



Leukocyte Interleukin, Injection
For Head And Neck Cancer

Multikine™ Pre-Surgical Cancer Therapy

November 24, 2023

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 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 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 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 and its website.

Equity Summary

CEL-SCI Corporation

NYSE American: CVM

Clinical Trial Stage

Completed 928-patient, global, multicenter, Phase 3 cancer immunotherapy study

Market Capitalization

~\$125 million

Avg. Daily Trading Volume

~ 1 million shares per day

Shares Outstanding

~ 50 million shares; completely clean cap structure

Share Price

~ \$2.52

Company Overview

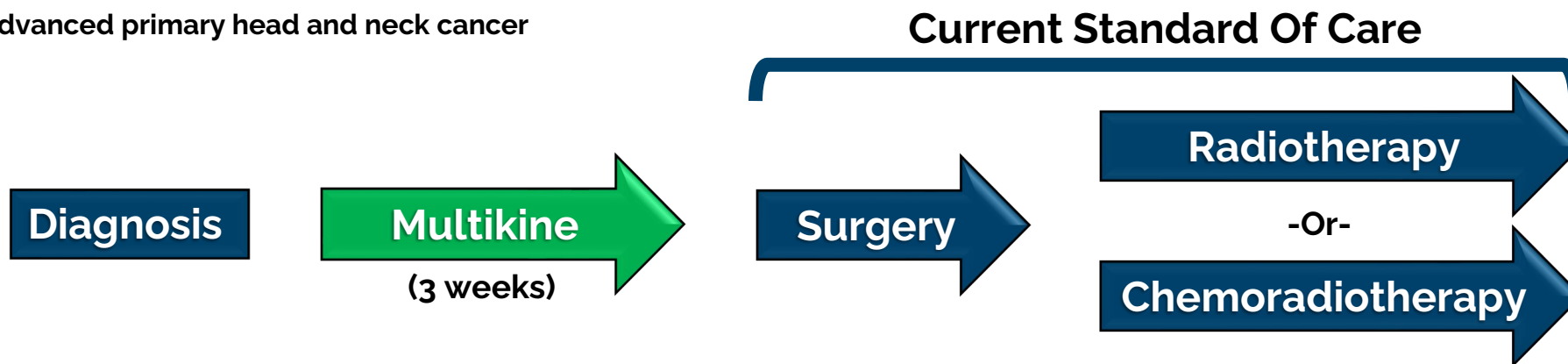
Our Mission	Create first pre-surgical cancer treatment, first for head and neck cancer, then other cancers.
Introducing Multikine	Multikine is an immune boosting drug which is administered right after diagnosis, before surgery and other treatments have damaged the immune system.
Why Does It Work?	Multikine is administered when the immune system is strongest. There have been no systemic toxicities or Multikine-related deaths reported in more than 700 human subjects.
We Have Now Defined Our Target Population	Advanced primary head and neck cancer patients with low PD-L1 tumor expression, no nodal involvement and no extracapsular spread (about 145,000 p.a. globally)
Phase 3 Results in the Target Population	Our results show that Multikine cut the risk of death in half at five years versus the control in the finalized target population.
Pathways to Approval	Pursuing accelerated/conditional approval pathways with the U.S. FDA, Health Canada, European Medicines Agency, and UK Medicines and Healthcare Products Regulatory Agency.

What Is Multikine?

- Multikine is a true first line immunotherapy — 3 weeks before surgery.
- It is a mixture of cytokines and biological molecules.
- Multikine induces a local immune anti-tumor attack before the immune system has been compromised by treatment or disease.

Multikine Treatment Regimen

Locally advanced primary head and neck cancer



73%
vs
45%



- **No Multikine-related deaths.**
- **Multikine-related adverse events before surgery were local and resolved after surgery.**
- **Adverse event rates in the Multikine and control groups were not significantly different.**

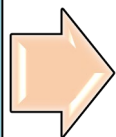
The Key is our Ability to Define The Target Population

- **The target population are advanced primary head and neck patients who present with:**
 - **No nodal involvement and no extracapsular spread** (via PET scan)
 - **Low PD-L1 tumor expression** (defined as TPS<10, via biopsy)
(Note, this differentiates Multikine from high PD-L1 checkpoint inhibitors.)
- **Physicians routinely assess these features at baseline.**
- **These tests are standard practice.**
- **These features define the patients who benefit from Multikine, an essential requirement for regulators to write an approval label.**
- **This represents about 145,000 patients globally per year.**

We Know How Multikine Works And Can Target This

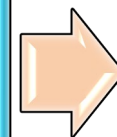
1.

We observed statistically significant pre-surgical responses after Multikine treatment.



2.

Pre-surgical responses lead to better survival.



3.

Therefore, selecting more patients predicted to have a pre-surgical response should lead to much better survival in the target population.

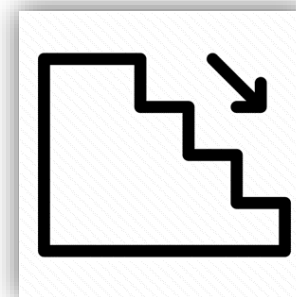
Pre-Surgical Responses Observed in the Phase 3 Trial

- A “pre-surgical response” is a significant change in disease before surgery.
- Pre-surgical responses lead to better survival.
- We saw two kinds of responses in the Phase 3 trial:
 - First, there were “reductions” in the size of the tumor—a reduction of 30% or more qualified as a “pre-surgical reduction” or “PSR” for short.
 - Second, there were disease “downstages,” e.g., the disease improved from Stage IV to Stage III. We call this a “pre-surgical downstaging” or “PSD” for short.



Reductions (PSR)

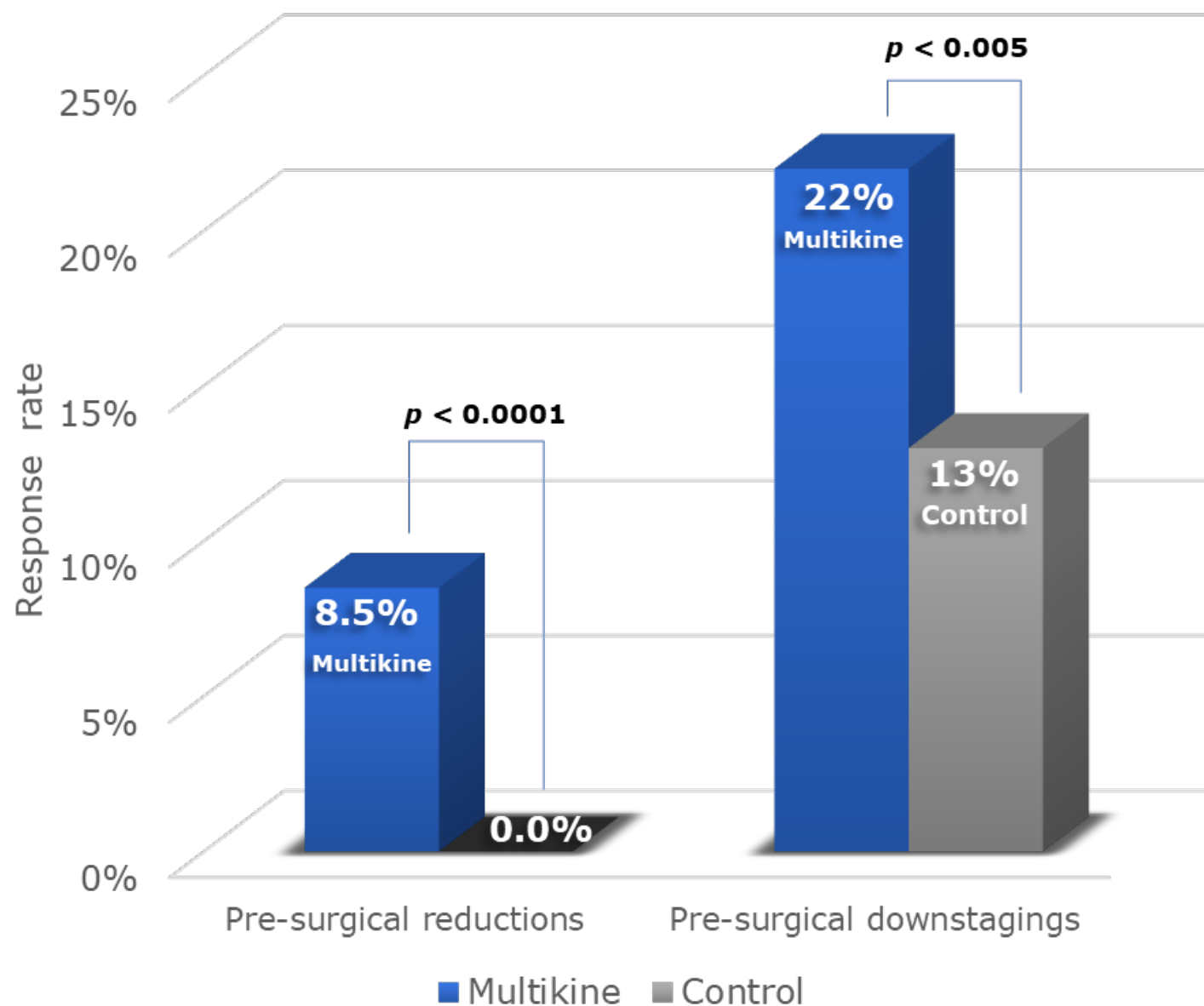
>30% reduction in tumor dimensions



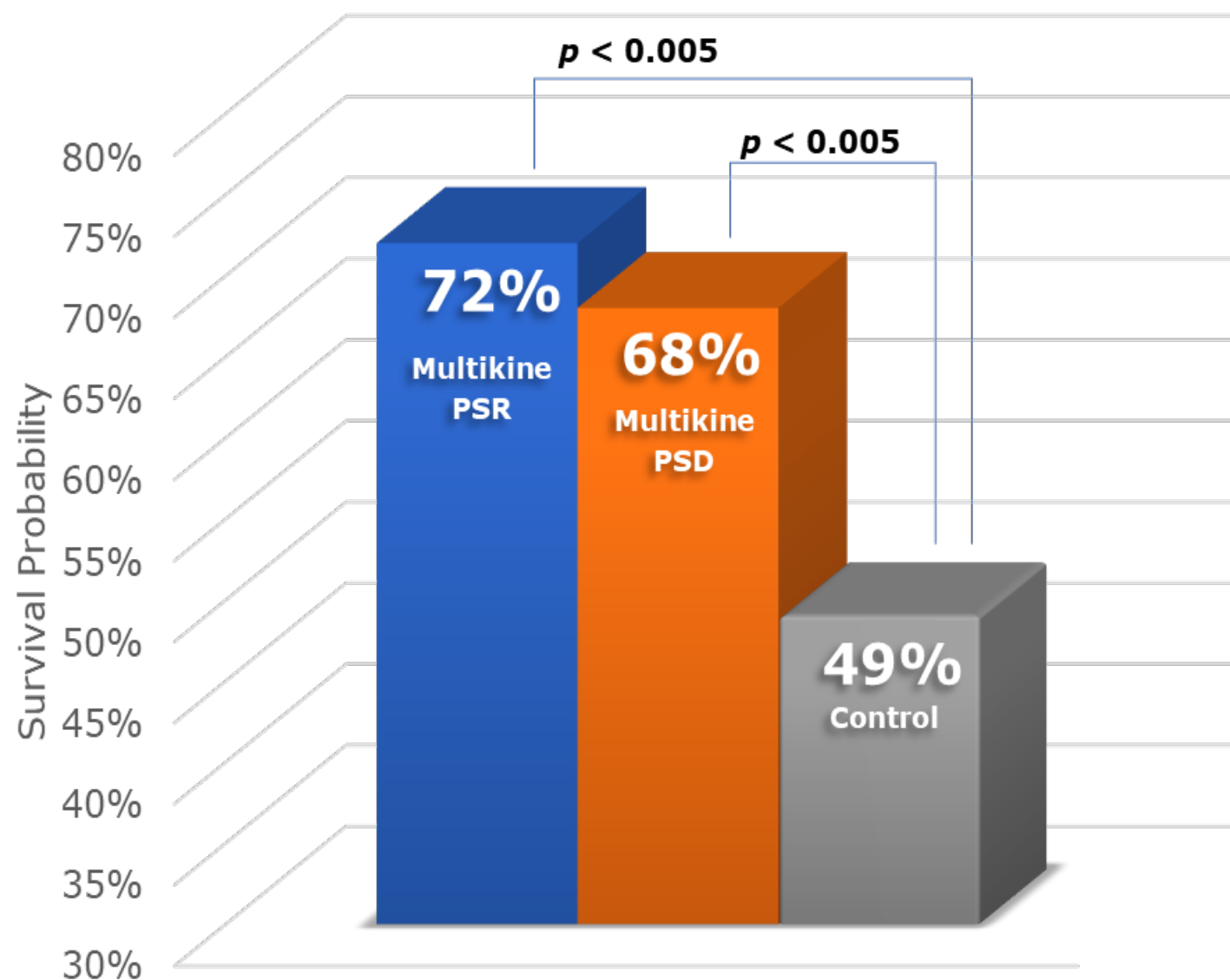
Downstages (PSD)

Stage IV to III,
Stage III to II

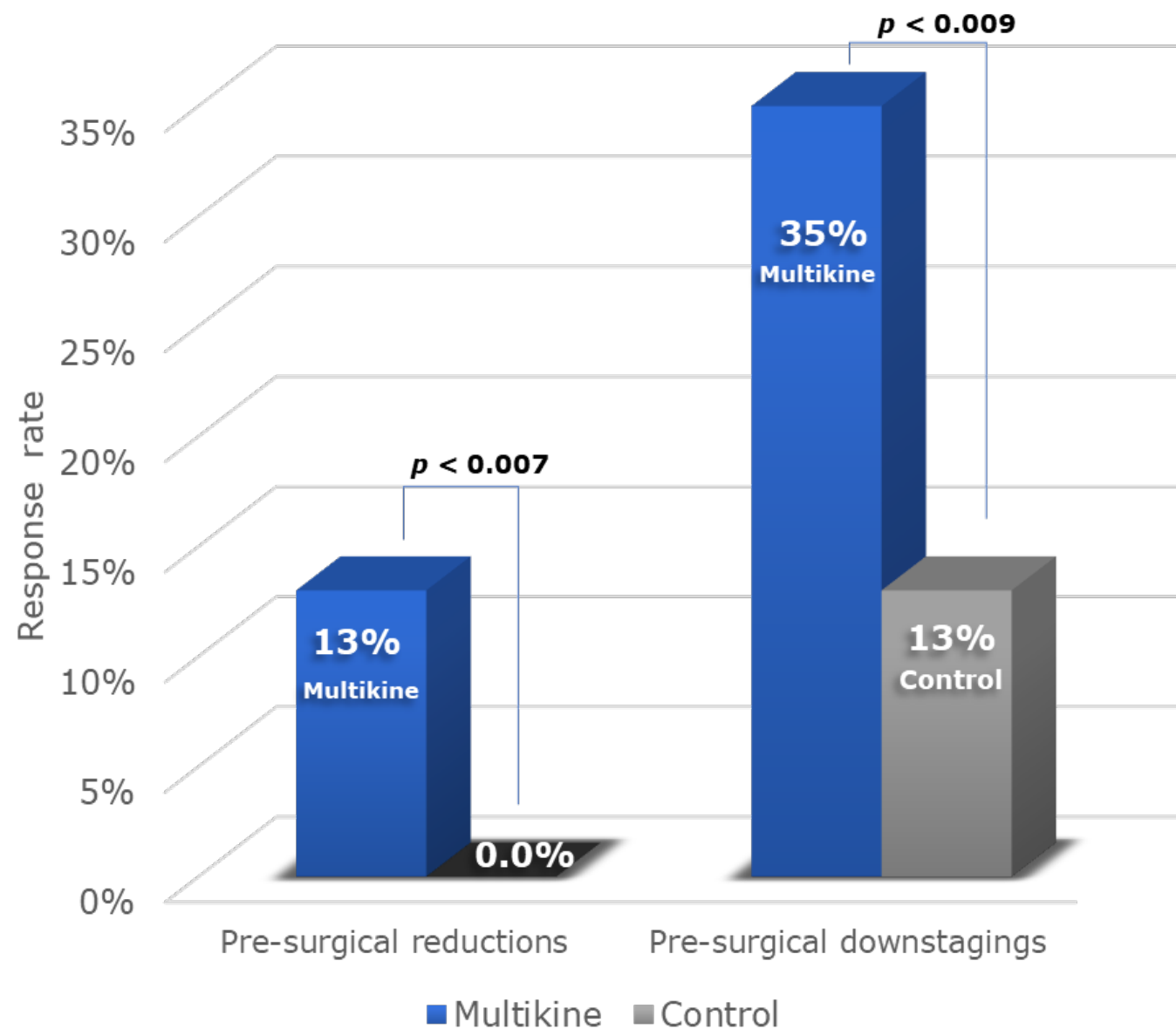
All Phase 3 Study Patients: Multikine leads to Pre-Surgical responses



All Phase 3 Study Patients: Pre-Surgical Responses Lead To Better Survival



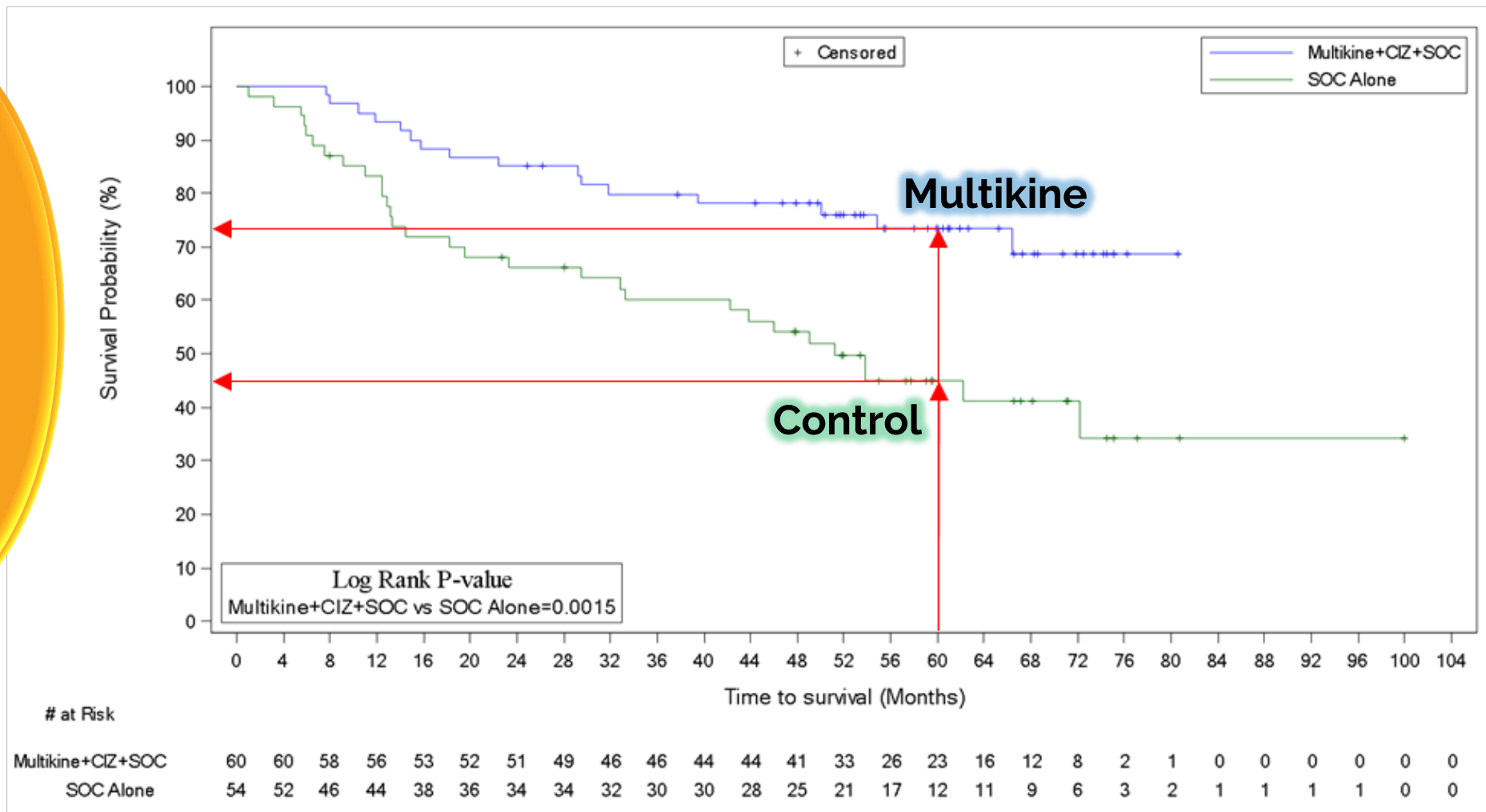
Higher Response Rates In The Target Population



Therefore, Multikine Leads To Better Survival

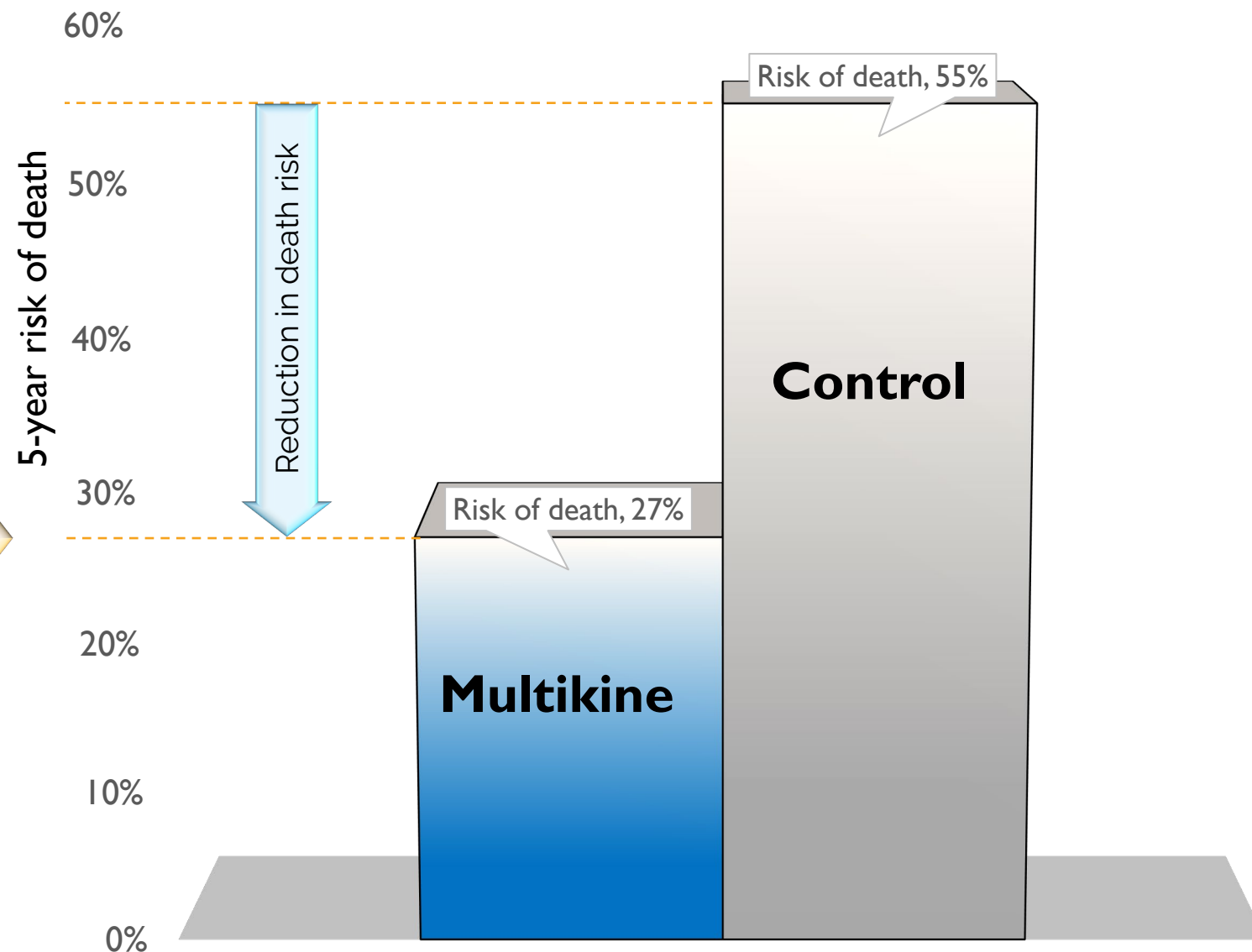
Kaplan-Meier Overall Survival for Multikine target population (n=114) in the Phase 3 study

**73%
vs
45%**



Our Data: Multikine Leads To Better Survival

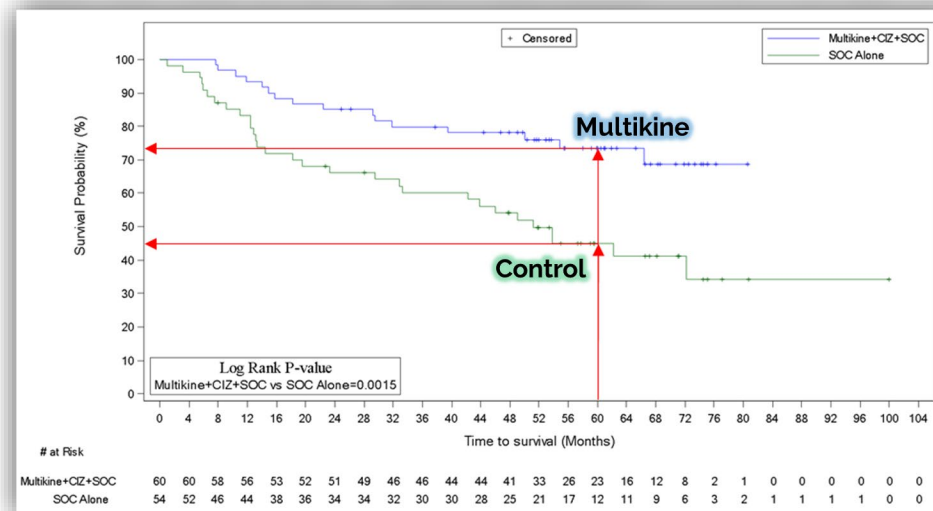
Multikine cut the 5-year risk of death *IN HALF* in the target population



Why Are We Confident In Gaining Approval of Our Drug?

- ✓ **73% survival for Multikine vs 45% in the control, at 5 years**
- ✓ **28% jump in 5-year absolute survival**
- ✓ **Statistically significant $p = 0.0015$**
- ✓ **5-year risk of death cut from 55% to 27%**
- ✓ **Hazard ratio = 0.35 (95% CIs [0.19, 0.66])**
- ✓ **Tumor reduction rate >13%**
- ✓ **Tumor downstaging rate >35%**
- ✓ **No safety signals or toxicities vs standard of care**

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



- ✓ **Europe, UK, Canada, USA**
- ✓ **Seeking approval based on current data**
- ✓ **Goal: get approval first, then complete confirmatory study if required**
- ✓ **Submissions filed 3Q23-1Q24**
- ✓ **Commissioning of manufacturing plant completed by 1Q24**

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 expected to be completed in Q4 2023, and validation expected to be completed in Spring 2024.



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.

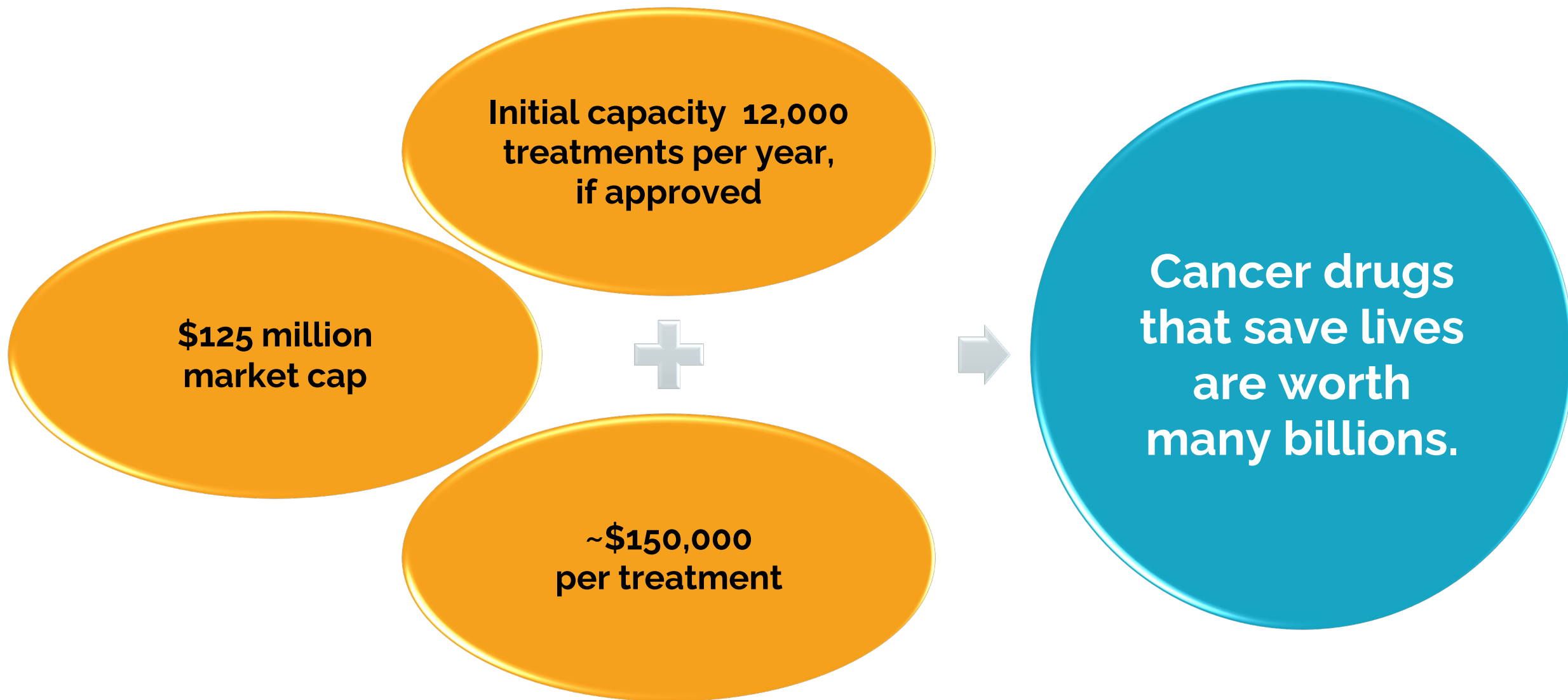
Inspected several times by European Qualified Person (QP)

- 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.

CEL-SCI's Value Proposition



Upcoming Milestones & Investment Highlights

We have observed statistically significant survival data in the final target population vs control in a Phase 3 study conducted for Multikine.

Multikine focuses on the 70% of patients not well served by the two leading approved drugs, Keytruda and Opdivo, which are not approved as pre-surgical treatments (CEL-SCI's intended market).

We plan to submit the target population data to the FDA and Health Canada in Q1 2024 and will collaborate with the FDA on the design of a clinical protocol that will allow us to generate the confirmatory data they require for approval of Multikine.

Submitted final target population data and requests for Scientific Advice to the EMA and UK MHRA and are hopeful for meetings in H1 2024. Europe has more than twice the number of head and neck cancer cases diagnosed each year as compared to the U.S.

Planning to file for NOC/C in Canada and potential commercialization as early as 2024, if approved.

With the completion of the manufacturing process expected to be completed in spring 2024, this will position CEL-SCI to supply approximately 12,000+ treatments per year.

The CEL-SCI Team



Geert Kersten, Esq.

- CEO 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



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

Top-Tier Physician Consultants



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

Thank you.

