



Multikine (Leukocyte Interleukin, Inj.) Cancer Immunotherapy

A Multi-Targeted Approach to Cancer Treatment

CEL-SCI Corporation

Eyal Talor, PhD
Chief Scientific Officer

8229 Boone Boulevard, Suite 802
Vienna, VA 22182, USA
-
Phone: **(703) 506-9460**

NYSE American: **CVM**

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.

FDA Disclaimer Statement

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. Moreover, no definitive conclusions can be drawn from the early-phase, clinical-trials data summarized in this presentation involving the investigational therapy Multikine (Leukocyte Interleukin, Injection). Further research is required, and early-phase clinical trial results must be confirmed in the well-controlled Phase 3 clinical trial of this investigational therapy that is currently in progress. 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.

Potential conclusions could only be drawn if the initial observations in the early-phase studies relating to the potential adverse events associated with Multikine administration in treating head and neck cancer are confirmed in the well controlled Multikine Phase 3 clinical study, CEL-SCI's Phase 3 study is completed successfully, and the FDA licenses the product following their review of all of the data related to Multikine submitted in CEL-SCI's license application.

Product Candidates

Indications and current stage of development

Candidate	Preclinical	Phase 1	Phase 2	Phase 3	Marketing approval
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MULTIKINE

Head and neck cancer

Neoadjuvant therapy in patients with squamous cell carcinoma of the head and neck (administered right after diagnosis, before the first standard cancer treatment) – Global Pivotal Phase 3 Study

HPV

Anal warts in HIV/HPV co-infected patients in collaboration with U.S. Navy

HPV

Cervical dysplasia in HIV/HPV co-infected patients (University of Maryland)

L.E.A.P.S. Technology

Pandemic Flu treatment:
(NIAID)

Rheumatoid Arthritis CEL-4000:
(US Gov. Grant – IND Enabling Studies)

Breast Cancer

Working to Create the First Cancer Drug to Be Administered Before Surgery

Multikine is administered to previously untreated, newly diagnosed head and neck cancer patients right after diagnosis for three weeks before the current standard of care treatments (surgery followed by radiation or combined radio-chemotherapy). There is no delay of surgery or follow on standard of care treatments. The intent of adding Multikine treatment to the current standard of care treatment regimen is to either cure the patient or increase the time to recurrence of the patient's cancer since there is a known correlation between increased time to recurrence and increased survival of patients. No severe toxicity was reported as being associated with Multikine when it was added to the current standard of care in phase II clinical trials. Our experience in our Phase 3 study with respect to toxicity has not been different what was seen during the Phase 2 studies.

The most common misconception with respect to the use of Multikine is that it is in competition with FDA approved immunotherapies (e.g., Keytruda, Opdivo, and CAR-T). In contrast to Multikine these other immunotherapies are indicated only for patients whose cancers have recurred following standard of care treatment (surgery etc.) or those patients with metastatic cancer where surgery is no longer an option. The use of these other cancer immunotherapies in the patient population being treated with Multikine would be inappropriate and unethical because they are administered over many months, which would cause a delay in the application of the currently used standard of care treatment which is potentially curative on its own. Further, the extreme toxicities that may be associated with these new products would preclude their use in patients that are potentially curable by the current standard of care.

We are at the end of an eight year Phase III clinical trial to prove this novel way of treating cancer.

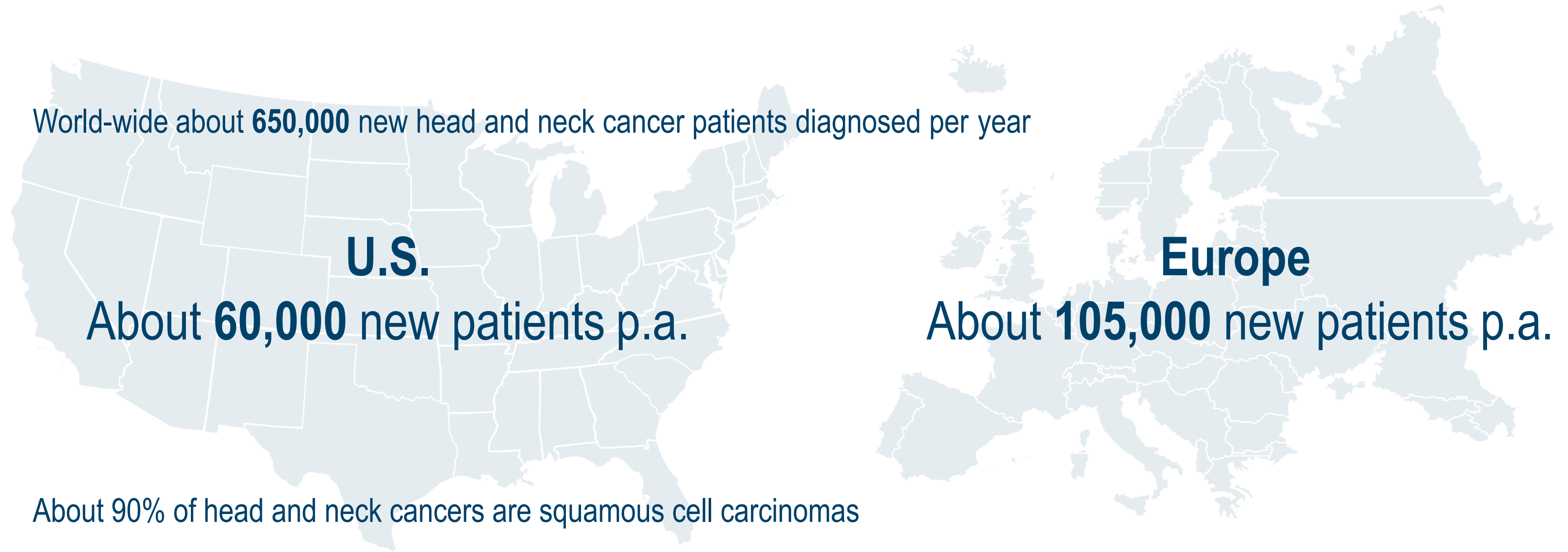
Why Head and Neck Cancer as a First Target?

Advanced primary (not yet treated) head and neck cancer was selected as the first indication because:

- Represents a large, unmet medical need
 - Last FDA approval of a therapy for advanced primary head and neck cancer was many decades ago (unmet medical need)
 - FDA granted Orphan Drug designation
 - H&N cancer represents about 6% (650,000 patients) of the world's cancer cases
- One worldwide established first-line standard of care for head & neck cancer (NCCN Guidelines)
 - Ability to conduct a study world-wide
 - Our goal is to be added to existing regime and become part of new standard of care (SOC)
- We believe that Multikine's administration is ideally suited for the established SOC in H&N cancer
 - SOC is comprised of surgery followed by either radiation or concurrent radiation/chemotherapy
 - During the 3-4 week preparation & scheduling of surgery, the Multikine treatment regime is administered for 3 weeks, 5 times per week, as a neoadjuvant treatment with no impact on scheduling of and administration of SOC treatment
- If we are able to successfully develop Multikine for the treatment of head and neck cancer, we also plan to develop Multikine for the treatment of other cancers

Head and Neck Cancer Market

- World-wide about **650,000** new head and neck cancer patients diagnosed per year



- About 90% of head and neck cancers are squamous cell carcinomas
- Following approval, Multikine would be used in newly diagnosed patients with advanced primary squamous cell carcinoma of the head and neck right after diagnosis, before surgery, radiation and chemotherapy. As a neoadjuvant treatment.
- Since the current Phase 3 study aims to improve the overall survival of patients receiving SOC, we believe that Multikine, if approved, could become part of a new standard of care consisting of Multikine plus the 'old' SOC

We Believe That Manufacturing is a Strategic Asset

- Multikine is a complex biologic requiring special manufacturing
- We spent over 10 years and ~\$80 million developing and validating the manufacturing process
- We explored the option of hiring an outside company to manufacture Multikine for Phase 3 studies
 - Only 2 sites existed and neither of them offered the service on a contract basis
- We had to build a dedicated manufacturing facility for ~\$25 million before entering Phase 3 studies ⁽¹⁾
- Manufacturing in-house helps us to protect our IP and allows for more control when working with the FDA and other Regulators to secure approval of Multikine

(1) Represents aggregate construction costs of which we funded \$10 million and signed a lease to pay for the remaining \$15 million

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

- cGMP and BSL-1 facility
 - Built specifically for Multikine – but could easily be Multi-use
 - State-of-the art facility
 - Over 73,000 ft² of Manufacturing and R&D space available
 - About 35,000 ft² fully developed – room for growth
 - Scaled for commercial use
- About \$80 million was spent on manufacturing development and validation and about \$25 million on the manufacturing plant
- Construction began in August 2007 and Plant and Process validation was completed in 2010
- 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
 - Trade-secret

Multikine Supplies The Cytokines Needed for Tumor Rejection

- The cytokines listed to the right are those known to be present in Multikine
- Research at the US National Institutes of Health (NIH) has shown that the cytokines (shown in **red**) are the ones that are required to mount a rejection episode including tumor rejection
- Multikine is injected 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 still intact immune system does what it is meant to do - destroy the cancer
- The goal is to kill the tumor micrometastases thought to be responsible for recurrence, thereby reducing cancer recurrence and increasing survival.

Major Cytokine(s) and other Cellular Products in Multikine

IL-1 α	IL-6
IL-1β	IL-8
IL-2	TNF-β
IL-3	G-CSF
TNF-α	RANTES
IFN-γ	MIP-1α
GM-CSF	MIP-1β

11 Clinical Studies Have Been Completed Across Indications

Phase	Indication	No. of subjects	Countries	Published paper
Phase 1/2	Head & Neck Cancer Recurrent	16	U.S. & Canada	N/A
Pilot Study	Head & Neck Cancer Recurrent	4	U.S.	Arch Otolaryngol Head and Neck Surgery
Phase 1/2	Head & Neck Cancer Pre-surgery	12	Israel	Arch Otolaryngol Head and Neck Surgery
Phase 2	Head & Neck Cancer Pre-surgery	28	Canada	N/A
Phase 2	Head & Neck Cancer Pre-surgery	31	Hungary	Laryngoscope, ASCO Annual Meeting
Phase 2	Head & Neck Cancer Pre-surgery	21	Hungary	ASCO, Journal of Clinical Oncology and Oral Oncology
Phase 2	Head & Neck Cancer Pre-surgery	30	Poland & Czech Republic	N/A
Pilot Study	Prostate Cancer Pre-Surgery Treatment	5	U.S.	Seminars in Oncology
Pilot Studies	Different cancer tumors	54	U.K. & others	Lymphokine
Phase 1	Cervical Dysplasia in HPV Induced Cervical Cancer	8	U.S.	Annals of the 33 rd International Congress of the Society of Gynecological Oncologists
Phase 1/2	HIV	15	U.S.	Antiviral Therapy
Total Patients		224		

Multikine Exhibits a Consistent Safety Profile Across Phase 1 and 2 Studies

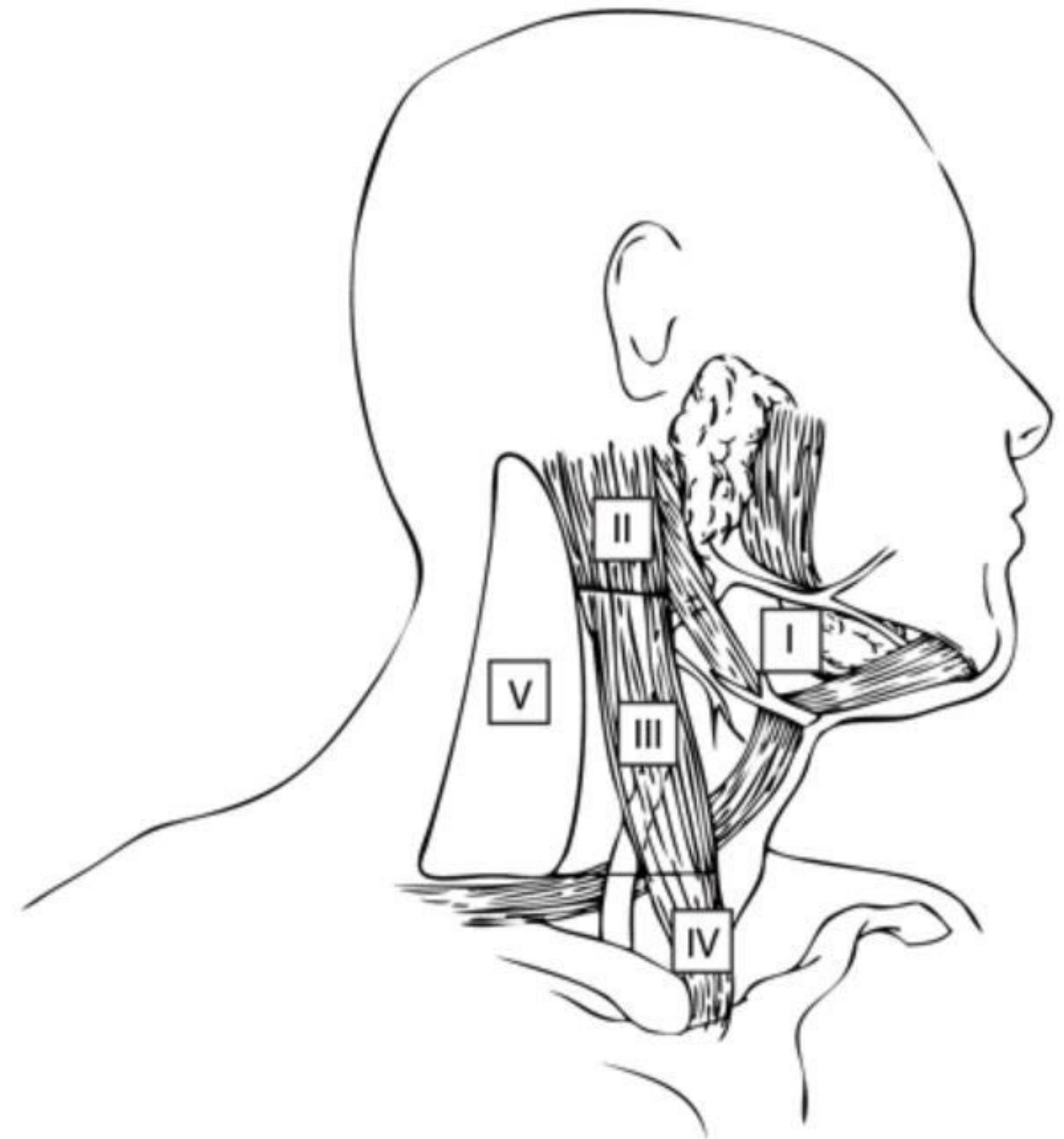
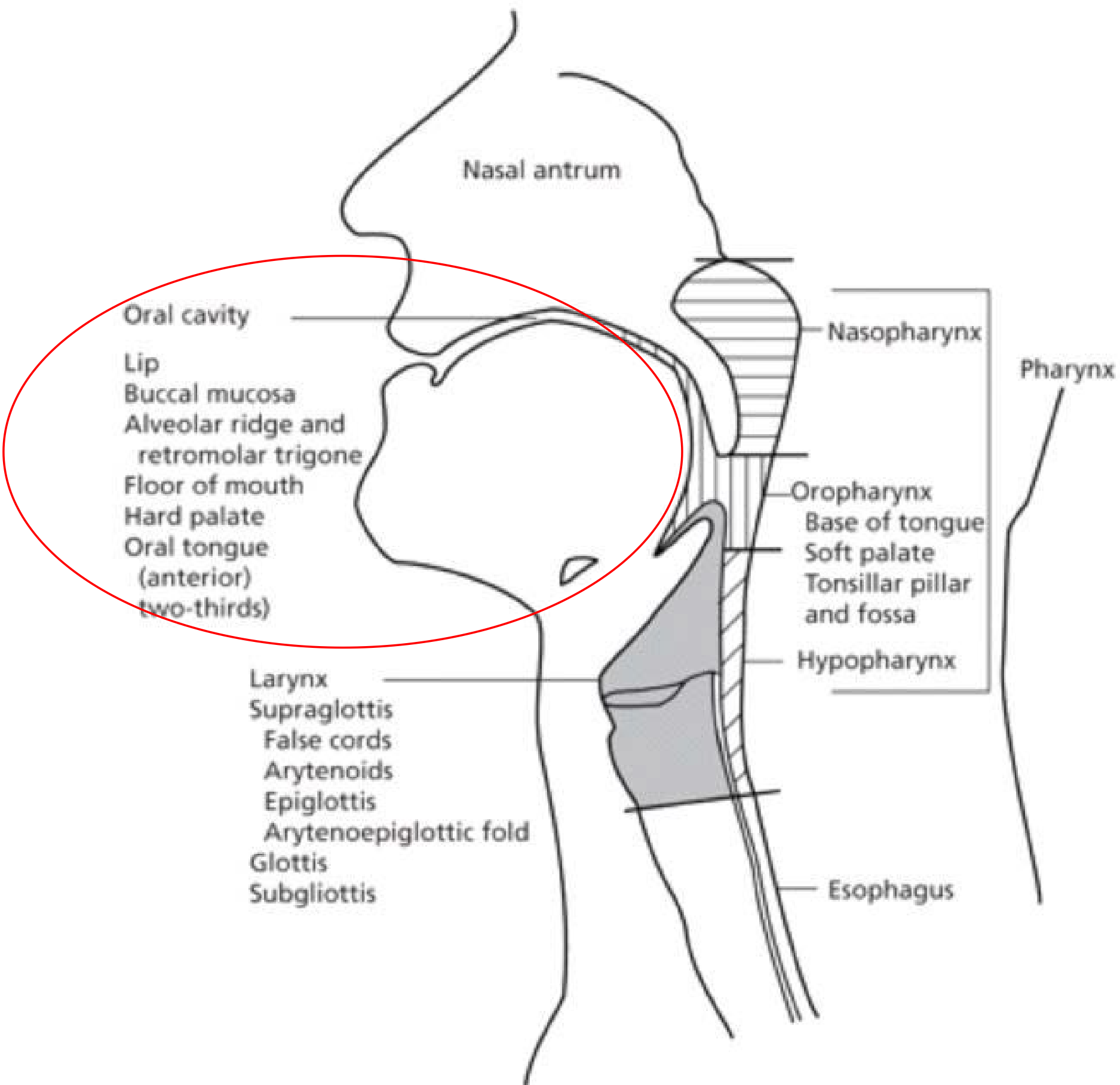
- Multikine is administered in supra-physiological doses locally (near or close) to the tumor and the adjacent lymph nodes. The known cytokines contained in Multikine are present in amounts well below any published levels that would impart toxicity.
- **Phase 1 and Phase 2 clinical trials with Multikine:** Most commonly reported Adverse Events associated with the administration of the investigational therapy Multikine were:
 - Pain at the injection site
 - Local minor bleeding at the injection site
 - Edema at the injection site
 - Diarrhea
 - Headache
 - Nausea
 - Constipation(as reported by the Phase 1 and 2 clinical investigators)

NOTE: No SAE directly associated with Multikine was reported

- Phase 2 Study by Feinmesser et al published on a series of 12 patients with advanced primary SCCHN* treated with Multikine Investigational product candidate concluded that: “No significant toxic effect of the treatment was registered in any of the patients participating in the study during or after treatment.” (Arch Otolaryngol H&N Surg. (Vol 129), AUG 2003)

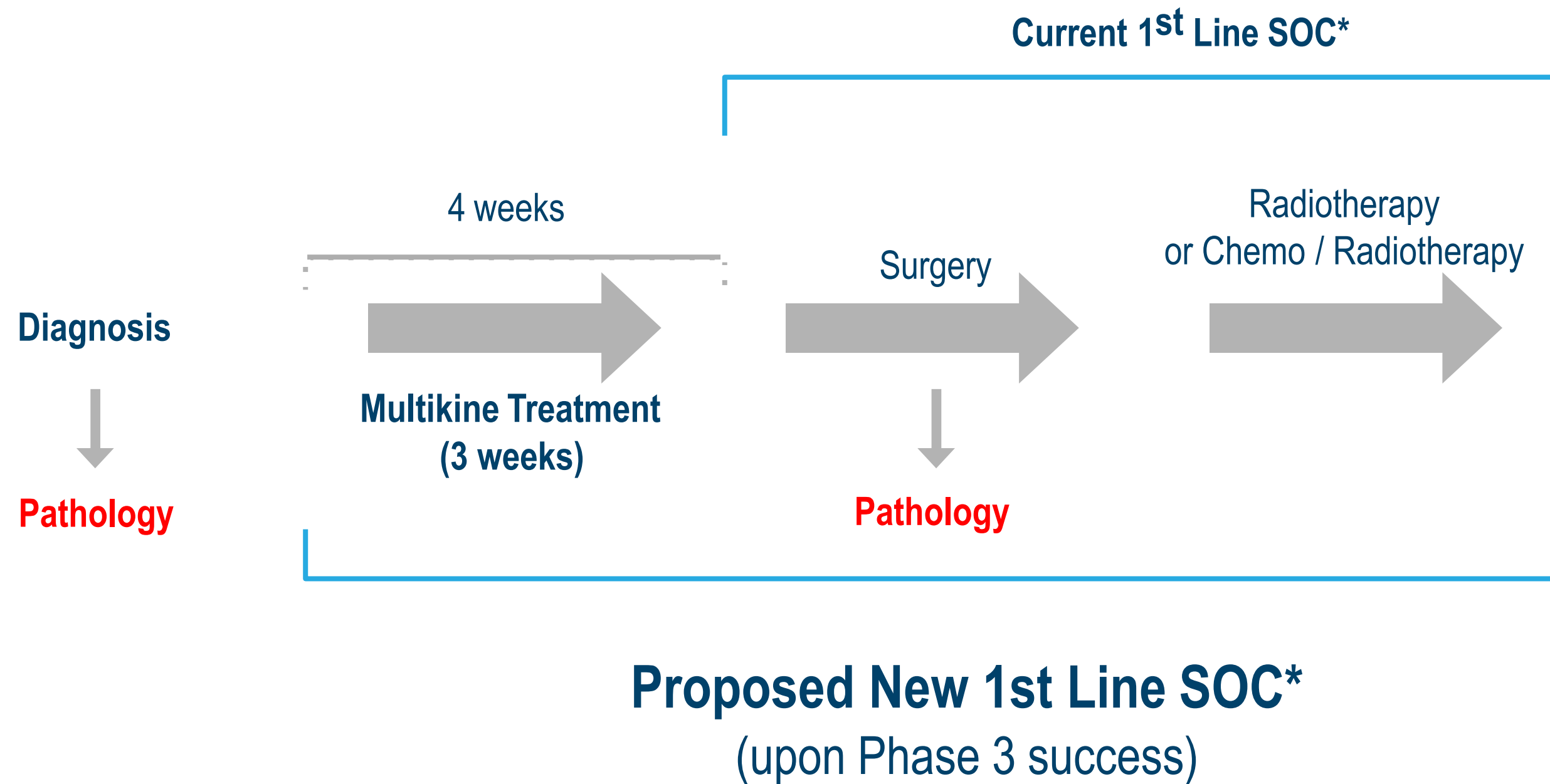
* SCCHN = Squamous Cell Carcinoma Head & Neck

NCCN Guidelines – Standard of Care

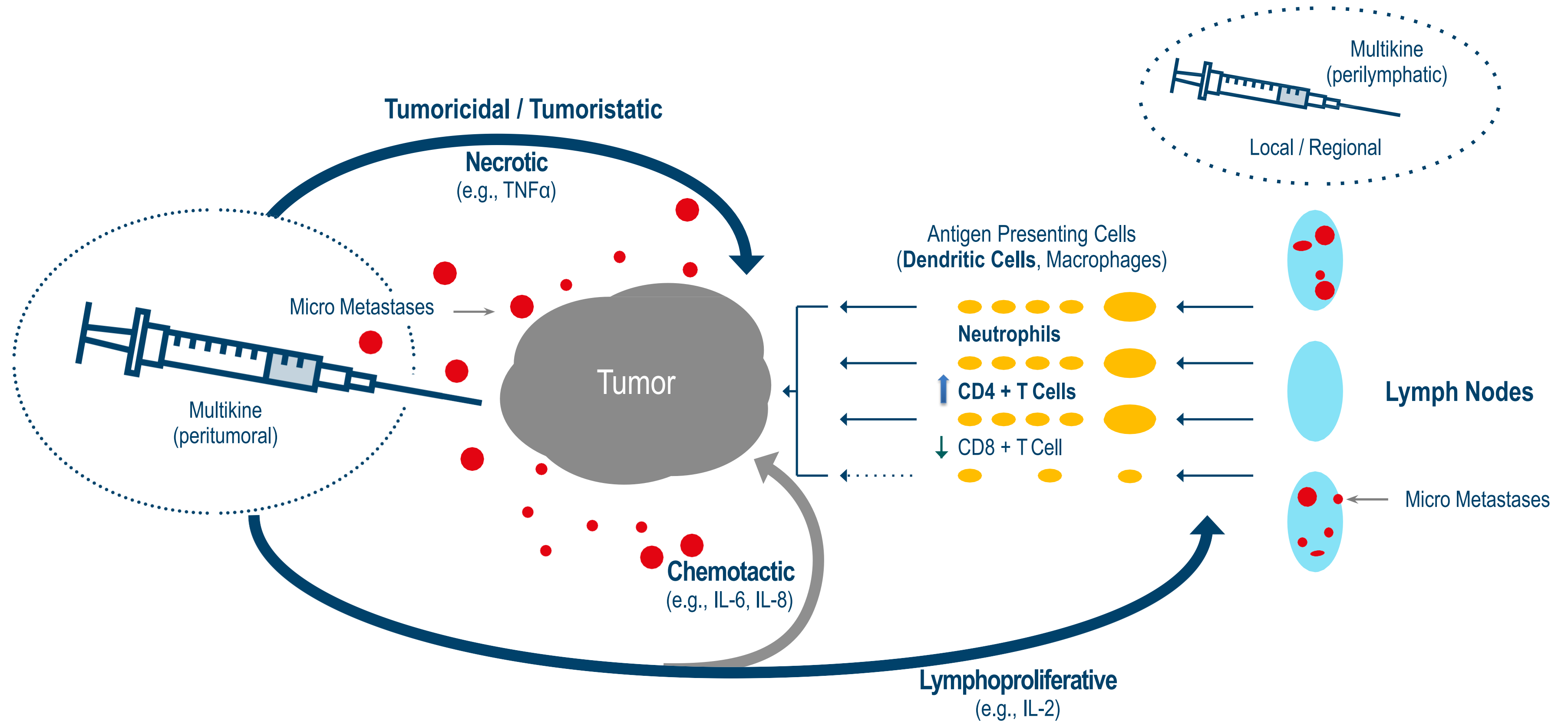


The Timing of Multikine Treatment Regimen Phase 3

Advanced Primary Head and Neck Cancer



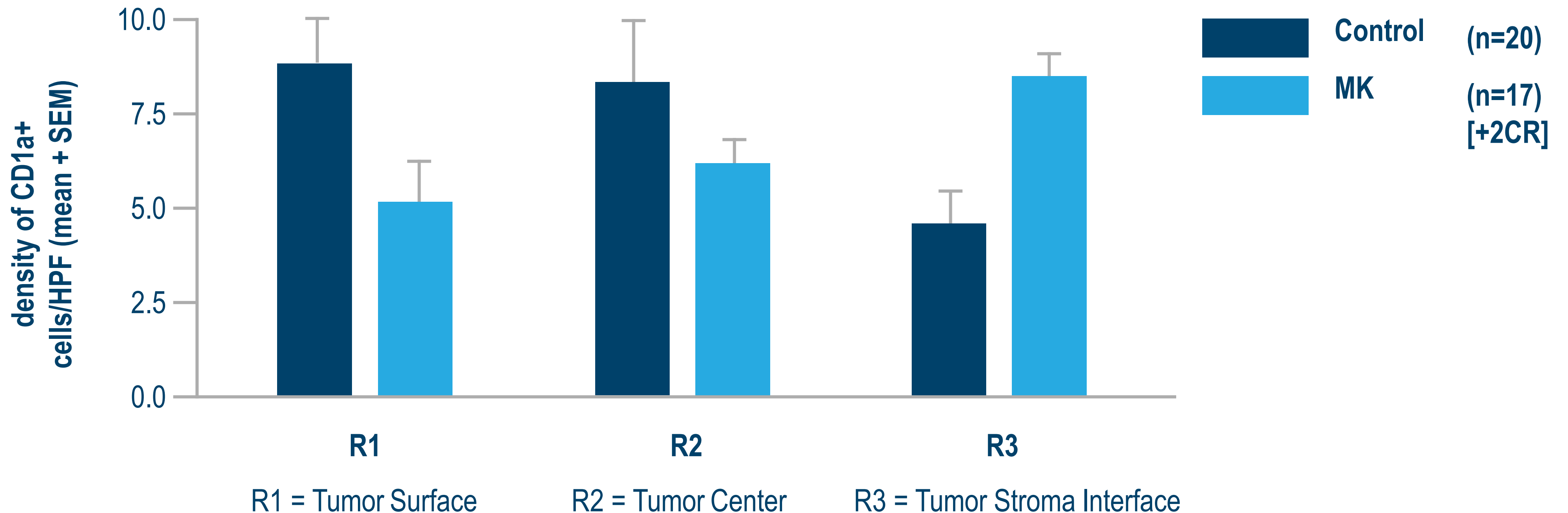
Mechanism of Action Stimulates an Immune Response at the Injection Site



Observed Effects Following Multikine Treatment Regimen – Phase 2

Dendritic cells (CD1a) Infiltrate Redistribution*

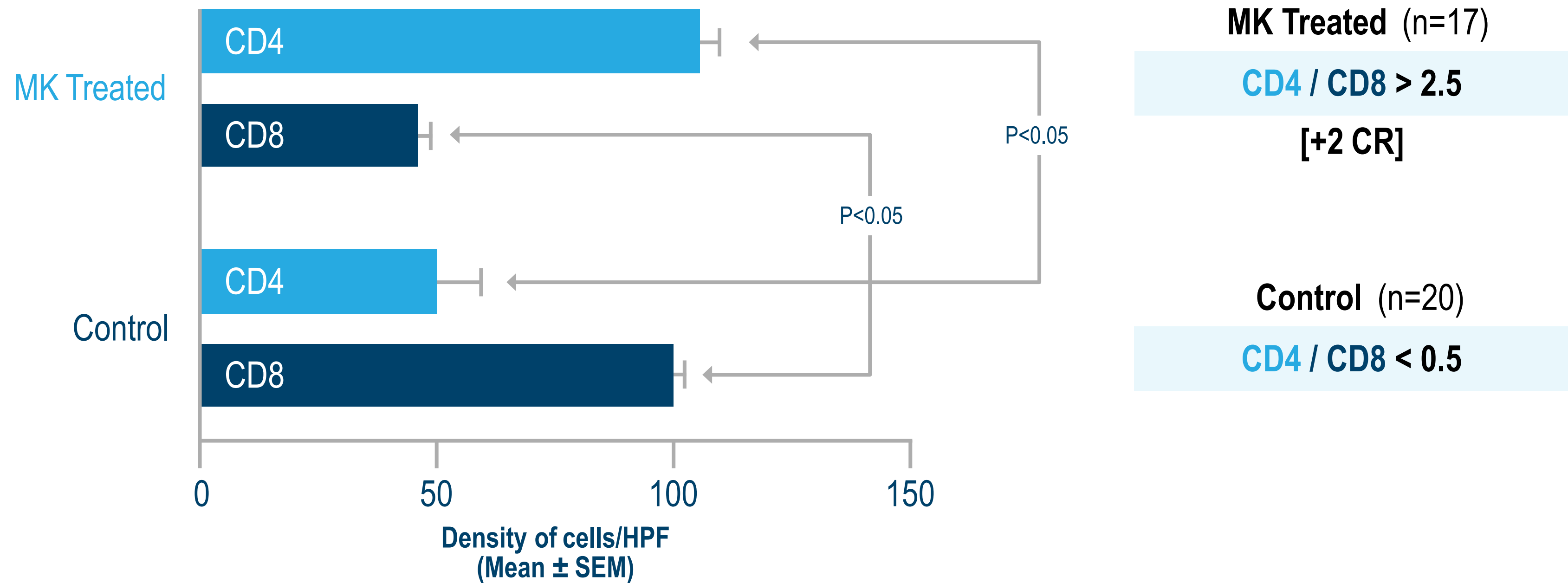
[Locally Advanced Primary H&N Cancer]



* Timar et al: Journal of Clinical Oncology 2005

Observed Effects Following Multikine Treatment Regimen – Phase 2

An Apparent Shift in Tumor Microenvironment

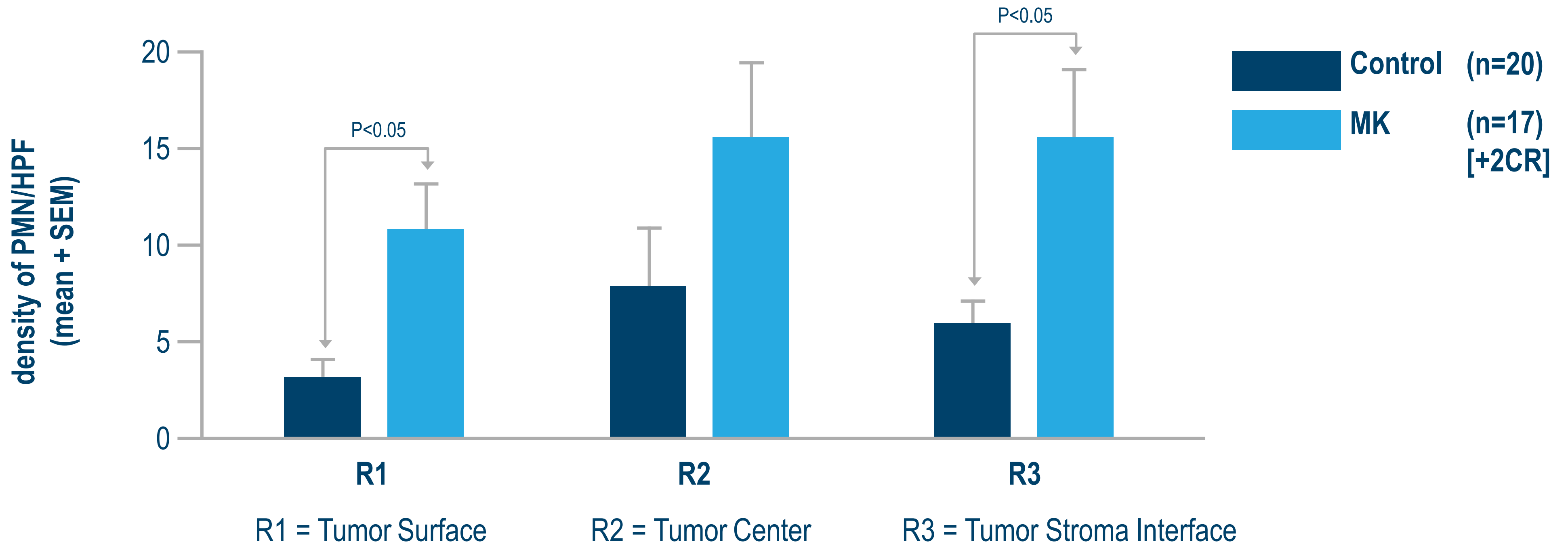


Multikine Treatment Effect on Host CD4 and CD8 Tumor Infiltrating Cell Density in OSCC
(Locally Advanced Primary H&N Cancer)

* Talor et al., ASCO Annual Meeting Proceedings 22(14S): 189S, 2004
Adapted from: Timar et al., Journal of Clinical Oncology 23(15) May 20, 2005

Observed Effects Following Multikine Treatment Regimen – Phase 2

Increased Neutrophil (MPX) Infiltrate* [Locally Advanced Primary H&N Cancer]



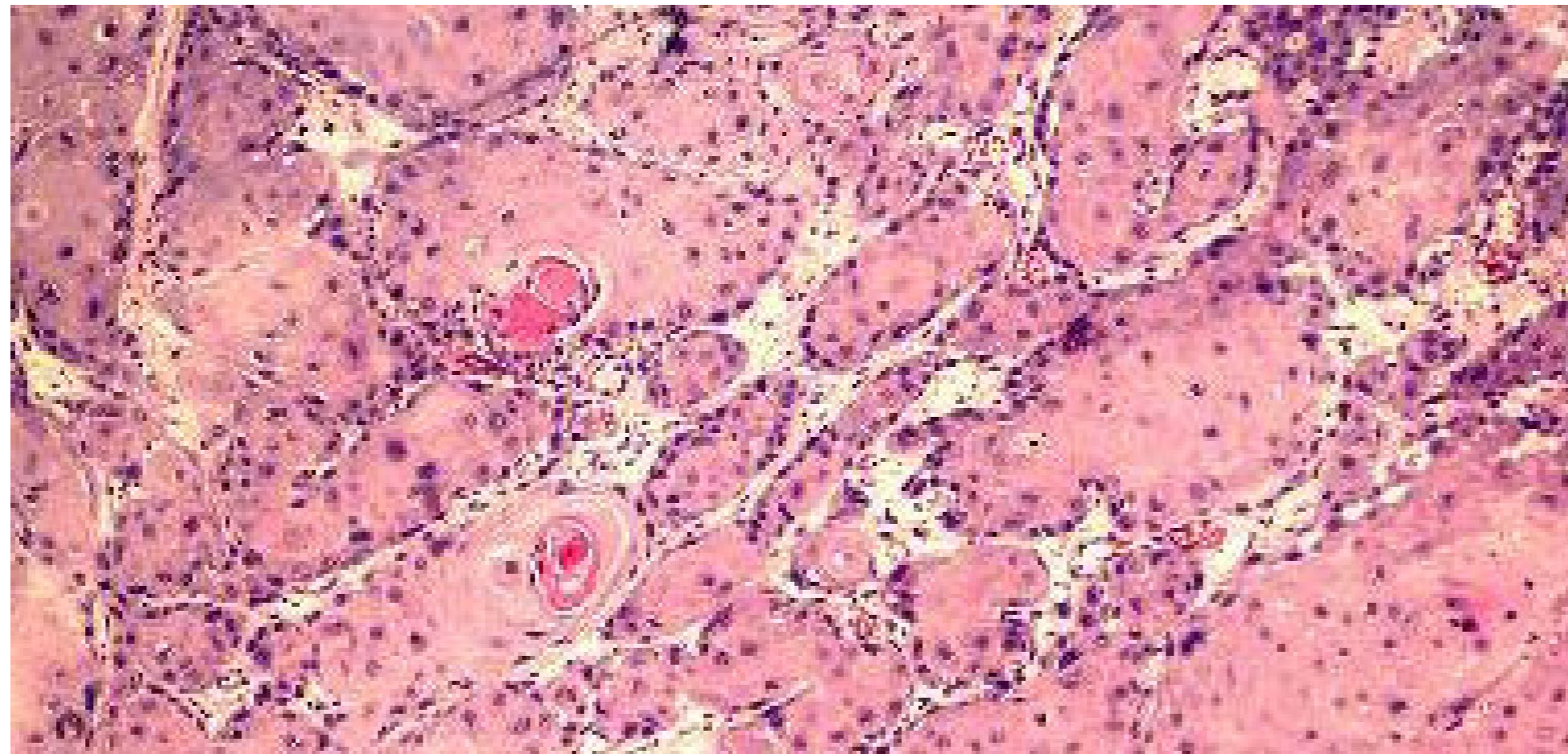
* Timar et al: Journal of Clinical Oncology 2005

Non-Multikine Treated vs. Multikine Regimen Treated – Phase 2 Results

Oral Squamous Cell Carcinoma

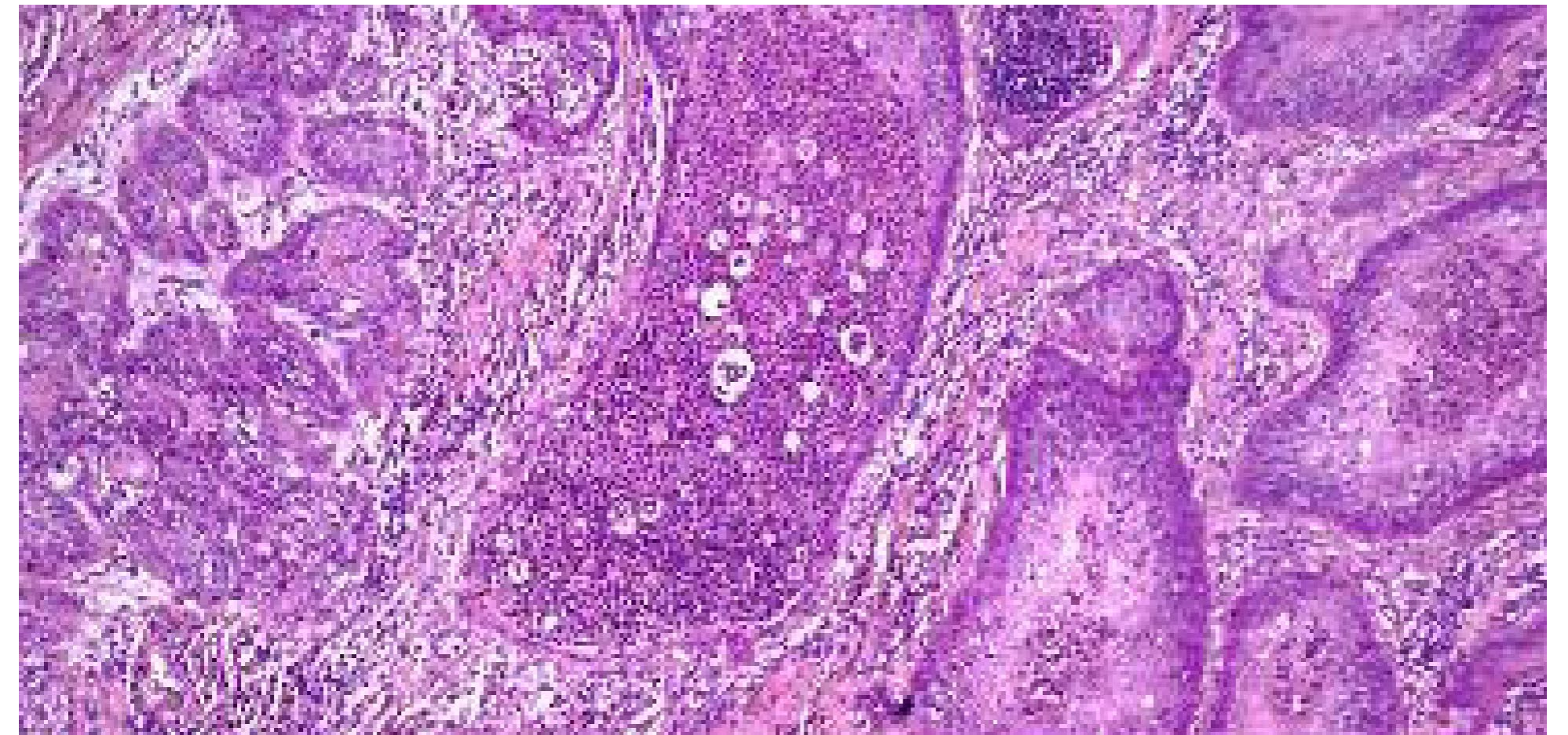
(Locally Advanced Primary H&N Cancer)

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 regimen treated

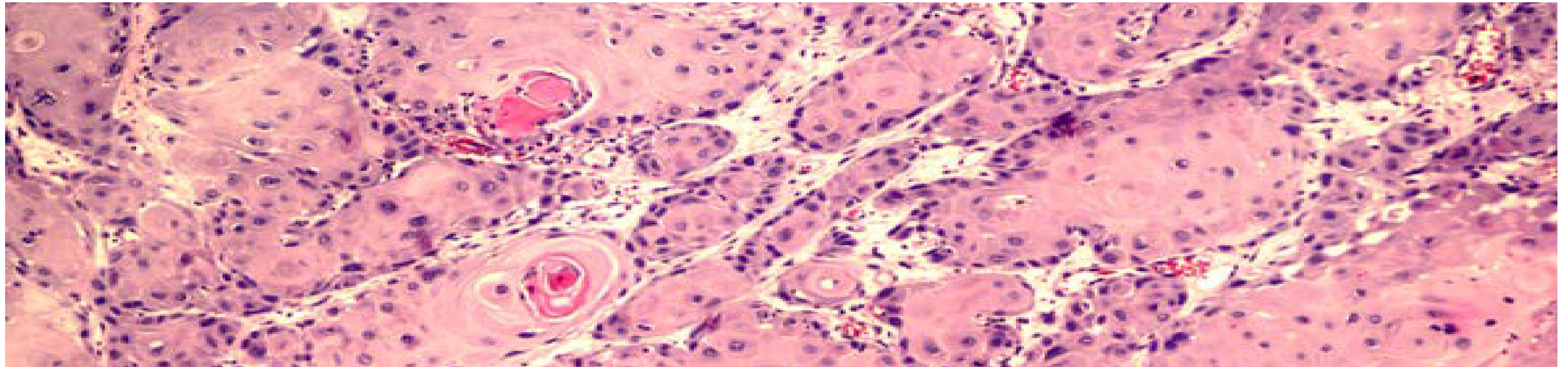
Entire cancer nest is necrotic and filled with debris and leukocytes

Conventional Treatment (SOC)

Oral Squamous Cell Carcinoma

(Locally Advanced Primary H&N Cancer)

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



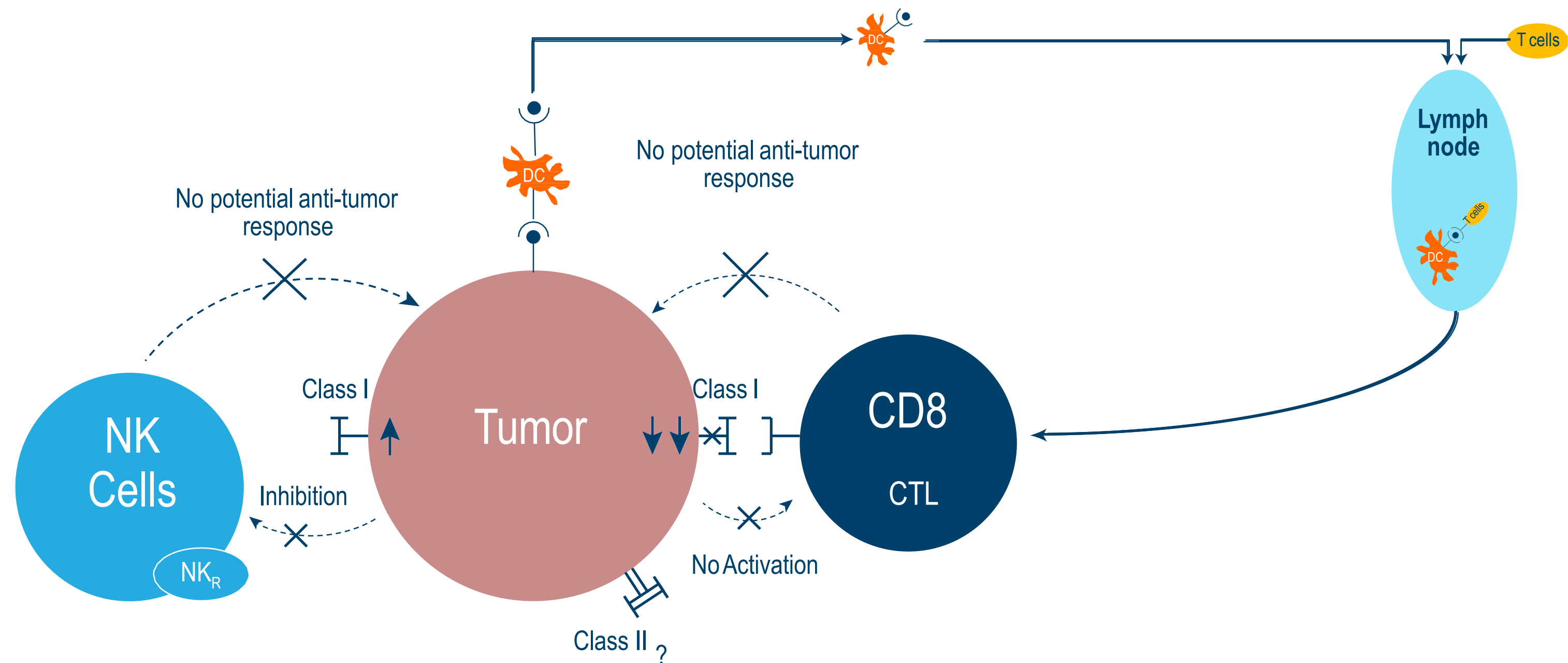
Non-Multikine treated

Lack of necrosis in the epithelial nests of OSCC

Multikine – How it Helps the Immune System Kill Cancer Cells

How Multikine is Designed to Circumvent the Tumor Defense Mechanisms

In patients not treated with Multikine, CD8+ T-cells and NK cells are “blocked” by the tumor. Therefore they are unable to trigger a potential anti-tumor immune response.

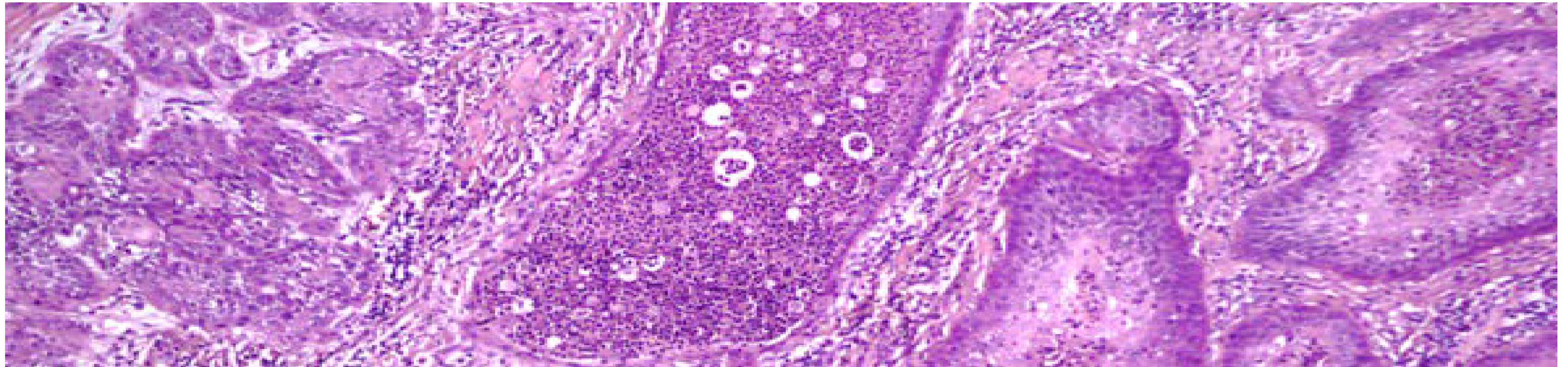


Multikine Treatment Regimen

Oral Squamous Cell Carcinoma

(Locally Advanced Primary H&N Cancer)

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



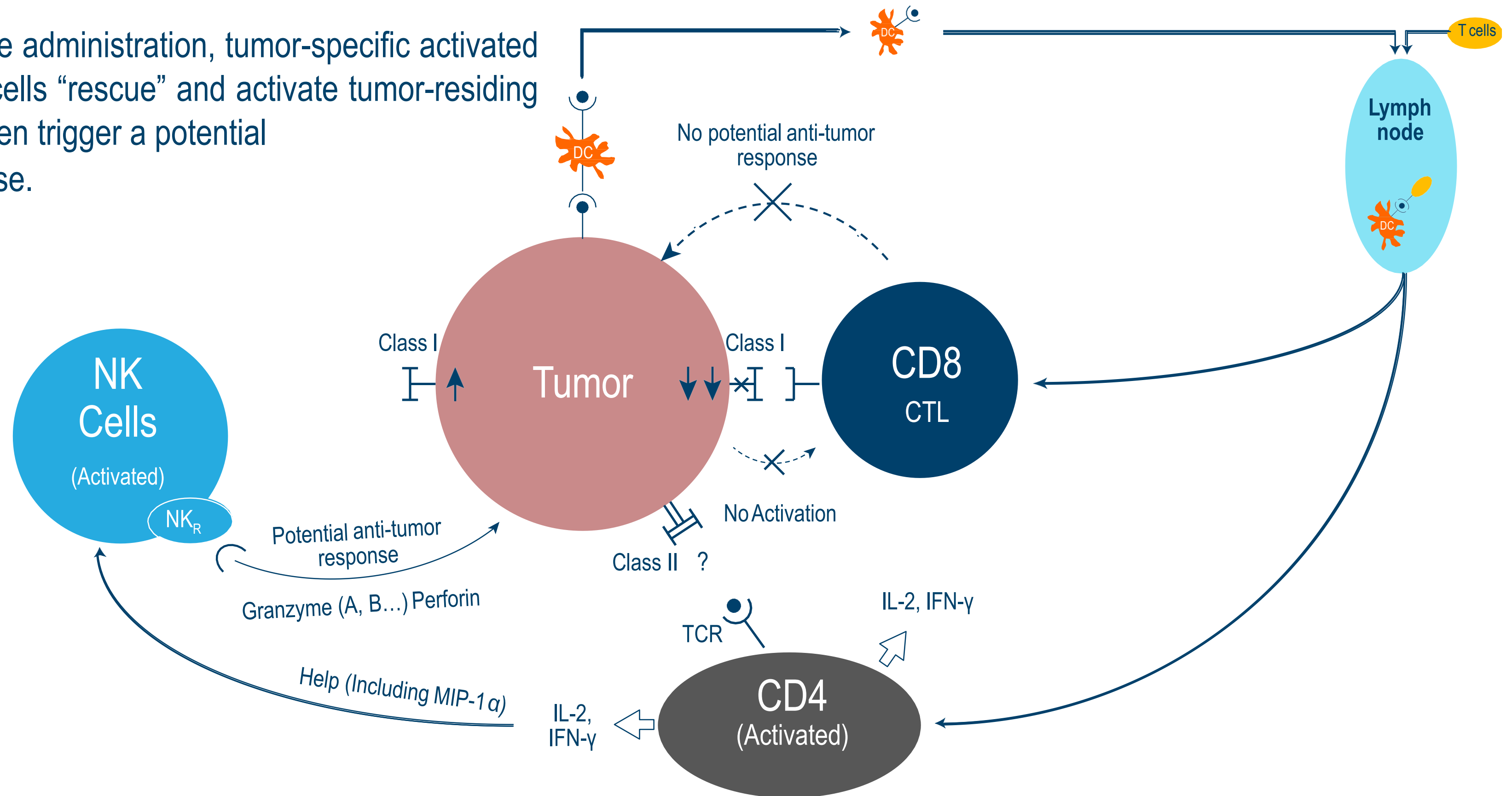
Multikine regimen treated

Entire cancer nest is necrotic and filled with debris and leukocytes

Multikine – How it Helps the Immune System Kill Cancer Cells

How Multikine is Designed to Circumvent the Tumor Defense Mechanisms

Following Multikine administration, tumor-specific activated CD4+ (helper T) cells “rescue” and activate tumor-residing NK cells, which then trigger a potential anti-tumor response.



Multikine Pathology and other Results - Final Phase 2 Study

The Final “Proof of Concept” Phase 2 study (21 treated patients and 20 controls), following multiple Phase 2 studies that tested different treatment regimens, selected the best treatment for patients. The Multikine treatment regimen in this final Phase 2 study is the same as used in the Phase 3 study

Of the evaluable patients - **10.5%** of patients had no remaining cancer cells (by pathology) following 3 weeks (x5/wk) of Multikine treatment regimen

Timar et al: Journal of Clinical Oncology 23 (15) May 20, 2005
and Talor et al, Oral Oncology Supplement (2) No. 1, May 2007

The remaining treated patients in the study had about a **50%** average reduction in the number of cancer cells (by pathology) following 3 weeks (x5/wk) of Multikine treatment regimen

Timar et al: Journal of Clinical Oncology 23 (15) May 20, 2005

42.1% Overall Response Rate (RECIST) in Phase 2 study

Timar et al: Journal of Clinical Oncology 23 (15) May 20, 2005

Other observations:

(as reported by clinical study investigators)

Reduction in pain. Patients are able to open their mouths more easily.

Patients with tongue cancer can move their tongues again within a few days.

Many patients gain weight

Multikine Increased Overall Survival (OS) by 33%

Approximately three years after the same “Proof of Concept” Phase 2 study we obtained the patients’ and their families’ consents for a survival follow-up

Survival results in this Final “Proof of Concept” Phase 2 study were compared to results from 55 clinical trials in the same patient population (Advanced Primary SCCHN) treated with SOC only

Follow-up Endpoint	Standard of Care (SOC)* +/- All other Treatment Modalities	Multikine** + Standard of Care	% Improvement over SOC***
Overall Survival (at 3.3 years from treatment)	47.5%	63.2%	33.1%

* Survey of 55 clinical trials; advanced primary H&N cancer (published 1987 – 2007)
** Multikine Treatment Regimen: Phase 2 Clinical Trial (Timar et al, JCO, 23(15): May 2005)
*** Talor et al, Oral Oncology Supplement (2) No. 1, May 2007 Literature survey of 55 clinical trials; advanced primary H&N cancer (published 1987 – 2007)

How Does the Multikine Treatment Patient Population Differ from the Checkpoint Inhibitor Patient Population?

The checkpoint inhibitor Keytruda® by Merck was approved for head and neck cancer in June 2019, but it was approved for a very different patient population than that which CEL-SCI is pursuing.

Keytruda was approved for patients with head and neck squamous cell carcinoma that has spread (metastatic) or recurred after the initial cancer treatments and cannot be removed by surgery, and where the tumor tests positive for PD-L1.

CEL-SCI is pursuing the advanced primary patients who have just been diagnosed with advanced primary squamous cell carcinoma of the head and neck and are scheduled for “intent to cure” treatment with surgery plus radiation or chemoradiation.



IT-MATTERS

Global Phase 3 Head & Neck Cancer Study

CEL-SCI Corporation

Eyal Talor, PhD
Chief Scientific Officer

8229 Boone Boulevard, Suite 802
Vienna, VA 22182, USA
-
Phone: **(703) 506-9460**

NYSE American: **CVM**



Phase 3 Study of Multikine® (Leukocyte Interleukin, Injection)* NCT# 01265849



Developing a Novel Immunotherapy as First-Line Treatment for Advanced Primary Head and Neck Cancer

* 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

8229 Boone Blvd., Ste 802
Vienna, VA 22182
(703) 506-9460
www.cel-sci.com

Multikine H&N Cancer Phase 3 Study Summary

- Open-label Phase 3 Study
- Started enrolling early 2011, fully enrolled by September 2016
- 928 patients enrolled in the study
- The study is event driven. We are waiting for 298 events to occur among the two main groups (combined number of patients about 800)

Multikine Phase 3 Trial Design

Study Conducted in 24 Countries on 3 Continents

Location	Countries
North America	USA and Canada
Europe	UK, Austria, France, Spain, Italy, Hungary, Poland, Russia, Ukraine, Belarus, Serbia, Croatia, Bosnia, Turkey, Romania
Asia / Far-East	Israel, Taiwan, Malaysia, Philippines, India, Sri Lanka, Thailand
Study Total Number of Sites	93

Multikine Phase 3 Trial Design

Schematic: Randomization and Treatment of Enrolled Patients



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/m² (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 defined as those with: positive surgical margins, 2 or more clinically positive nodes, or extra capsular nodal spread, perinural invasion, etc (any or all of the above).

Head and Neck Tumors of Interest for this Phase 3 Study

- Oral Cavity
 - Tongue (oral portion only)
 - Floor of mouth
 - Cheek
- Soft Palate

Standard of Care for Advanced Primary SCCHN

- Definitive Surgery – with curative intent
- Postoperative Radiation Therapy
- Radiotherapy + concurrent Chemotherapy for High-Risk Patients

Source: NCCN Guidelines

Disease Stages Eligible for Multikine Trial

- T1 N1-2 M0
- T2 N1-2 M0
- T3 N0-2 M0
- T4* N0-2 M0

Disease Stage III and IVa
(Advanced Primary Disease)

* T4 is allowed if invasion of the mandible is minimal (defined as <0.5cm as confirmed by CT, and or MRI with CT imaging mandatory) and can be salvaged by marginal mandibulectomy (retention of function and having intact mandible post surgery).

Complete AJCC Staging Criteria are listed in Protocol

TNM Classification and Corresponding Tumor Stage

Nodal Involvement	Primary Tumor			
	T1	T2	T3	T4
	NE	NE	Stage III	Stage IVa
	Stage III	Stage III	Stage III	Stage IVa
	Stage IVa	Stage IVa	Stage IVa	Stage IVa

- Notes:**
- 1. Stage IVb (T4b primary and all N3 disease) are not eligible.
 - 2. All disease must be M0
 - 3. NE = Not Eligible

Complete AJCC Staging Criteria are listed in Protocol

Multikine Study Endpoints

- **Primary Endpoint:**
 - Overall Survival (10% improvement over SOC alone)
- **Secondary Endpoint:**
 - Progression Free Survival
 - Local/Regional Control
 - Safety
 - Histopathology of Tumor infiltrate
 - Quality of Life
- **Tertiary Endpoint:**
 - Tumor Response

When Will the Phase 3 Study End?

- Patients are currently being followed for overall survival and other protocol specified endpoints. Two hundred ninety eight (298) events (deaths) must occur among the 2 main comparator groups (almost 800 patients out of the 928 patients enrolled) to be able to assess if the primary endpoint of this pivotal Phase 3 study has been met
 - A 10% improvement in overall survival in patients treated with Multikine treatment regimen plus Standard of Care (SOC) vs. patients treated with SOC alone
- The last patient was enrolled in the study in September 2016
- The study protocol assumes an overall survival rate of about 55% at 3 years for the SOC treatment group alone, but obviously patients die beyond 3 years
- Approximately 135 patients were enrolled in the study from 2011 to 2013, about 195 were enrolled in 2014, about 340 in 2015, and about 260 in 2016
- The scientific literature does not suggest an improvement in survival rates for the patients enrolled in our Phase 3 study for the past 10 years
- "In contrast to declines for the most common cancers, death rates rose from 2012 through 2016 for ... sites within the oral cavity and pharynx ..." (American Cancer Society, January 8, 2019)

Estimated Overall Survival (OS) using the SOC for the Study Population Enrolled in CEL-SCI’s Phase 3 Clinical Trial - Using SEER Database

Year	OS Estimate	95% Confidence Bound
1	71.42%	(69.84%, 72.92%)
2	53.86%	(52.09%, 55.59%)
3	46.59%	(44.74%, 48.42%)
4	41.98%	(40.02%, 43.93%)
5	36.75%	(34.475%, 39.03%)

- Three (3) Year OS – Approximately 47%
- Five (5) Year OS – Approximately 37%

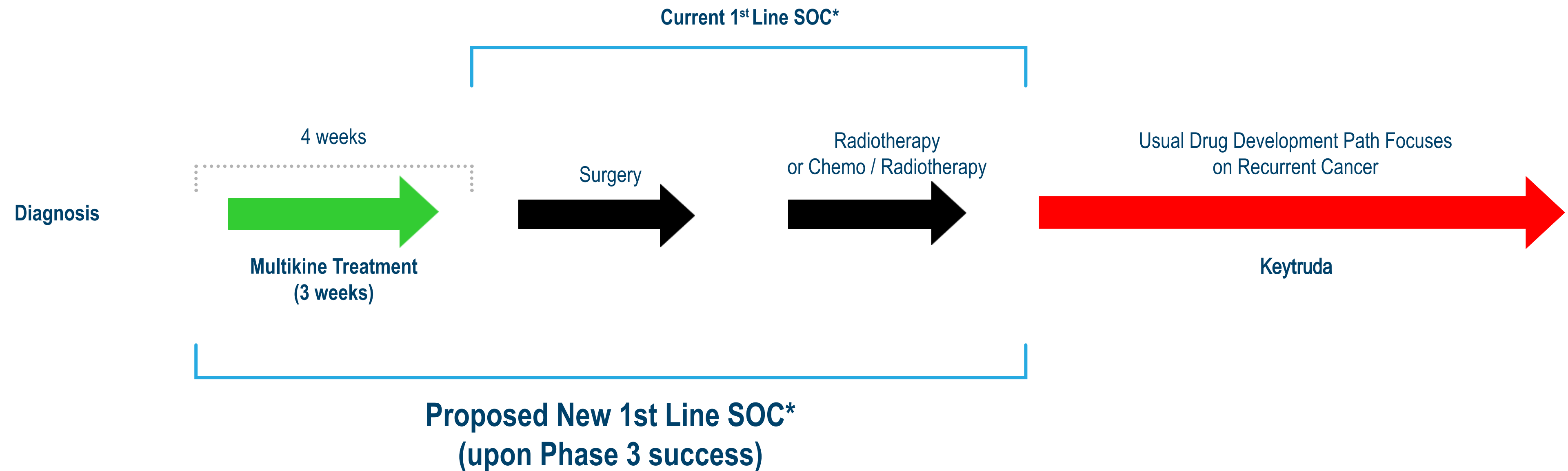
The SEER Data was queried and data extracted by an external Statistical Group.

What is SEER data? SEER is an authoritative source for cancer statistics in the United States. The Surveillance, Epidemiology, and End Results (SEER) Program provides information on cancer statistics in an effort to reduce the cancer burden among the U.S. population. SEER is supported by the Surveillance Research Program (SRP) in NCI's Division of Cancer Control and Population Sciences (DCCPS).

- In CEL-SCI's Phase 3 study, approximately 135 patients were enrolled in the study from 2011 to 2013, approximately 195 were enrolled in 2014, approximately 340 in 2015, and approximately 260 in 2016

Phase 3 Study Design -Timing of Multikine Treatment Regimen

Advanced Primary Head and Neck Cancer





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Chief Scientific Officer

8229 Boone Boulevard, Suite 802
Vienna, VA 22182, USA

-

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