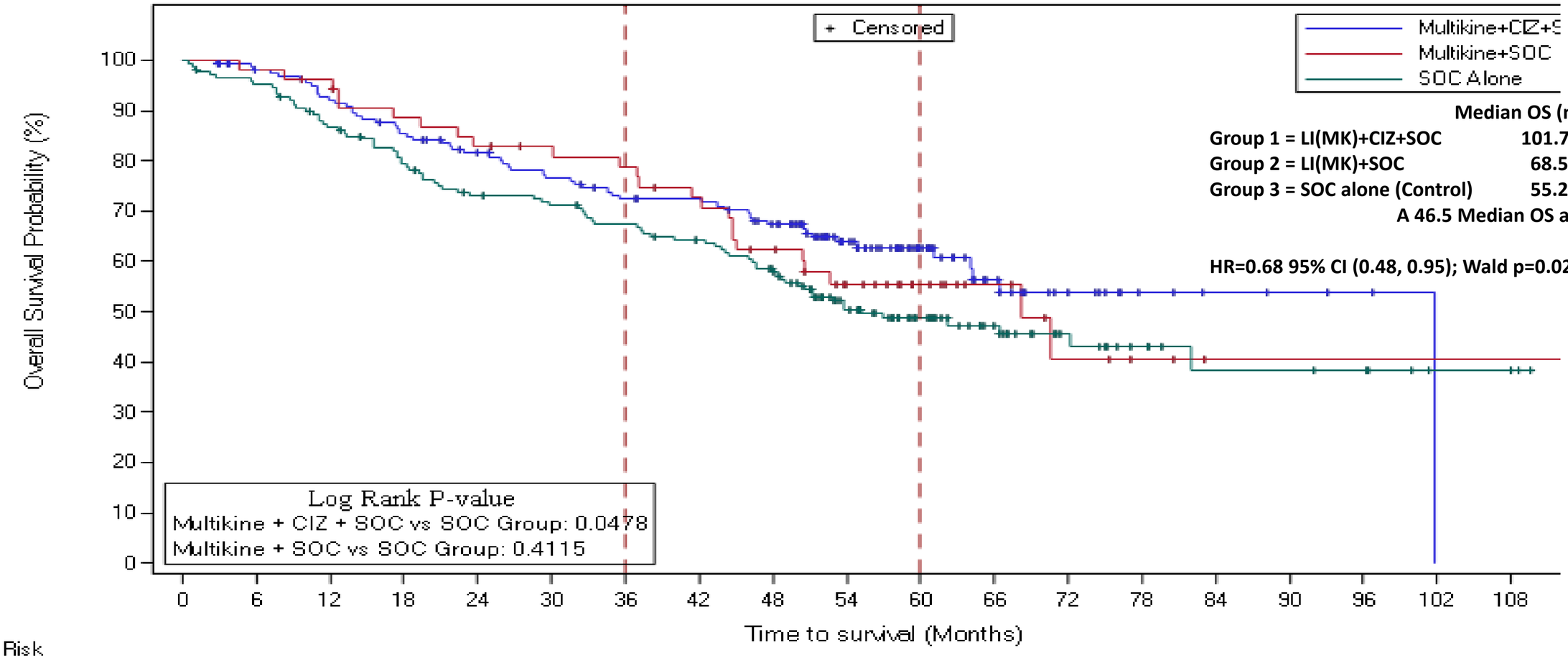
Overall Survival: ITT (p=0.4051) (n=923, 462 deaths)



at Risk

tikine+CIZ+SOC	395	349	301	263	232	209	192	176	156	117	80	55	34	18	12	8	5	1	1
Multikine+SOC	134	118	101	87	81	76	70	64	58	47	33	19	11	3	1	1	1	1	1
SOC Alone	394	341	292	254	228	213	198	188	168	126	94	67	39	24	16	13	11	6	2

OS ITT Low Risk: LI(MK)+CIZ+SOC Advantage (p=0.0478) (n=380, 166 Deaths)



Median OS (months)

Group 1 = LI(MK)+CIZ+SOC	**101.7**
Group 2 = LI(MK)+SOC	**68.5**
Group 3 = SOC alone (Control)	**55.2**

A 46.5 Median OS advantage

HR=0.68 95% CI (0.48, 0.95); Wald p=0.0236

at Risk

tikine+CIZ+SOC	158	150	140	129	118	110	102	100	89	61	39	22	13	6	4	3	2	0	0
Multikine+SOC	54	53	51	46	43	41	39	35	29	21	14	9	5	3	1	1	1	1	1
SOC Alone	168	159	143	129	117	113	106	99	87	61	43	30	18	12	8	8	7	3	2

Talor E., et al, ASCO '22 Abstract/ Poster #6032

Tumor Response Rate pre-surgery: Phase 3 (Study CS001P3)

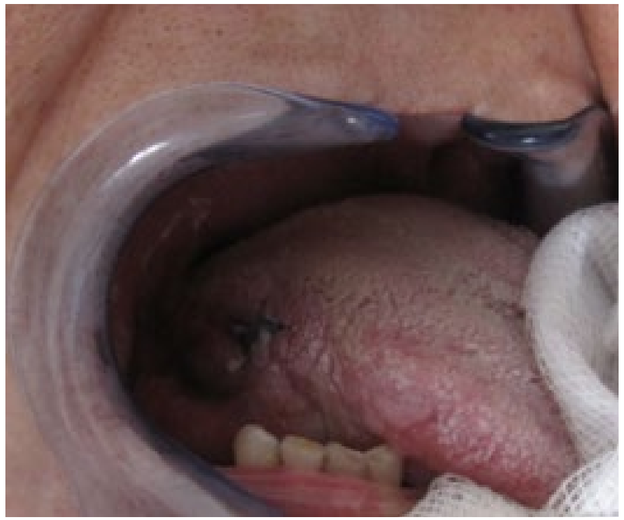
	ITT Pre-surgical responders							
	ITT Group 1 (N=395)		ITT Group 2 (N=134)		ITT Groups 1+2 (N=529)		ITT Group 3 (N=394)	
Risk group	N	%	N	%	N	%	N	%
Pre-surgical response rate	32	8.1	13	9.7	45	8.5	0	0
[95%CI (%)]	[5.6, 11.2]		[5.3, 16.0]		[6.4, 11.2]		[0, 0.93]	
p- value vs ITT Group 3*	<0.0000001		<0.0000001		<0.0000001			
Complete response	5	1.3	0	0	5	0.9	0	0
Partial response	27	6.8	13	9.7	40	7.6	0	0

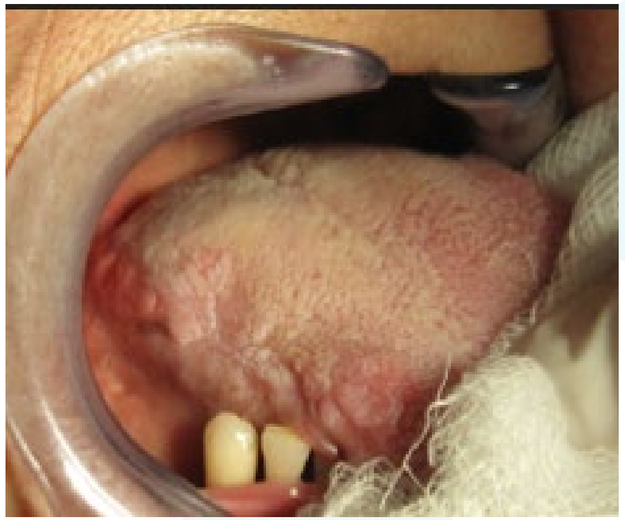
- *Two-sided Fisher Exact test
- Response per RECIST v1.0 confirmed at surgery (by pathology); 34 lower risk, 10 higher risk, 1 unclassified risk
- No spontaneous responses ever reported in the literature OSCC

Talor E., et al, ASCO '22 Abstract/Poster #6032

Clinical: Phase 3 (Study CS001P3)

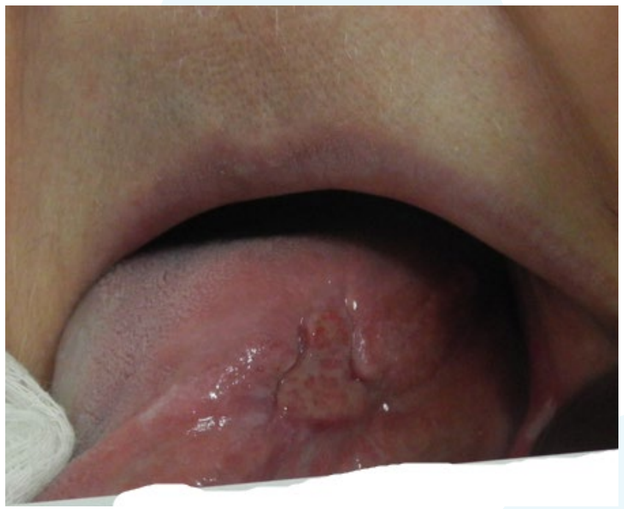
Lavin P., et al, ESMO '22 Abstract/Poster 690P

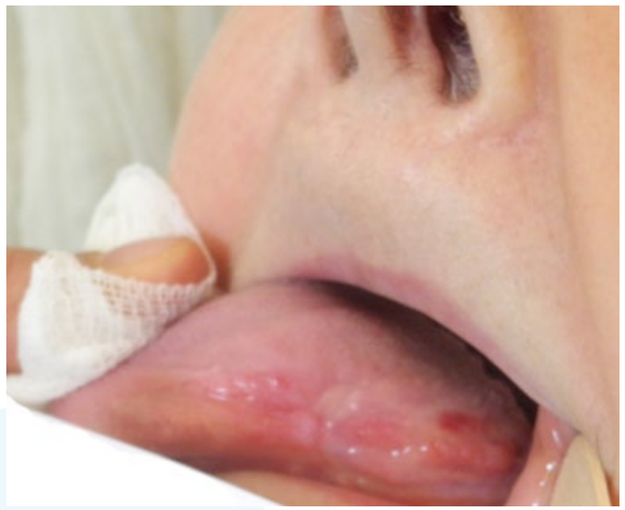




Screening/Baseline

Post-LI(MK) pre-Surgery (within 3 weeks)
pCR (CR confirmed by Pathology at surgery)

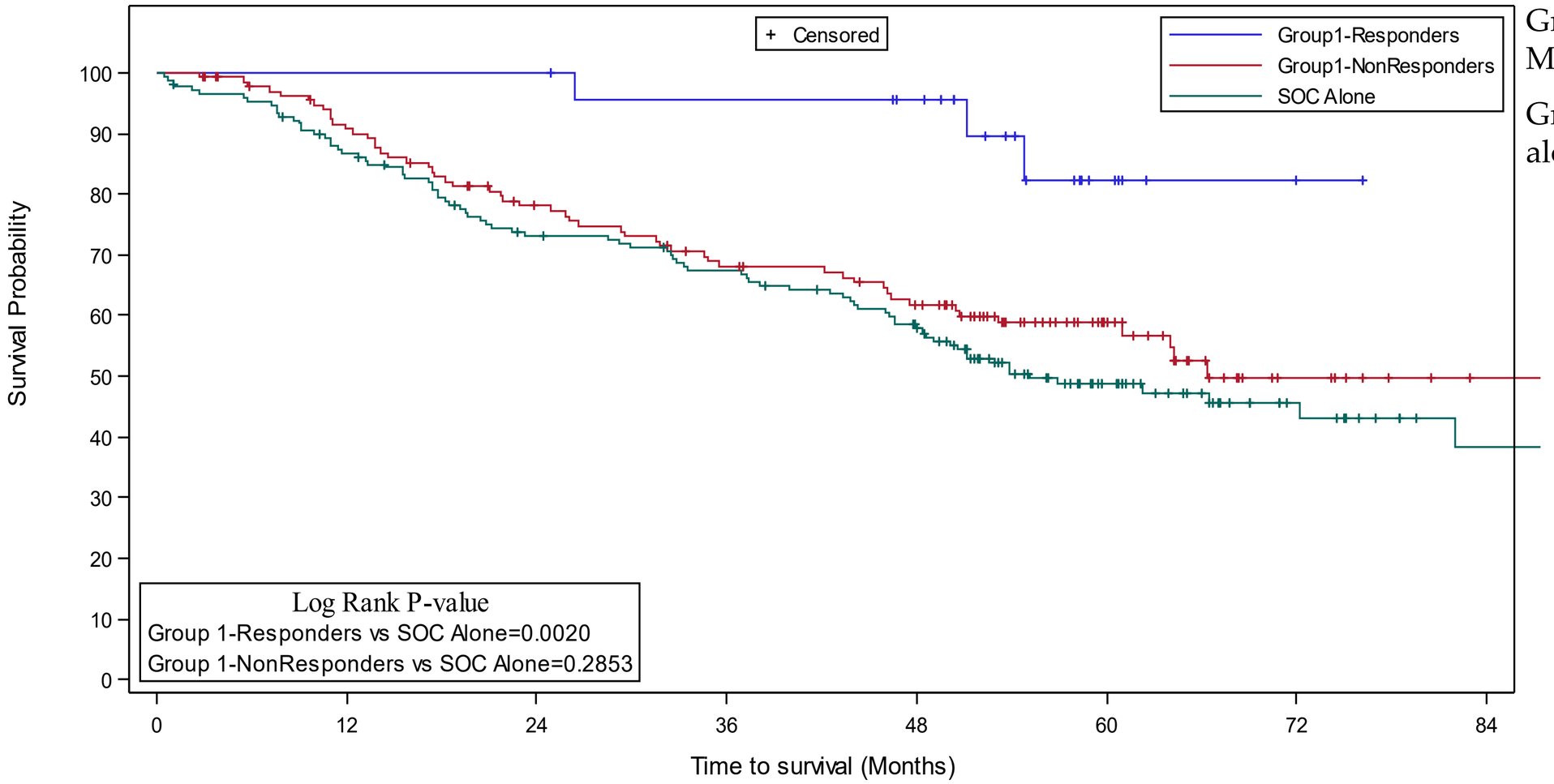




Screening/Baseline

Clinical (OS): Phase 3 (Study CS001P3) ITT LR

K-M of LR Group 1 PSRs, LR Group 1 non-PSRs, and LR Group 3 (N=326)

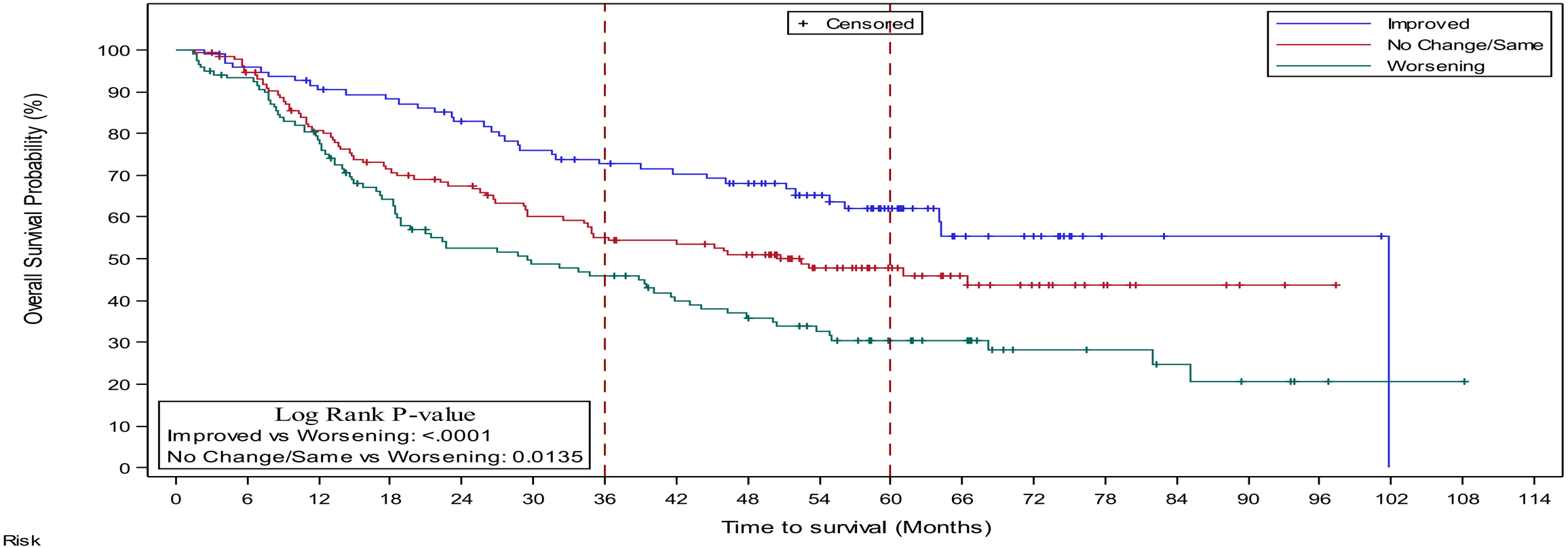


Group 1 = MK+CIZ+SOC

Group 3 = SOC alone (Control)

AJCC Stage Migration Pre-surgery Impact on OS

Overall (ITT) Group 1 (TN) improvement, no change (relative to entry) resulted in OS benefit



at Risk

Improved	95	90	84	81	74	68	63	60	55	42	27	15	11	3	2	2	2	0	0	0
No Change/Same	134	124	104	91	84	73	67	64	58	41	29	20	13	7	4	2	1	0	0	0
Worsening	118	108	89	71	56	52	49	40	36	29	22	18	9	8	6	4	2	1	1	0

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)

What If We Could Avoid/Reduce Chemotherapy Through a Better Selection Process

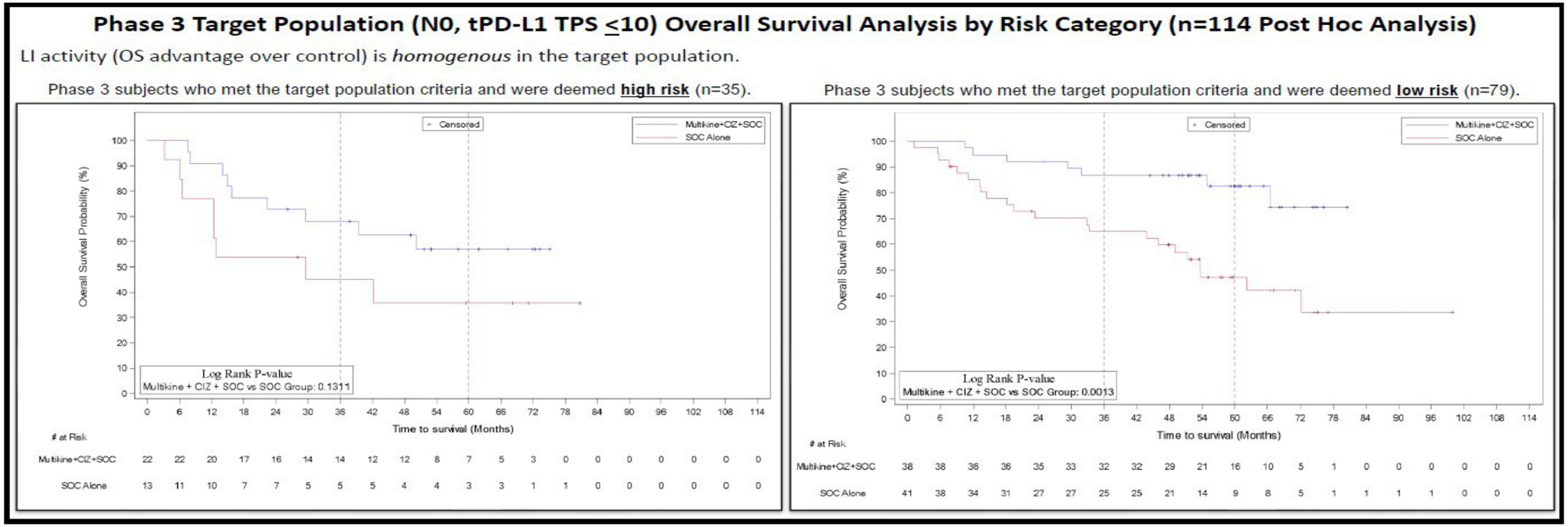
→ The selection process included 35 patients out of 114 who received chemoradiotherapy (79 received only Radiotherapy after surgery)

→ Chemotherapy is expected to negatively affect immune response

→ The data shows that without chemotherapy the 5-year survival would increase from 73% to 82.6%;

→ And would further improve the hazard ratio from 0.35 to 0.27

[Data Presented at European Society for Medical Oncology in September 2024]



Cellular Biomarkers and Ranges Pre-defined for Pathology Immunohistochemistry

Prospectively Defined Biomarkers (2 [L/H] or 3 levels [L/M*/H])

1. p16: 10% positivity threshold
2. HLA: L<45, H>90
3. B2M: L<40, H>80
4. MR1: L<50, H>100
5. TPDL1: L<10, H>20
6. CD4: L<600, H>1200
7. CD8: L<400, H>800
8. CD3: L<1000, H>2000
9. FOXP3: L<250, H>500
10. CD20: L<250, H>500
11. CD68: L<50, H>100
12. CD163: L<60, H>120
13. CD1a: L<15, H>30
14. CD208: L<2, H>8
15. MPOX: L<30, H>60
16. PD1: L<10, H>20
17. CTLA4: L<9, H>18
18. PDL1: L<10, H>20
19. CD25: L<40, H>80
20. NK p46: L<2, H>8

Key:
L = Low
M* = Medium (defined as neither High nor Low)
H = High

Pathology IHC : Clearly Defined And Well-Understood

Immunohistochemistry (IHC) DAB reaction, Positive cells are brown, All IHC photos same magnification; Bar = 200 µm

(Top row = Multikine treated; Bottom row = Control)

Figure 1. LI(MK) Treated: High CD4 T cell density in tumor stroma

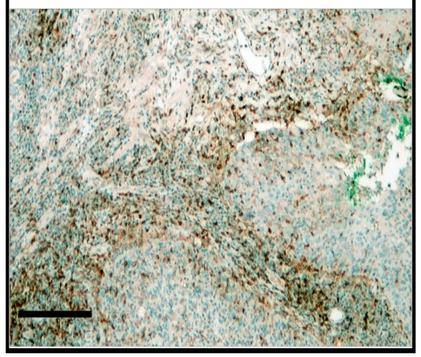


Figure 2. LI(MK) Treated: High CD8 T cell density in the tumor stroma

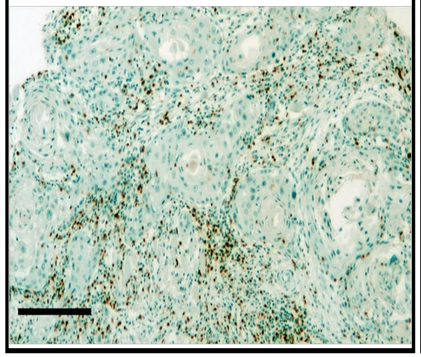


Figure 3. LI(MK) Treated: High CD68 macrophage cell density in the tumor stroma

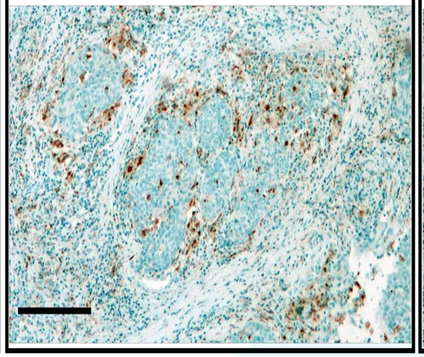


Figure 4. LI(MK) Treated: Low CD1a dendritic cell density in the tumor stroma

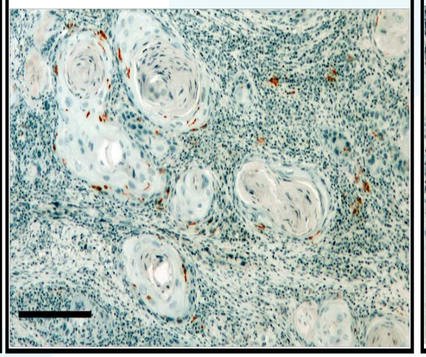


Figure 5. LI(MK) Treated: Low tumor cell PDL1 expression/negativity.

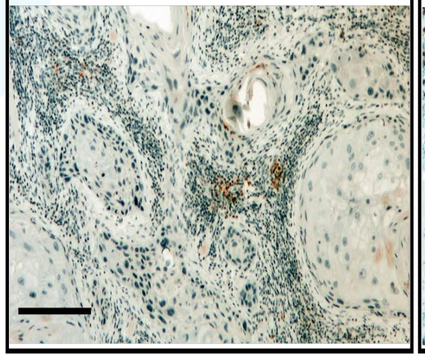


Figure 6. LI(MK) Treated: High CD20 B cell density in the tumor stroma

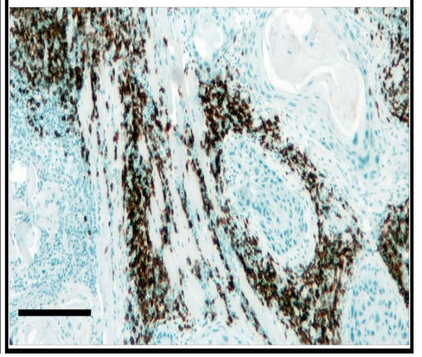


Figure 1a. SOC only (control): Low CD4 T cell density in tumor stroma

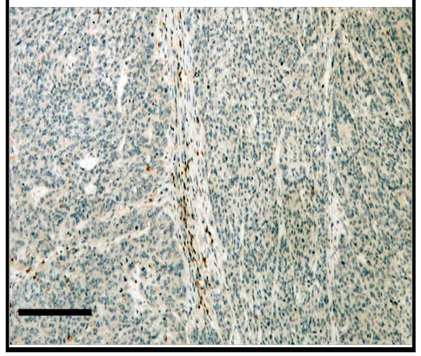


Figure 2a. SOC only (control): Low CD8 T cell density in the tumor stroma

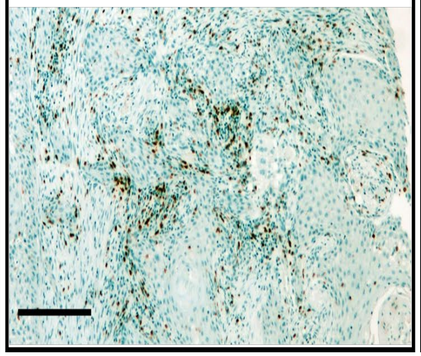


Figure 3a. SOC only (control): Low CD68 macrophage cell density in the tumor stroma

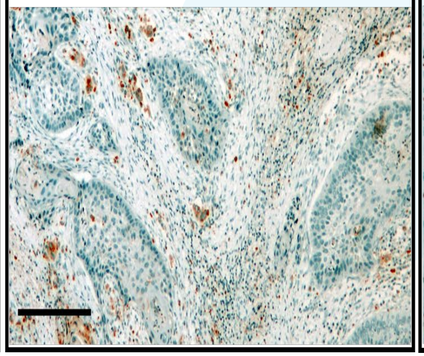


Figure 4a. SOC only (control): High CD1a dendritic cell density in the tumor stroma

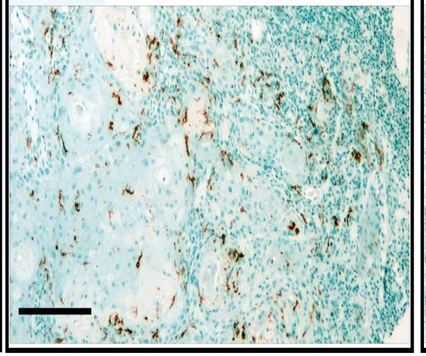


Figure 5a. SOC only (control): High tumor cell PDL1 expression

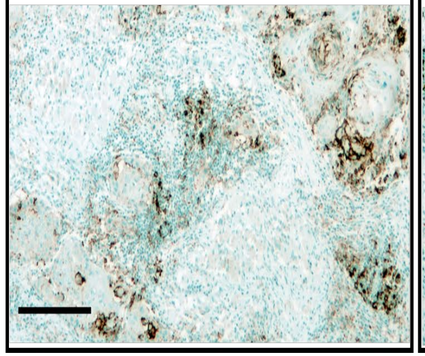
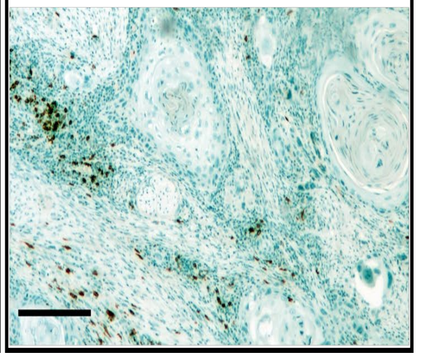


Figure 6a. SOC only (control): Low CD20 B cell density in the tumor stroma



*3,3′-diaminobenzidine (DAB)

Prospectively Defined Ratios and Combinations of Cellular Biomarkers

Two ratios were constructed with L, M, and H thresholds (based on above definitions of H & L, M was neither H nor L) as follows:

1. CD8/FOXP3 ratio: 1 and 2
2. CD4/CD8 ratio: 1 and 2

Fourteen combinations were constructed as follows:

1. CD3+ and CD25+ All Positive
2. CD3+, CD8+, and CD25+ All Positive
3. CD3+, CD4+, and CD25+ All Positive
4. CD3+, CD4+, CD8+, and CD25+ All Positive
5. CD1a+ and TMR1+ All Positive
6. CD1a+ and NK p46+ All Positive
7. CD1a+ and CD163+ All Positive
8. CD3+, CD4+, CD25+, and NK p46+ All Positive
9. CD3+, CD4+, CD25+, and CD163+ All Positive
10. CD3+, CD4+, CD25+, CD1a+, and TMR1+ All Positive
11. CD3+, CD4+, CD25+, CD1a+, TMR1+, and CD163+ All Positive
12. CD3+, CD4+, CD25+, CD1a+, TMR1+, and NK p46+ All Positive
13. CD3+, CD4+, CD25+, CD1a+, TMR1+, CD163+, NK p46+ All Positive
14. CD3+, CD4+, CD25+, CD1a+, CD163+, and NK p46+ All Positive

Immunohistopathology Supports MoA of Multikine

Significant Outcomes All Favoring MK + CIZ + SOC vs SOC

	Histopathology Results: Proportion Statistically Significant, 1-sided p≤0.025		
Endpoint	Overall Group (n=453) Favoring Group 1**	Lower-risk Group (n=210)* Favoring Group 1	Overall Group (n=453) Favoring SOC (Group 3)***
OS	26/93	21/93	1/93
PFS	17/93	16/93	2/93
LRC	18/93	17/93	2/93
Totals	61/279 (21.9%>>2.5%)	54/279 (19.4%>>2.5%)	5/279 (1.8% <2.5%)

*There were no significant tests (0/279) favoring SOC alone in the lower-risk group
** Group '1' = MK+CIZ+SOC; ***High risk group only
Note: <2.5% = by chance alone

CEL-SCI

Clear Pathway to Market for Major Unmet Need

- In the target population from the Phase 3 trial, Multikine showed a significant survival benefit of 73% vs 45% in the control group at 5 years, with a statistically significant log rank p-value of 0.0015. That is a 28% absolute survival benefit. We only need 10% to succeed in the upcoming trial.
- The hazard ratio for Multikine in the target population from the Phase 3 trial was 0.35 (95% CI: 0.19-0.66), which is well below the 0.7 threshold needed for success in the planned new study.
- Multikine demonstrated tumor elimination and tumor size reductions over 30% in just 3 weeks, compared to no tumor response in the control group, with no safety signals or toxicities reported.
- Multikine addresses an unmet medical need as the first potential pre-surgical treatment for head and neck cancer. Not only does it focus on the population where no other drug has shown survival benefit, but it also focuses on those patients (low/negative PD-L1) who cannot respond well to checkpoint inhibitors due to their lack of PD-L1 to inhibit.
- There are over 50 cancer drugs that have been approved where they initially failed on a broader population, but showed promise on a subset, and then went on to succeed in a prospective trial. Some examples include: Herceptin, Keytruda, Tagrisso, Opdivo, Padcev, Alectinib, and Lorlatinib.
- A confirmatory study of 212 patients has been cleared by the FDA, with plans to start in Q1 2025, targeting the same patient population that showed excellent long-term survival benefits in the completed Phase 3 study.