

Multikine<sup>TM</sup> "A First-In-Class Cancer Immunotherapy"

Activating the immune system to fight cancer BEFORE the ravages of surgery, radiation and chemotherapy

**NYSE American: CVM** 

### **Forward Looking Statements**

#### This presentation contains forward-looking statements that involve risks and uncertainties. Please refer to our public filings for full disclosure.

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 forwardlooking words such as "anticipates," "believes," "expects," "intends," "future," "could," "estimates," "would," "plans," "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 actual results, performance 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 by applicable laws and regulations, we undertake no and foreign regulatory requirements; the therapeutic obligation to update these forward-looking statements benefits and effectiveness of our product candidates; to reflect new information, events or circumstances the safety profile and related adverse events of our after the date of this presentation. In light of these product candidates; our ability to manufacture sufficient risks and uncertainties, the forward-looking events and 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 licensesrelated 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.

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## What are main things a patient looks for in a cancer drug?

- 1) Patients want to be cured or live much longer
- 2) Patients are concerned about toxicity and side effects

Our Multikine cancer immunotherapy addresses both:

- Multikine increases the survival rate at 5 years from 45% to 73%.
- The Multikine treatment has been reported to be very safe and has not been associated with toxicities commonly seen in cancer treatments. It has also been shown to increase the quality of life.



#### What is Multikine?

- Investigational Phase 3 cancer immunotherapy
- Activates immune system before it is weakened by surgery, radiation and chemotherapy
- Targets newly diagnosed patients, not those who have failed prior therapy
- Completed 928-patient Phase 3 trial in head & neck cancer
- Potential to expand to other solid tumors (cervical, melanoma, etc.)

#### The key idea:

By giving Multikine immunotherapy before the ravages of surgery, radiotherapy and chemotherapy we activate the full power of a patient's natural immune system to fight cancer and are therefore able to have very large survival benefit without toxicity.



### **How Multikine Works**

• Multikine is a mix of natural cytokines that prime immune cells

Administered near tumor and draining lymph nodes before surgery

Helps immune cells overcome tumor defenses

• Mass-produced and non-toxic, becomes tumor-specific at site



### The Need for Innovation in Head & Neck Cancer

#### Head & neck cancer:

- 6th most common cancer
- about 900,000 newly diagnosed patients p.a.
- multi-billion \$ market
- Severe unmet medical need
- The targeted patient population has no viable alternatives

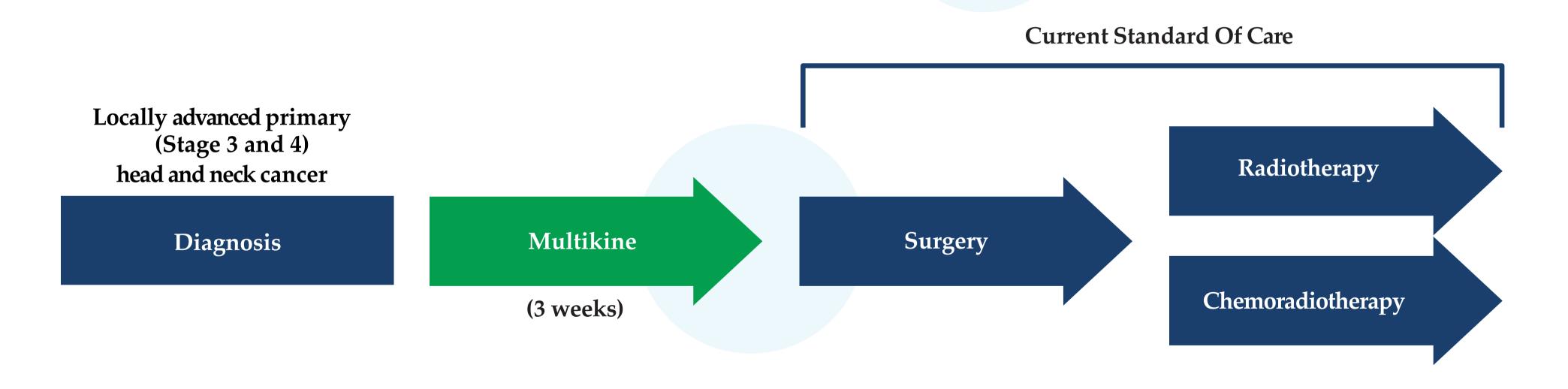
Multikine emerges as a beacon of hope as an investigational immunotherapy designed to activate the patient's own immune system before standard treatments, fundamentally aiming to change the therapeutic paradigm.



## Current Standard of Care for These Very Sick Head & Neck Cancer Patients

Treatment sequence: Multikine is given before the standard therapies, right after diagnosis.

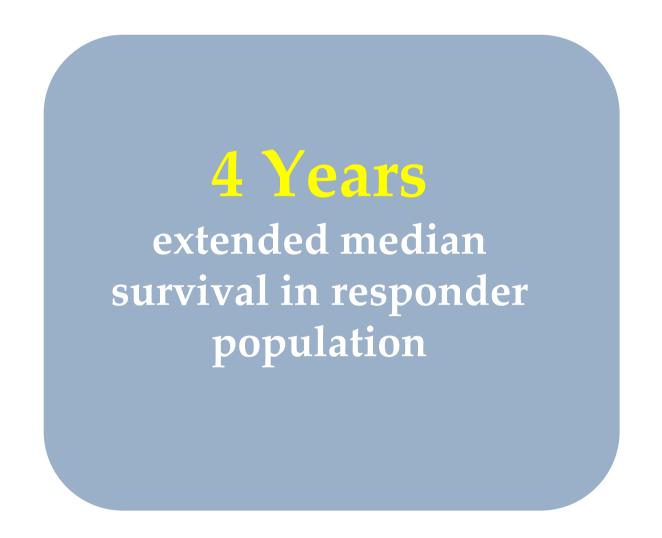
It enhances the immune system when it is strongest.

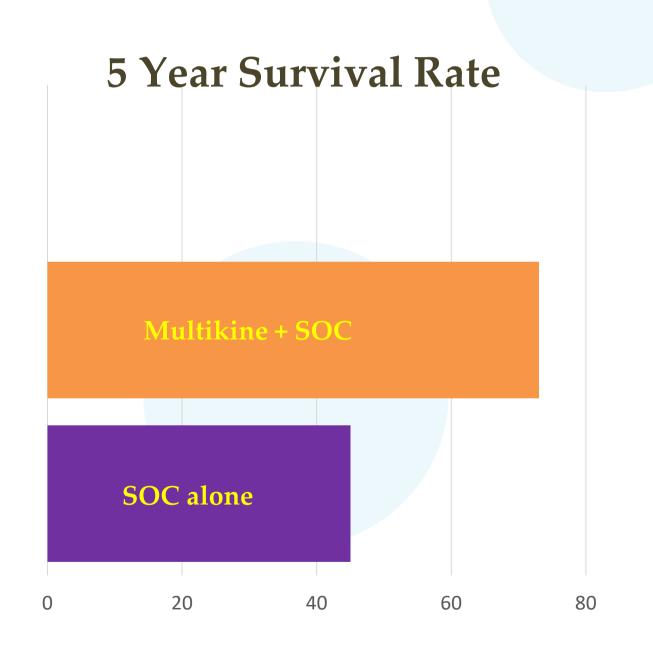




## Clinical Breakthrough: Transforming Patient Outcomes

In a 928 patient Phase 3 study of head & neck cancer patients, Multikine has demonstrated unprecedented survival benefits in a specific subpopulation. These results are not just statistically significant; they represent a clinically meaningful extension of life, offering profound hope for patients and their families.







Multikine was reported to be safe and well tolerated.



The specific indication is newly diagnosed patients with advanced squamous cell carcinoma of the head and neck, with no lymph node involvement and low PD-L1.

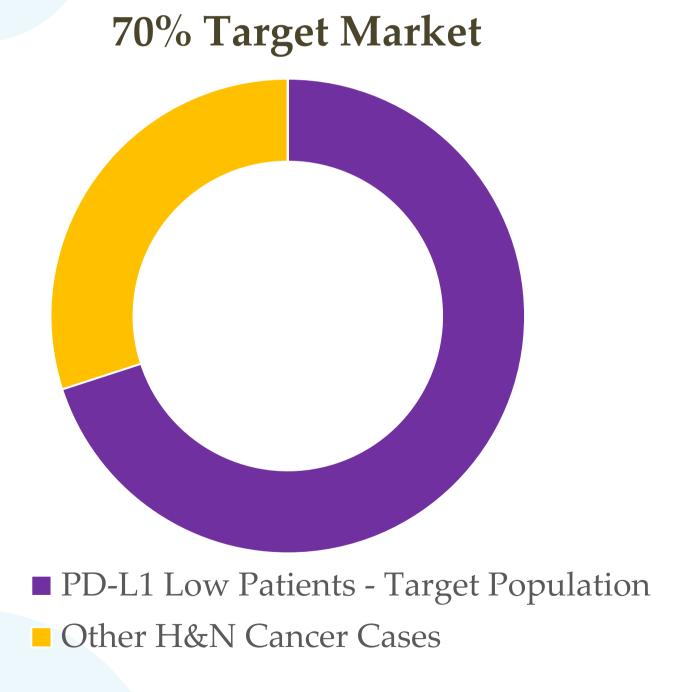
# Market Opportunity: Targeting a Significant Patient Population

Multikine is poised to address a substantial segment of the head and neck cancer market, particularly patients with low or zero PD-L1 expression who are not served by the current blockbuster immunotherapy Keytruda.

This represents a significant global patient population with a pressing need for new treatment options.

4 years of life extension for patients who do not benefit from Keytruda. That group of patients was 70% of the newly diagnosed patients in our Phase 3 study.

About 100,000 PD-L1 Low H&N Cancer Patients Annually are Multikine's initial target market (Global Estimate)

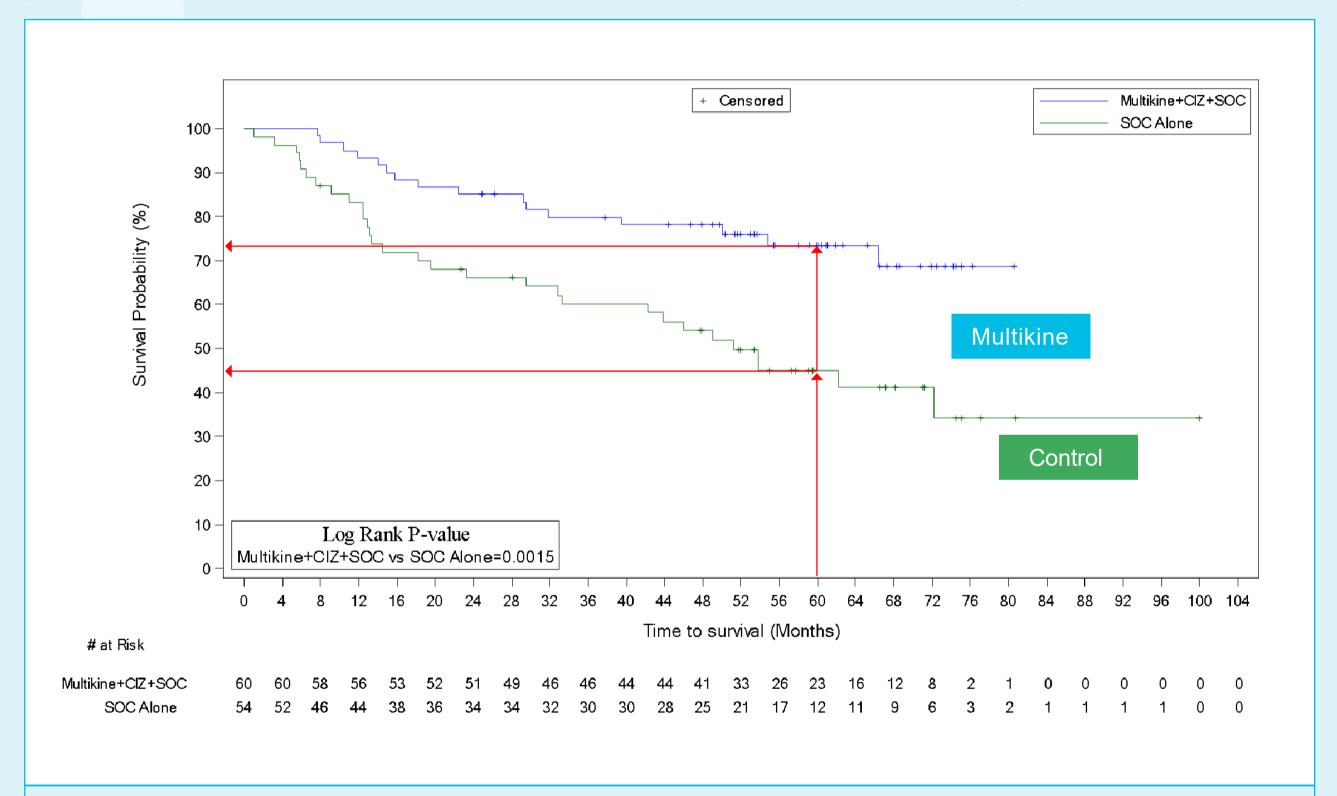




# Multikine Improved Survival in the Completed Phase 3 Study

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

- No safety signals or toxicities vs standard of care
- 5-year survival: 73% (Multikine) vs. 45% (Control)
- Statistically very significant (log rank p = 0.0015)
- Survival curves separate early and survival benefit increases with time
- Hazard ratio = 0.35 (95% CIs [0.19, 0.66])



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

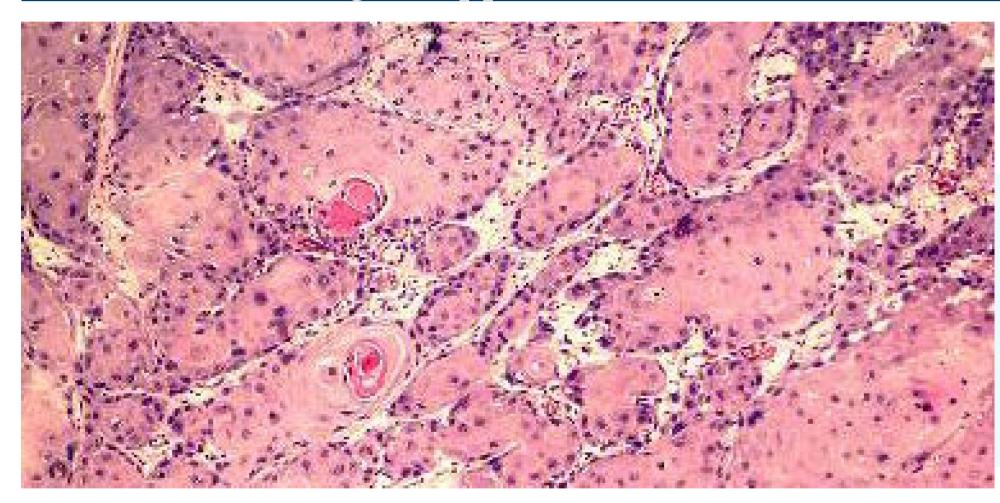


# Some Patients Have Complete Tumor Elimination in Just 3 Weeks, Confirmed by Pathology

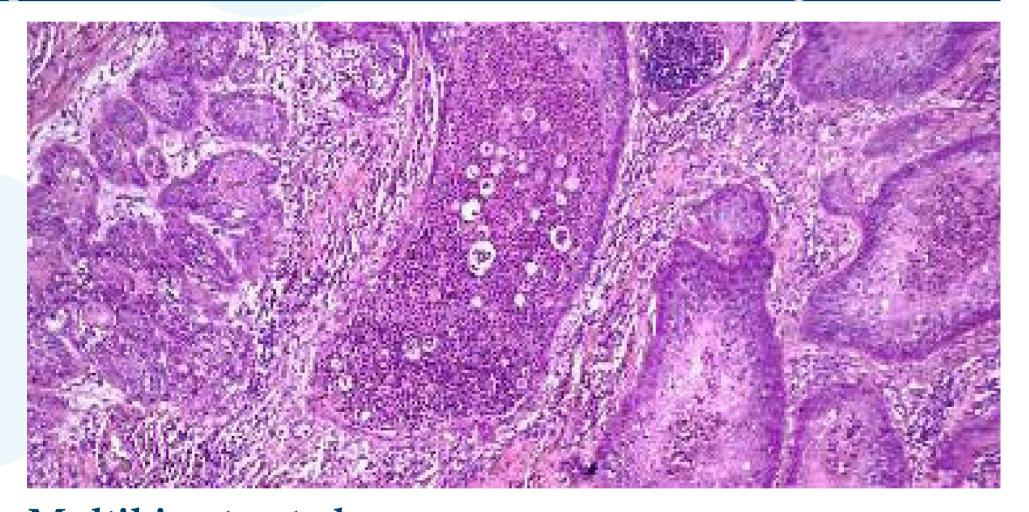
#### Oral Squamous Cell Carcinoma

(Locally Advanced Primary H&N Cancer)

#### Histological appearance of necrosis in Oral Squamous Cell Carcinoma (OSCC) [HE staining]:



Non-Multikine treated
Lack of necrosis (cell death) in the epithelial nests



Multikine treated

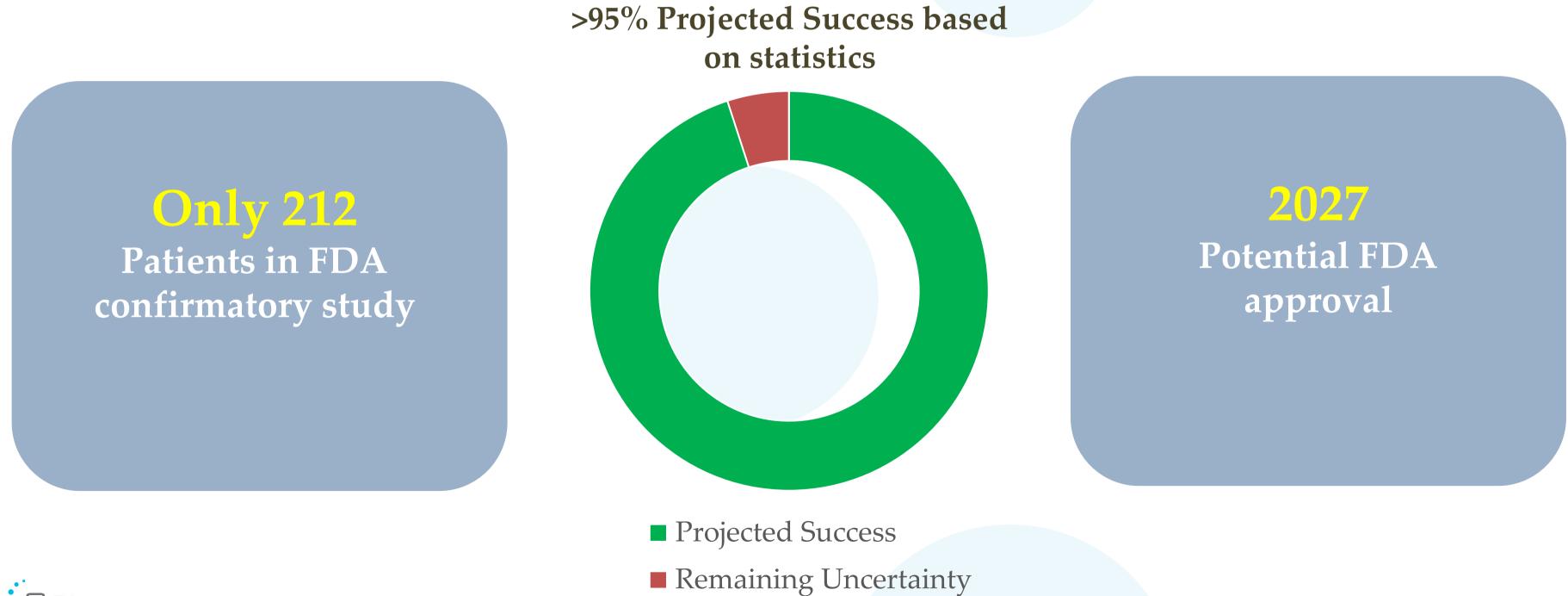
Entire cancer nest is necrotic (cancer cells are dead) and filled with debris and leukocytes



## Regulatory Outlook: A Clear & De-Risked FDA Pathway

Productive discussions with the U.S. FDA have outlined a clear and de-risked path forward for Multikine.

The path involves a targeted confirmatory study for drug approval with an over 95% probability of success, underscoring the robustness of the existing clinical data from the prior Phase 3 study.





# Navigating Challenges: A Strategic Dual-Track Approach

A robust dual-track strategy is in place to accelerate Multikine's path to approval for patients globally.

#### Track 1: Saudi Arabia Focus

Saudi FDA encouraged us to apply for Breakthrough Designation

If Breakthrough Designation is granted, Multikine would be available for sale/ reimbursement by early fall 2025

Revenue to Help Fund our U.S. Confirmatory Study

Partnership with Leading Saudi Pharma Company Aligned with Saudi Arabia's Vision 2030

#### Track 2: U.S./Global Partnering

Ongoing U.S. and Global Partner
Discussions to Fund Confirmatory Study

Potential for Saudi Investment to Fund Confirmatory Study

Favorable signals from U.S. FDA:
On May 22, Dr. Marty Makary, Commissioner of the FDA, told the U.S. Senate that the FDA's goals include: "Cancer therapies that are so powerful, a tumor is eliminated without the need for surgery or chemo."



## Saudi Arabia: Strategic Gateway

- **Likelihood of success**: The Saudi Arabian Food and Drug Authority (SFDA) encouraged CEL-SCI to apply for Breakthrough Medicine Designation based on the Multikine Phase 3 data. If granted, Multikine would be available for sale/reimbursement potentially by early fall 2025. Saudi Arabia has a national healthcare system, which could lead to substantial near-term revenues from Multikine sales.
- **Large market**: Saudi Arabia has a population of 37 million + 16 million ex-pats. A Saudi approval serves as an entry point to one of the largest and fastest-growing pharmaceutical markets in the world—the Middle East and North Africa (MENA) region, where the incidence of head and neck cancer is expected to double by 2030.
- **Strategic Alignment**: Multikine's potential approval capitalizes on the long-standing and economically focused U.S.-Saudi relationship, which has historically fostered significant bilateral investment, particularly in strategic sectors like healthcare.
- **Vision 2030 Catalyst**: CEL-SCI's entry into the Saudi market is timed with Saudi Arabia's transformative Vision 2030 which is injecting billions into healthcare and actively seeking international pharmaceutical innovation. Vision 2030 is a Saudi government plan aimed at diversifying the economy and establishing Saudi Arabia as a global leader in industries such as biotechnology.
- Enhanced Capital Access: A local approval is a key enabler for attracting Saudi-based investment, forming strategic partnerships, and potentially leveraging government incentives aimed at building a vibrant domestic life sciences ecosystem.



# Manufacturing Readiness: Prepared for Global Supply

An investment of over \$200 million has been made into Multikine manufacturing, ensuring that Multikine can be produced at scale to meet anticipated global demand upon approval.

\$2 B

Potential annual manufacturing capacity (value)

+\$200 M

Invested in state-ofthe-art facility





#### **Barrier to competition – Process of manufacture**

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

#### c GMP and BSL-1 facility near Washington, DC

- → Built specifically for Multikine
- → Over 73,000 ft<sup>2</sup> of Manufacturing and R&D space available
- → Proprietary automated cold fill to ensure no loss of biological activity during fill
- → Inspected by the QP for the manufacture and release of Sterile Medicinal Products (per ICH and EU Directives/Regulations)

## **NYSE American: CVM**

- 6.8 million shares outstanding.
- Clean cap structure. No warrants, convertibles, etc.
- Very actively traded stock.
- Geert Kersten, CEO of CEL-SCI, purchased \$200,000 worth of CEL-SCI restricted stock in late July 2025.



## The Vision: A Transformative Future for Patients

Multikine represents more than just a drug; it is a **potential paradigm shift in cancer care** (by activating an anti-tumor immune response **before** surgery, radiation and chemotherapy). Our immediate goal is to bring this life-extending therapy to head and neck cancer patients globally, starting with strategic early market access and progressing to broader approvals. Multikine can then be developed for many other cancers.

#### A Multi-Billion Dollar Opportunity with a Clear Path to Commercialization.

We are seeking partners and investors who recognize the profound value of a de-risked, late-stage oncology asset with groundbreaking clinical data and an innovative strategy for global market entry.

#### **Upcoming Potential Catalysts**

Potential commercial availability and patient access in Saudi Arabia as soon as early fall of 2025

Partnership with a leading Saudi Pharma Company

Potential to Commence U.S. Pivotal Trial early 2026 with a Partner; Approval as Early as 2027

Approval in Saudi Arabia Might Support Regulatory Access in Other countries!?



# Thank you!

