CEL-SCI
Empowering Immune Defenses

Multikine (Leukocyte Interleukin, Inj.) Cancer Immunotherapy

Activating the immune system of cancer patients before surgery and radiation

October 2022

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.

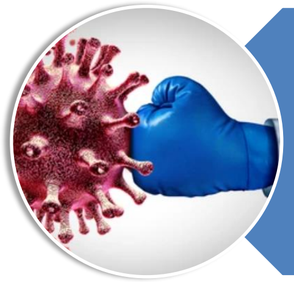
All forward-looking statements contained herein are expressly qualified in their entirety by this cautionary statement, the risk factors set forth under the heading “Risk Factors” and elsewhere in our public filings, and in the documents incorporated or deemed to be incorporated by reference therein. 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.

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.

Summary

1. **Our novel concept is to activate the immune system to fight cancer before it is destroyed by surgery, radiation, etc.**
2. **We ran the largest and longest (10 years) Phase 3 study ever in head and neck cancer.**
3. **We picked advanced primary head and neck cancer as a first target because no one has been successful in this disease in many decades.**
4. **Head and neck cancer is believed to be the 5th biggest cancer in the world.**
5. **We showed a 4-year survival benefit when giving our investigational drug Multikine followed by surgery and radiation.**
6. **Some of the patients had zero tumor left after only a 3-week treatment with Multikine.**
7. **Our drug Multikine did not add any toxicities to the treatment.**
8. **We are now working on approval to market Multikine in the US and other countries.**
9. **Over 200,000 people per year would qualify for this indication. This could make Multikine a blockbuster drug.**

Our Goal was to Create a Non-Toxic Cancer Medicine



The immune system is key to our fight against cancer.

- Activate it to fight cancer BEFORE surgery and radiation have damaged it.
- Cancer immunotherapy drugs are typically given after those first treatments.

Our immunotherapy is called Multikine*

- It is given for 3 weeks right after diagnosis, before surgery and radiation.

Multikine is a copy of the pro-inflammatory cytokine immune response that our bodies produce every day.

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Phase 3 Data Shows we did Create a Novel Non-Toxic Cancer Medicine

Survival and tumor elimination data from the largest head and neck cancer study in the world.

- There is a 4 year survival benefit for head and neck cancer patients receiving our Multikine followed by surgery and radiotherapy.
- Some patients have no tumor left in just 3 weeks.
- No toxicity was added to the overall treatment.

Peer reviewed data were released at the 2022 ASCO meeting in June and ESMO in September. Additional data will be released at scientific conferences and in major peer reviewed scientific publications.

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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.

IL-1 α | IL-1β | IL-2 | IL-3 | TNF-α | IFN-γ | GM-CSF

Major cytokines and other cellular products in Multikine

IL-6 | IL-8 | TNF-β | G-CSF | RANTES | MIP-1α | MIP-1β

How Does Multikine Work?

Multikine is injected 5 days a week for 3 weeks before any other cancer therapy around the tumor and near adjacent lymph nodes to stimulate the immune system to recognize the cancer cell antigens.

Once the immune system is able to “see” the cancer, the immune system does what it is meant to do—destroy the cancer.

THE GOAL:

Activate an anti-tumor immune response and increase survival.

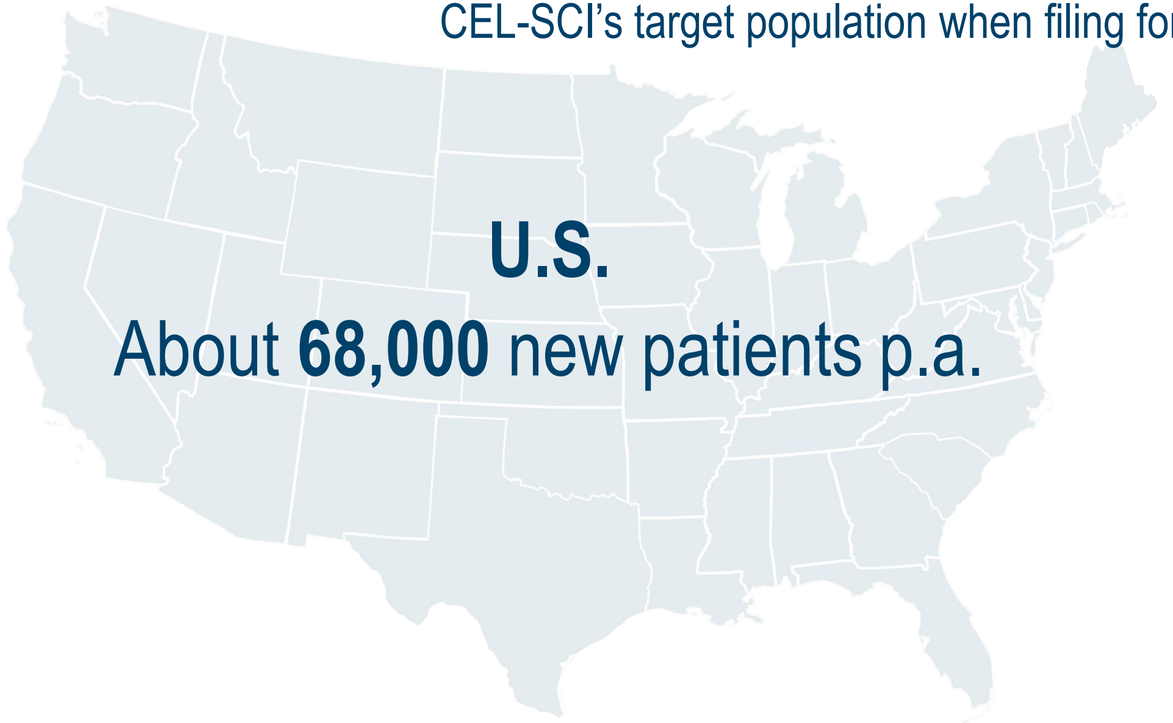
Why was advanced (stages III and IV) primary (not yet treated) head and neck cancer selected as the first indication?

- Last FDA approval of a therapy for advanced primary head and neck cancer was over 50 years ago.
- It represents a severe unmet medical need.
- Multikine was awarded Orphan Drug Status in the US.
- Head and neck cancer is a prevalent cancer.
- There is only one standard of care for advanced primary head and neck cancer throughout the world.

If approved, Multikine should become the first treatment given to patients scheduled for surgery and deemed for subsequent radiotherapy, but not chemotherapy.

Head and Neck Cancer Populations

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 **68,000** new patients p.a.

Europe

About **150,000** 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 over 20 countries; FDA approval expected to lead to approval in many countries

Multikine

A Severe Unmet Medical Need

The last FDA approval for advanced primary head and neck cancer was in the late 1950's.

Recent failures to develop effective SCCHN treatments			
Manufacturer	*Drug*	*Trial*	*Outcome*
Pfizer & Merck	Bavencio	JAVELIN 100	Terminated March 2020
AstraZeneca	Durvalumab	KESTREL	Failed February 2021
Boehringer Ingelheim	Afatinib	LUX-Head&Neck 2	Failed June 2019
Glaxo	Feladilimab	INDUCE-3/ INDUCE-4	Terminated April 2021
Bristol Meyers	Opdivo + Yervoy	CHECKMATE-651	Failed September 2021
Pfizer & Merck	Bavencio	GORTEX-REACH	Failed September 2021
Merck	Keytruda	KEYNOTE-412	Failed July 2022
AstraZeneca & Innate	Monalizumab + Erbitux	INTERLINK-1	Terminated August 2022

"There have been limited advances for patients with locally advanced HNSCC, and unfortunately, these results suggest that this disease remains very challenging to treat," said Dr. Eliav Barr, senior vice president, head of global clinical development and chief medical officer, Merck Research Laboratories following the recent Keytruda study failure in head and neck cancer.

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

cGMP and BSL-1 facility near Washington, DC, USA

- Built specifically for Multikine
- State-of-the art facility
- Over 73,000 ft^2 of Manufacturing and R&D space available
- About 45,000 ft^2 fully developed
- Proprietary automated cold fill to ensure no loss of biological activity during fill

Well over $100 million was spent. The facility was built before the Phase 3 trial started and the capacity was recently doubled in preparation for commercialization.

Inspected several times by European Qualified Person (QP)

- Inspected by the QP for the manufacture and release of Sterile Medicinal Products (per ICH and EU Directives)

Significant “know how” developed to manufacture Multikine – Method of Manufacture

- Patented, but the key protection lies in the manufacturing trade-secret

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

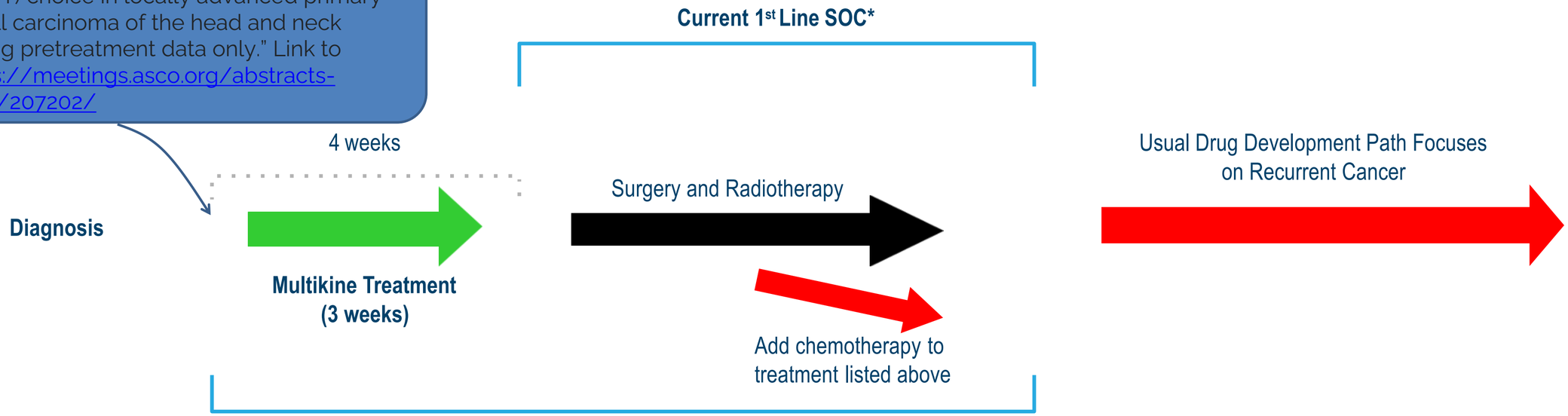
"Head and neck cancer is possibly the most horrific of all cancers. Not only does it take your life, but it takes your beauty, your voice and your dignity."

— from a discussion with a head and neck oncologist

Phase 3 Study Design -Timing of Multikine Treatment Regimen

Advanced Primary Head and Neck Cancer

•"Novel algorithm for assigning risk/disease-directed treatment (DDT) choice in locally advanced primary squamous cell carcinoma of the head and neck (SCCHN): Using pretreatment data only." Link to abstract: https://meetings.asco.org/abstracts-presentations/207202/



Proposed New 1st Line SOC* for patients receiving Surgery and Radiotherapy only (the black line)
CEL-SCI has developed a way of selecting patients for surgery and radiation before the surgery (ASCO 2022)

* Standard of Care

Phase 3 Results Published at ASCO

Overall survival advantage for patients with surgery and radiation:

- There is a 14.1% absolute advantage (62.7% vs 48.6%) in overall survival (OS) in surgery followed by radiotherapy treatment arm (lower risk for recurrence) at 5-years in patients with locally advanced primary squamous cell carcinoma of the head and neck.
- This group is called the lower risk for recurrence group, but “lower risk” does not mean low risk!
- The control group without Multikine still faced a high risk of death of over 50% at year five post-therapy.

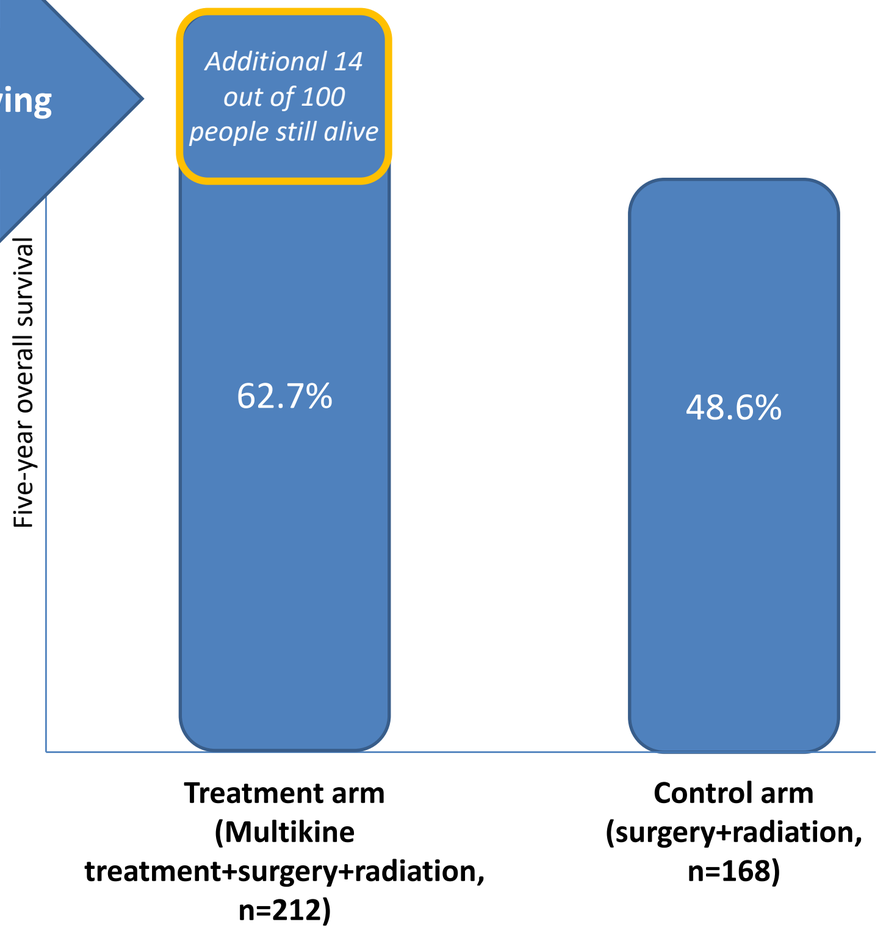
Overall survival prolongation for patients with surgery and radiation:

- Nearly four-year increase in median survival in this treatment arm
- 101.7 months versus 55.2 months

Phase 3 Trial Results: Summary Of Very Significant Survival Benefit

Ten-year clinical trial of Multikine
Five-year overall survival

14.1% absolute survival advantage in patients receiving surgery + radiation



Phase 3 Results Published at ASCO

Partial and complete tumor responses before surgery (Early responses)

- 8.5% of Multikine-treated patients (45 of 529) in the overall intent-to-treat (ITT) population (n=923)
- 16.0% of Multikine-treated patients (34 of 212) in the surgery plus radiation treatment arm
- Five of these early responders in the Multikine+CIZ treatment arm were confirmed to have complete tumor response at surgery
- Zero early response were seen in the SOC (control) alone (consistent with literature)

Early responders had very significant reductions is death rates:

- In the overall ITT population, 22.2% death rate (n=45) among Multikine responders versus 54.1% death rate for the Multikine non-responders (n=484) (two-sided Fisher Exact test $p<0.0001$; HR=0.301)
- In the surgery plus radiation treatment arm, 17.6% death rate (n=34) among Multikine responders versus 42.7% death rate for the Multikine non-responders (n=178) (two-sided Fisher Exact test $p=0.0067$; HR=0.348)

Phase 3 Results

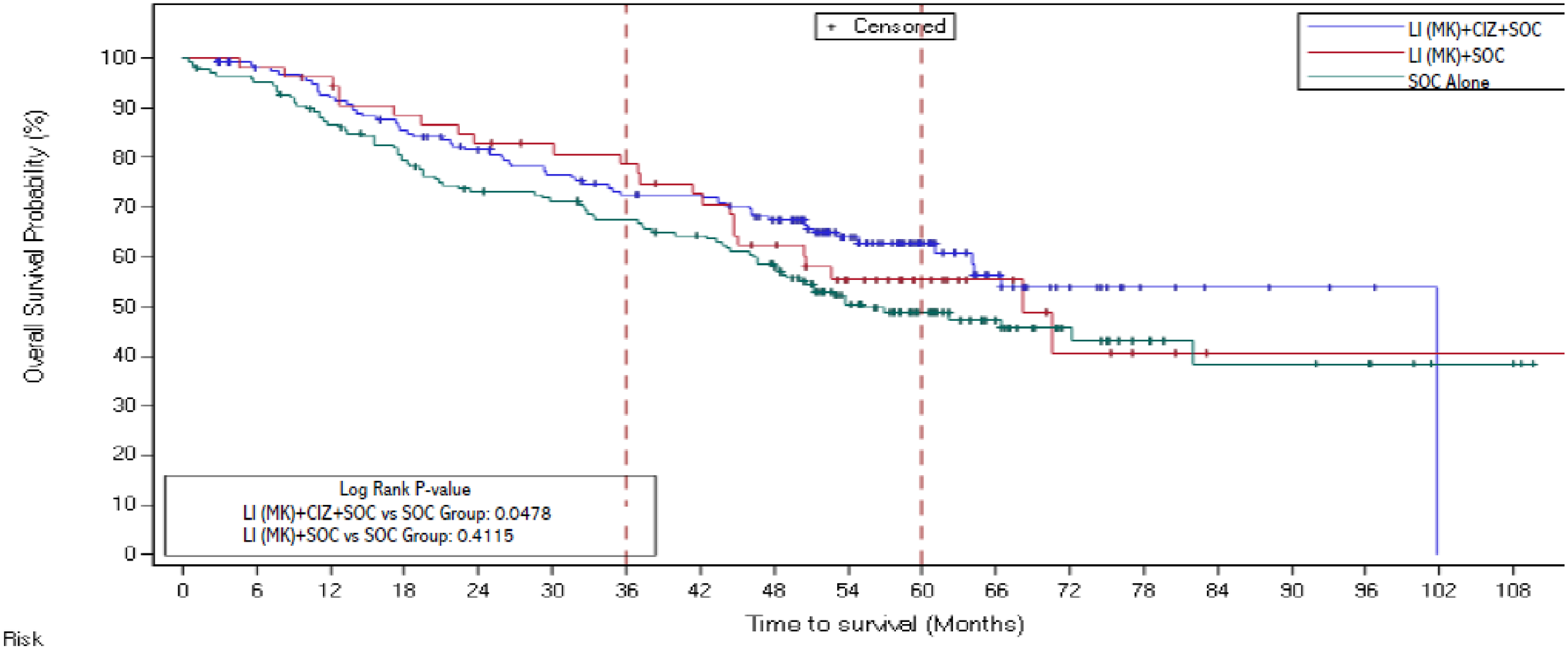
Histopathological analysis confirmed the effect of Multikine

- 61 markers, ratios, and combinations showing a statistically significant effect (two-sided $p<0.05$) favoring the Multikine+CIZ cohort versus the SOC alone (control)
- For overall survival, progression-free survival, and locoregional control outcomes

Additional (confirmatory) progression-free survival (PFS) benefit in the treatment arm scheduled to receive surgery and radiation

Overall Survival (OS) of the Study Lower Risk Population (n=380)

Kaplan-Meier (K-M) life tables for the study lower risk population. Group 1 = LI (MK)+CIZ+SOC; Group 2 = LI (MK)+SOC; Group 3 = SOC alone. ULR = Unstratified Logrank, SRL = Stratified Logrank



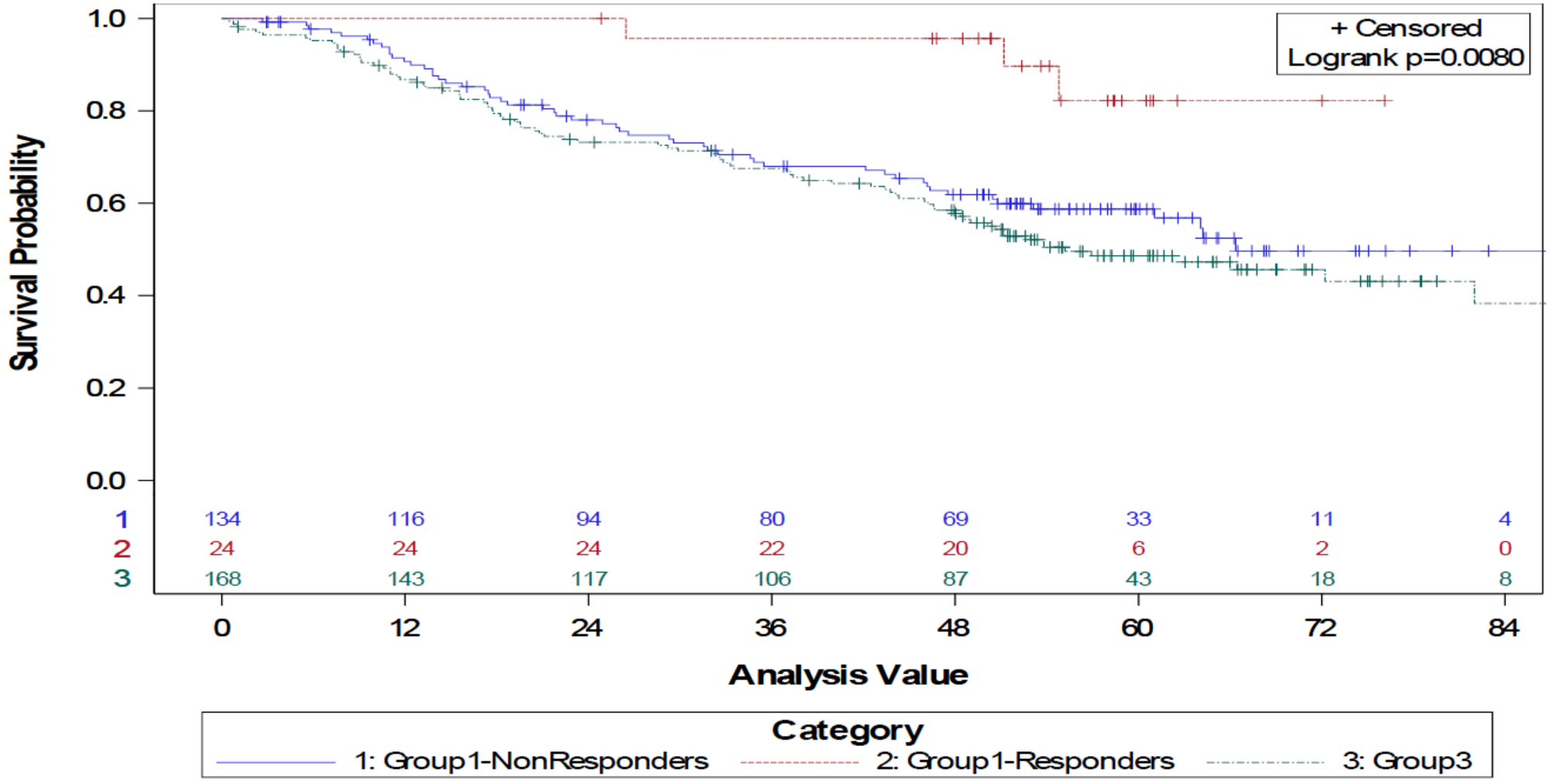
at Risk

LI (MK)+CIZ+SOC	158	150	140	129	118	110	102	100	89	61	39	22	13	6	4	3	2	0	0
LI (MK)+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

Overall Survival: ITT Population
Lower Risk [LR] (N= 380) Responders vs Non-Responders vs SOC

LOG RANK: LR-RESPONDERS VS LR-NON-RESPONDERS, P=0.0104; LR-RESPONDERS VS LR-SOC, P=0.002; LR-NON-RESPONDERS VS LR-SOC, P=0.2853

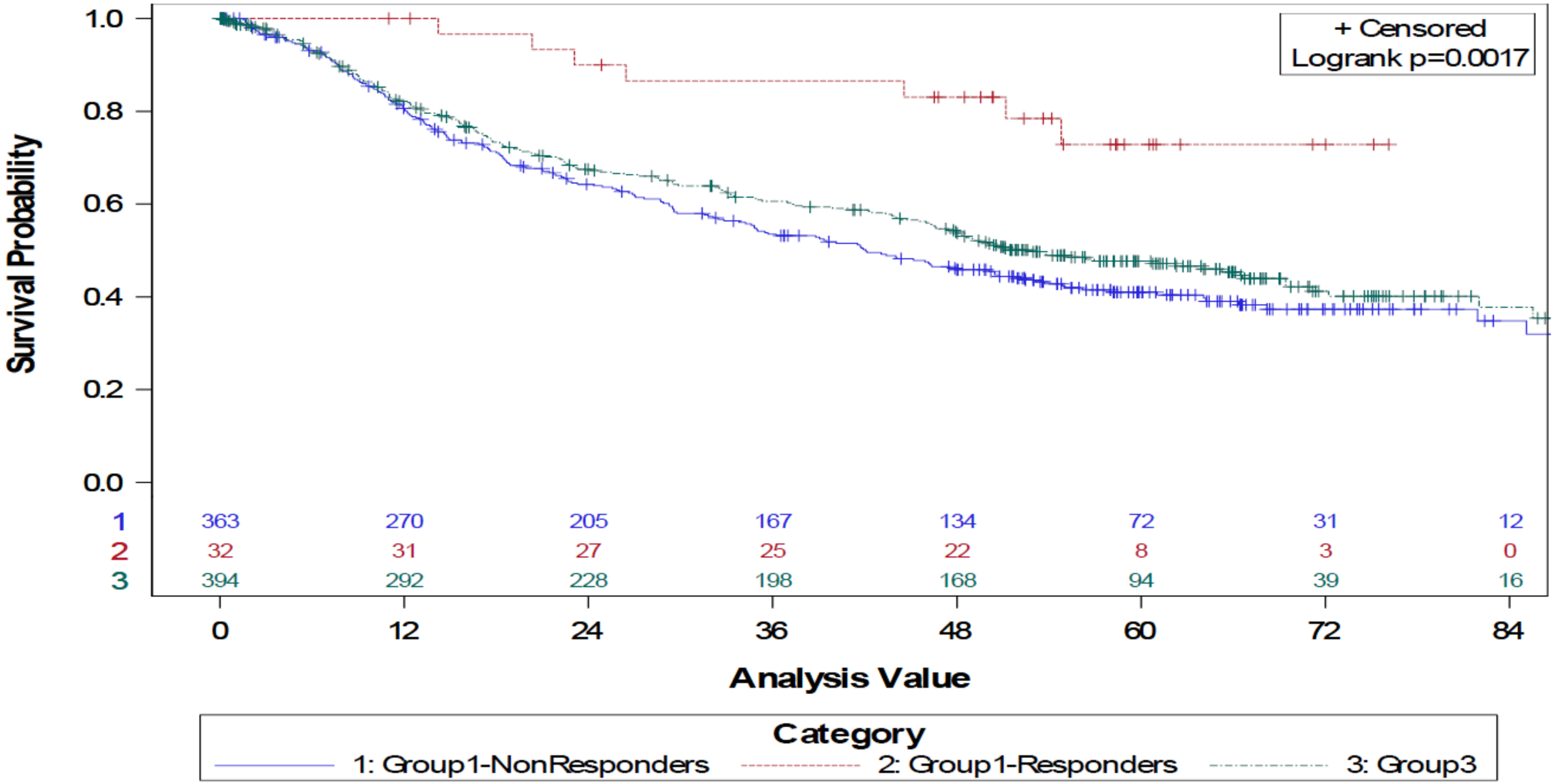
- **Early response is prognostic with a carryover effect observed for non-responders**



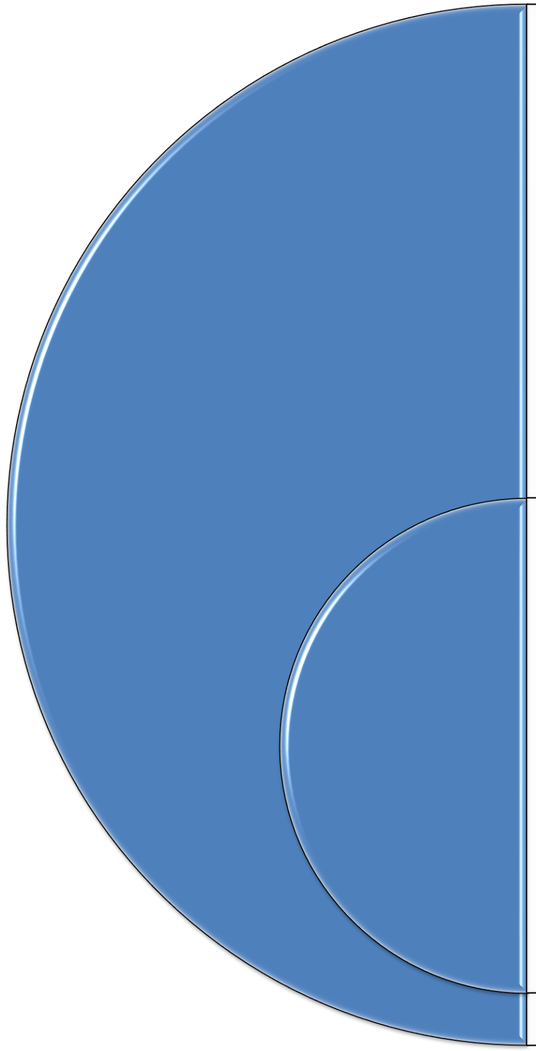
Overall Survival (OS): ITT Population (N= 923)
Overall Risk Responders vs Non-Responders vs SOC

LOG RANK: RESPONDERS VS NON-RESPONDERS, P=0.0007; RESPONDERS VS SOC, P=0.0037; NON-RESPONDERS VS SOC, P=0.1070

- **Early Response is prognostic for Overall Survival**



Phase 3 Trial Results: Ten-Year Clinical Trial In 928 Patients



In the entire population:	• 8.5% of patients saw partial or complete tumor response in the three weeks prior to surgery • Vs. zero (0) tumor response before surgery in control group • Tumor response → lower death rate (22.2% vs 54.1%) • No evidence of spontaneous tumor responses in the literature for head and neck cancer • No toxicity was added to overall treatment
In the surgery-plus-radiation treatment arm who did not receive chemotherapy (n=380, prespecified):	• 14.1% absolute 5-year overall survival benefit • Difference between survival of 62.7% and 48.6% • Almost 4 years median overall survival benefit • 16.0% of patients saw partial or complete tumor response in the three weeks prior to surgery • Vs. zero (0) tumor response in control group • Tumor response → lower death rate (17.6% vs 42.7) • Histopathology confirmation with 61 markers • Confirmatory progression-free survival

Early Response Conclusions

Early tumor response was prognostic and predictive of survival in the subjects who exhibited early response irrespective of their risk group allocation. These data set the stage for an overall survival advantage confirmation. For the lower risk LI (MK)+CIZ+SOC group, there was a 306% (100 x (1-0.246)/0.246) survival prolongation for 15.2% in this treatment group. Assuming no survival prolongation for the remaining 84.8% in this treatment group, this projects an overall 46.5% survival prolongation (3.06x15.2%); this corresponds to a 0.68 HR (1/1.465) which is exactly what was observed for the LI (MK)+CIZ+SOC group with lower risk classification. The significant 0.68 HR for the lower risk population LI (MK)+CIZ+SOC vs. SOC equates to a 47% survival prolongation, characterized by a 5-year 14.1% absolute[22] OS advantage, and a 46 month median OS advantage over lower risk SOC alone.

Thus, a LI (MK) response not only is prognostic but also predicts a favorable survival outcome.

Who is Working with us on the FDA Application, other than our own team?

1. **We have retained the services of two leading CROs to help: ICON and Ergomed**
2. **Phil Lavin, our statistician, has a team of experts working with us:**

   Dr. Lavin is a well-known biostatistician with a long history supporting clinical trials. He was a member of the Biostatistics faculty at the Harvard School of Public Health and the Department of Surgery at Harvard Medical School where he was affiliated for over 25 years. He co-founded Boston Biostatistics which became Aptiv Solutions before it was acquired by ICON plc. He has authored or co-authored over 180 peer-reviewed publications in the medical and statistical literature. He innovated a new study design used widely for medical devices (quasi-non-inferiority design). He has developed solutions for optimum timing of interim analysis, extending labeling for multiple endpoints, and devising composite endpoints and models for interim monitoring of adaptive studies. He has served as the Lead Biostatistician for >60 original FDA approvals to date including PMA's (37), NDA's(19), BLA's (4), 510k's (4), CE Mark's (4), a de novo, and an HDE with more pending.
3. **A former FDA Associate Commissioner and congressional insider experienced in strategically resolving regulatory and legislative issues**
4. **A former FDA legal counsel**
5. **A former FDA clinical reviewer**
6. **Key Opinion Leaders (KOLs) in the head and neck cancer community**

Steps In The Process For FDA Approval

Using the study data, we have identified and validated a way to determine what patient is supposed to receive radiotherapy as opposed to radiotherapy plus chemotherapy following surgery (ASCO 2022)

We are working with FDA towards preparing our Biologics License Application

We are working on peer review in top scientific journals and top scientific meetings

We are working on validating our commercial sized manufacturing facility in Maryland, USA

Equity Summary

CEL-SCI Corporation	NYSE American: CVM
Clinical Trial Stage	Working on marketing approval
Market Capitalization	~$150 million
Trading Volume	~ 0.5 million shares per day
Shares Outstanding	~ 43 million shares
Share Price	~ $3.50
Cash on Hand	$29 million, per the last quarterly filing

Reference slides for Early Tumor response and its Implications on Patient Survival:

Early Tumor Response Rates: Overall and NCCN Risk-based

- Among all 923 subjects and within lower/higher/missing risk populations:

Metric	LI (MK)+CIZ+SOC (n=395)	LI (MK)+SOC (n=134)	Combined LI (MK) (n=529)	SOC (n=394)
Overall ITT	8.1% (32/395)	9.7% (13/134)	**8.5% (45/529)**	**0% (0/394)**
Lower Risk	15.2% (24/158)	18.5% (10/54)	**16.0% (34/212)**	**0% (0/168)**
Higher Risk	3.5% (7/200)	4.3% (3/69)	**3.7% (10/269)**	**0% (0/198)**
Missing Risk	2.7% (1/37)	0% (0/11)	**2.1% (1/48)**	**0% (0/28)**

Early Tumor Response Results in Decreased Death Rate (Prognostic and Predictive of Survival):

In Randomized ITT Population – LI (MK) Early Response (CR/PR) prior to surgery

	Early Responders ([CR+PR]/n), (%)	Deaths % LI (MK) Early Responders / Remaining LI (MK)-Treated (n)	Hazard Ratio (HR) [95% CI]
All LI (MK) treated (Lower, Higher, and Missing Risk) (n=529)	45/529 (**8.5%**)	22.2% (10/45) Early Responders vs 54.1% (262/484) Early non-Responders 2-Sided Fisher Exact p-Value [**p<0.0001**]	**HR=0.301** [0.16, 0.566]
Combined Lower Risk LI (MK) treated (n=212)	34/212 (**16.0%**)	17.6% (6/34) Early Responders vs 42.7% (76/178) Early non-Responders 2-Sided Fisher Exact p-Value [**p=0.0067**]	**HR=0.348** [0.152, 0.801]
Lower Risk Group 1 LI (MK)+CIZ+SOC (n=158)	24/158 (**15.2%**)	12.5% (3/24) group 1 Early Responders vs 41.0% (55/134) Early non-Responders 2-Sided Fisher Exact p-Value [**p=0.0101**]	**HR=0.246** [0.077, 0.787]

NOTES: (1) Early response is highly prognostic for future survival. (2) No early responses in the control group.

OS ITT Lower Risk Entry -> Exit: % Alive 36, 48 and 60 Months (n=380)

		Treatment Group			Delta
Population	Milestone	LI (MK)+CIZ+SOC (’1’)	LI (MK)+SOC (‘2’)	SOC (‘3’)	‘1’ vs ‘3’
ITT (99.5%)	36 months	72.4% (64.4%, 78.9%)	78.8% (65.0%, 87.7%)	67.5% (59.7%, 74.1%)	4.9%
ITT (99.5%)	48 months	67.3% (59.0%, 74.3%)	62.3% (47.4%, 74.1%)	57.8% (49.7%, 65.0%)	9.5%
ITT (99.5%)	60 months	62.7% (54.0%, 70.2%)	55.5% (40.5%, 68.2%)	48.6% (40.4%, 56.4%)	14.1%
Improving Overall Survival Advantage Over Time					

CEL-SCI

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