

MultikineTM "First In Class Cancer Immunotherapy"

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

NYSE American: CVM

Forward Looking Statements

This presentation contains "forward-looking statements" within the meaning of the Private Securities Litigation 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," "plans," "would," "should," "continues" "potential," 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 cause our 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 Reform Act of 1995, Section 27A of the Securities Act of 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 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.

> 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

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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 CEL-SCI's future anticipated regulatory with 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.



What is Multikine?

- Multikine is an investigational cancer immunotherapy with *little to no toxicity* that activates the immune system of cancer patients. It is given <u>before</u> surgery, radiotherapy and chemotherapy have compromised or destroyed the immune system.
- THIS IS A FUNDAMENTAL CHANGE IN THE WAY WE TREAT CANCER PATIENTS because normally cancer drugs are developed for recurrent cancer patients, those patients who have already failed other treatments.
- Multikine has completed a 928 patient Phase 3 clinical trial in head and neck cancer.
- Our goal is to establish a new Standard of Care (SOC) for newly diagnosed head and neck cancer patients.
- Multikine is not tumor specific. Therefore, it should also be developed against other solid tumors such
 as cervical, anal, melanoma, bladder and breast cancer.



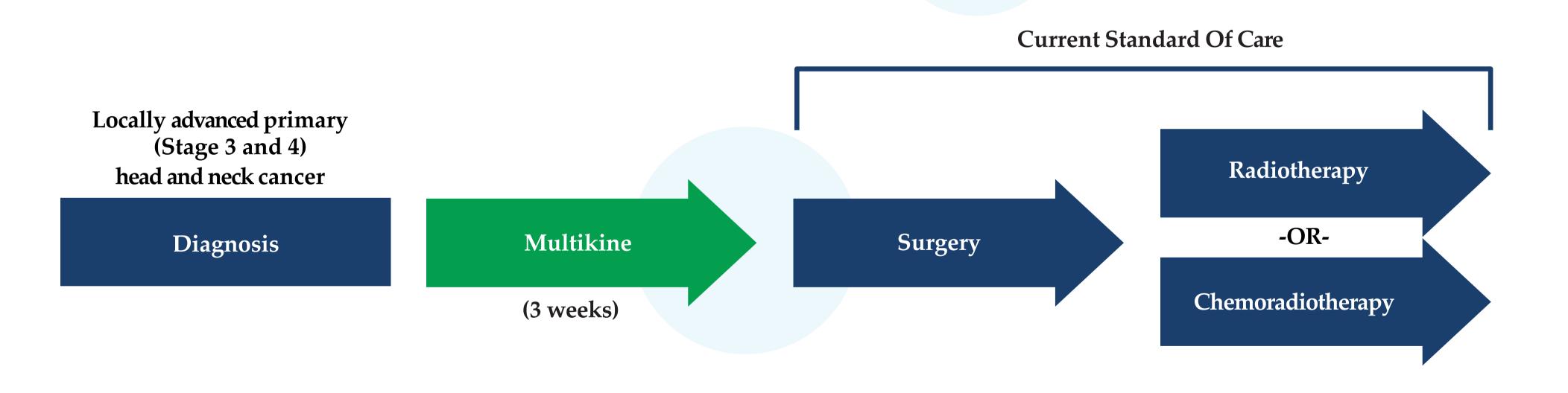
How Does Multikine Work?

- Multikine is a mixture of natural cytokines (regulators of our immune system).
- It helps the body's immune cells recognize a tumor when the immune system is strongest, before surgery, radiotherapy and chemotherapy.
- Published studies of cancer patients have shown anti-tumor immune cells infiltrating the tumor,
 but not able to destroy the tumor because the tumor's defense mechanisms blocks them.
- Treating with Multikine helps the body's natural immune cells overcome the tumor's defense mechanisms, enabling the immune cells to kill the tumor cells.
- It is a non-toxic, mass-produced (off-the-shelf) product, which becomes specific to a person's own tumor when injected near that person's tumor and adjacent draining lymph nodes.



This is the Current Standard of Care for These Very Sick Patients

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:





The Urgent Need for Innovation in Head & Neck Cancer

Head & neck cancer represents a significant global health challenge, with a multi-billion dollar market. For decades, patients have faced limited advancements in treatment options, highlighting a critical unmet need.

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

6th Biggest Cancer

Market size is many \$Billions

Decades

since new FDA-approved drugs for this initial treatment setting



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 PD-L1 expression who are not optimally served by current blockbuster immunotherapies.

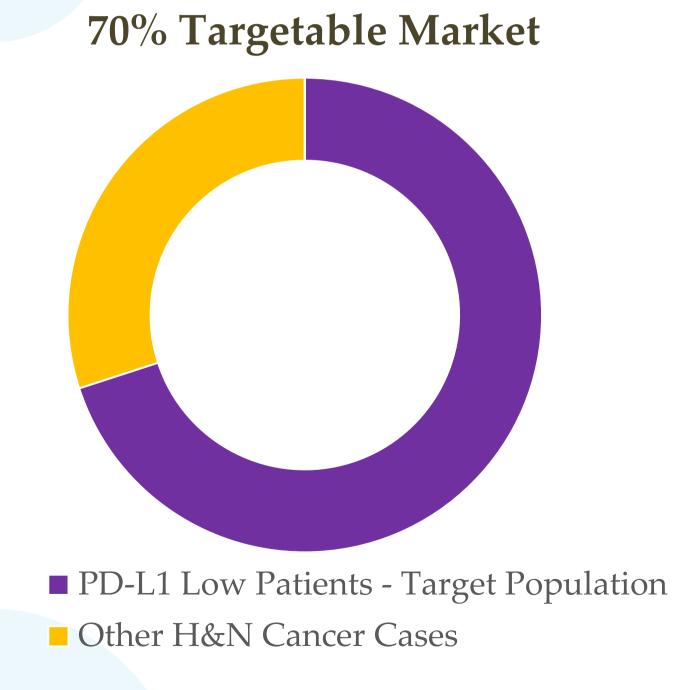
This represents a significant global patient population with a pressing need for new treatment options.

Addressing Keytruda/Opdivo Non-Responders

Multikine offers a novel approach for patients who may not benefit from existing PD-1/PD-L1 inhibitors

~100,000

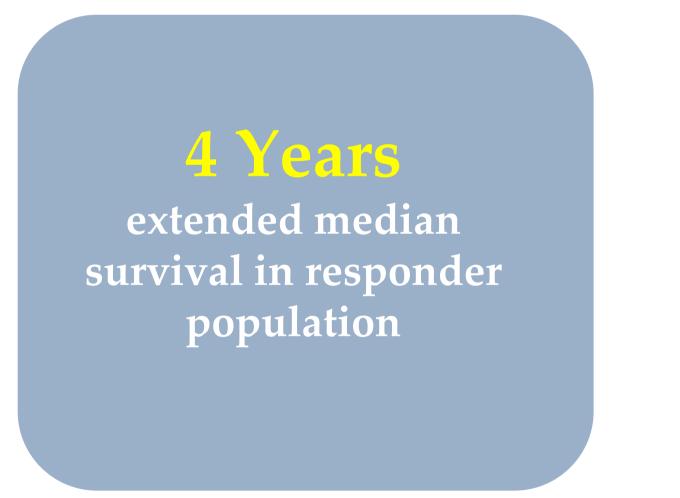
PD-L1 Low H&N Cancer Patients Annually (Global Estimate)

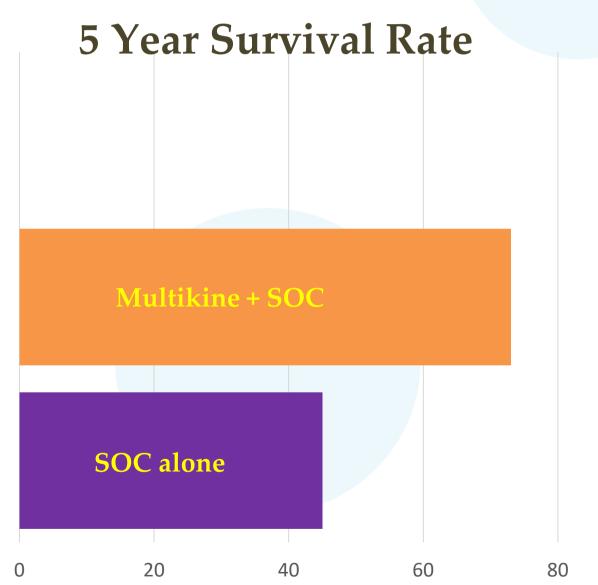


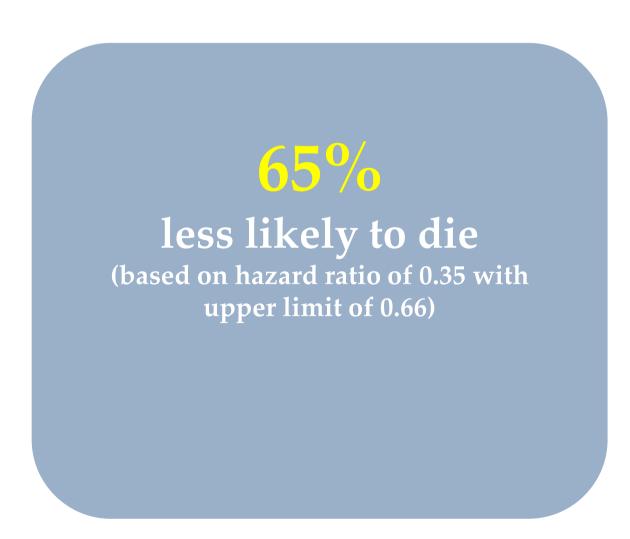


Clinical Breakthrough: Transforming Patient Outcomes

Multikine has demonstrated unprecedented survival benefits in a specific subpopulation of head & neck cancer patients. 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.

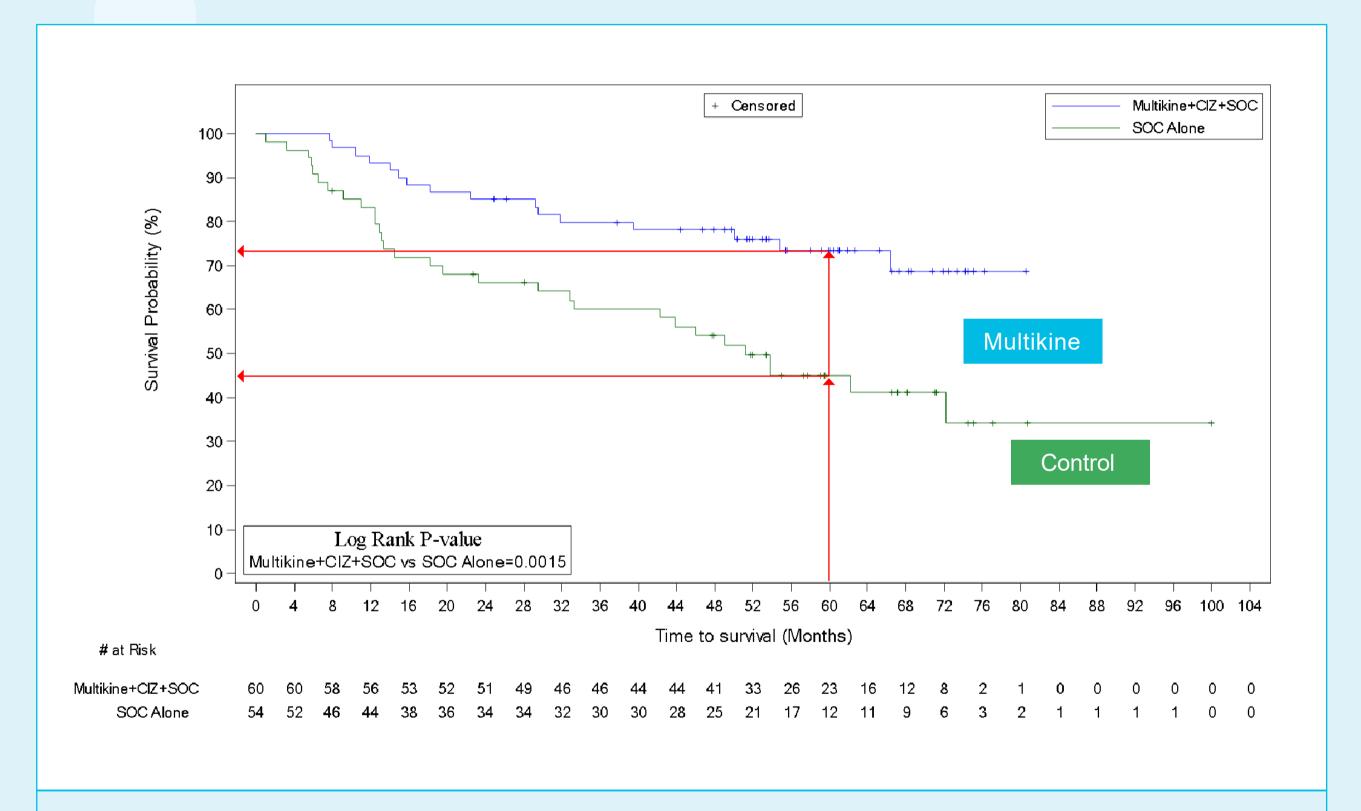


The specific indication is newly diagnosed patients with advanced squamous cell carcinoma of the head and neck, with no lymph node involvement and low PD-L1.

Multikine Improved Survival in the Completed Phase 3 Study Target Population (No lymph node involvement & PD-L1 low) for Confirmatory 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 immunooncology drugs as in the Multikine arm



5-year Overall Survival: 73% vs 45%

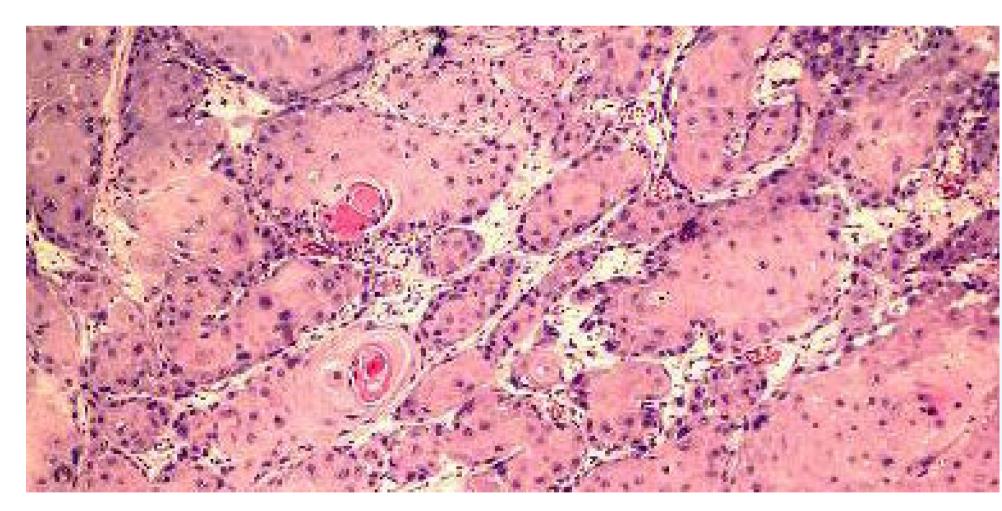


Some Patients Have Complete Tumor Responses in Just 3 Weeks

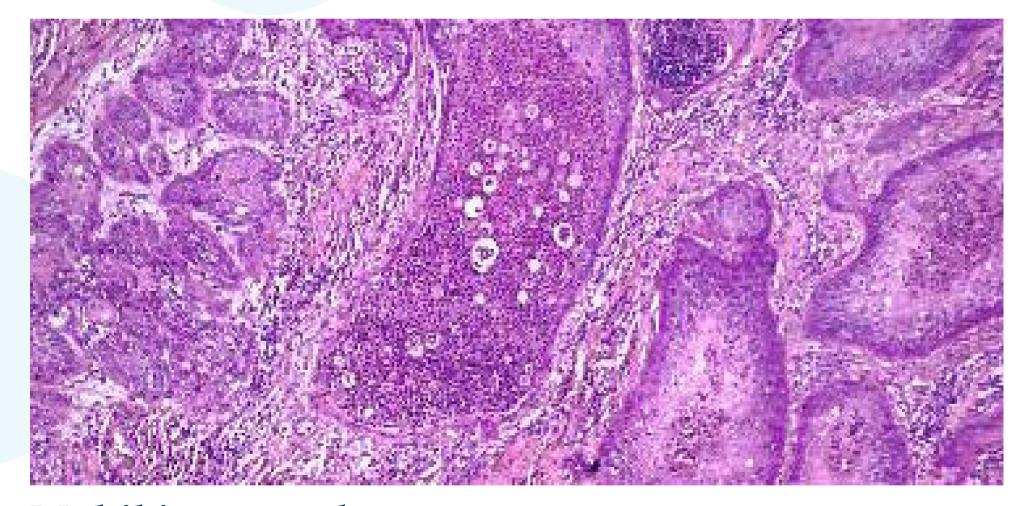
Oral Squamous Cell Carcinoma

(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



Navigating Challenges: A Strategic Dual-Track Approach

While the current biotech financing environment is challenging, a robust dual-track strategy is in place to secure funding and accelerate Multikine's path to patients globally. This is a funding challenge, not a drug efficacy or regulatory viability challenge.

Track 1: Saudi Arabia Focus

Met with Saudi FDA who encouraged us to apply for Breakthrough Designation

If Breakthrough Designation is granted, Multikine would be available for patient access and commercial use by Summer 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

U.S. and Global Partner Discussions to Start Confirmatory Study

Potential for Saudi Investment to Start Confirmatory Study

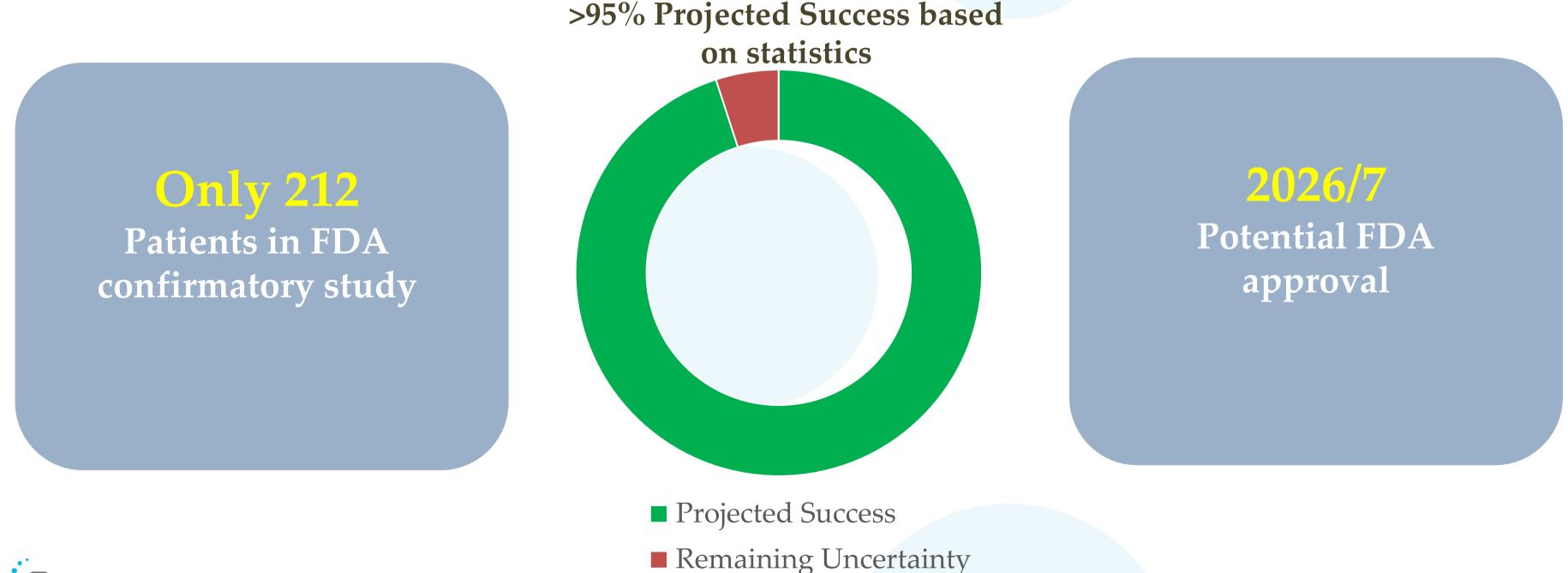
Favorable signals from U.S. FDA:
On May 22, Dr. Marty Makary, Commissioner of the FDA, told the U.S. Senate that the FDA's goals include: "Cancer therapies that are so powerful, a tumor is eliminated without the need for surgery or chemo."



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.

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





Why Saudi Arabia?

- **High Likelihood of Regulatory and Market 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 Breakthrough Designation is granted, Multikine would be available for commercial use and patient access potentially by summer 2025. Saudi Arabia has a national healthcare system with reimbursement, potentially leading to near-term revenues for CEL-SCI.
- **Gateway to a Growth 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:** This potential Multikine 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 ft² 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)

The Vision: A Transformative Future for Patients

Multikine represents more than just a drug; it's a <u>potential paradigm shift in cancer care</u>. 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 Early as Summer of 2025

Partnership with a Leading Saudi Pharma Company

Potential to Commence U.S. Pivotal Trial H2 2025 with a Partner; Approval as Early as 2026/7

Approval in Saudi Arabia Might Support Regulatory Access in Other Major World Markets!?



Thank you!

