



# Multikine (Leukocyte Interleukin, Inj.) Cancer Immunotherapy

A Multi-Targeted Approach to Cancer Treatment  
March 2019

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**CEL-SCI Corporation**

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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

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## 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**



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# 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 paralleled 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 all of the FDA approved immunotherapies (e.g., Keytruda, Opdivo, CAR-T, and many more) that have been recently in the news. 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.

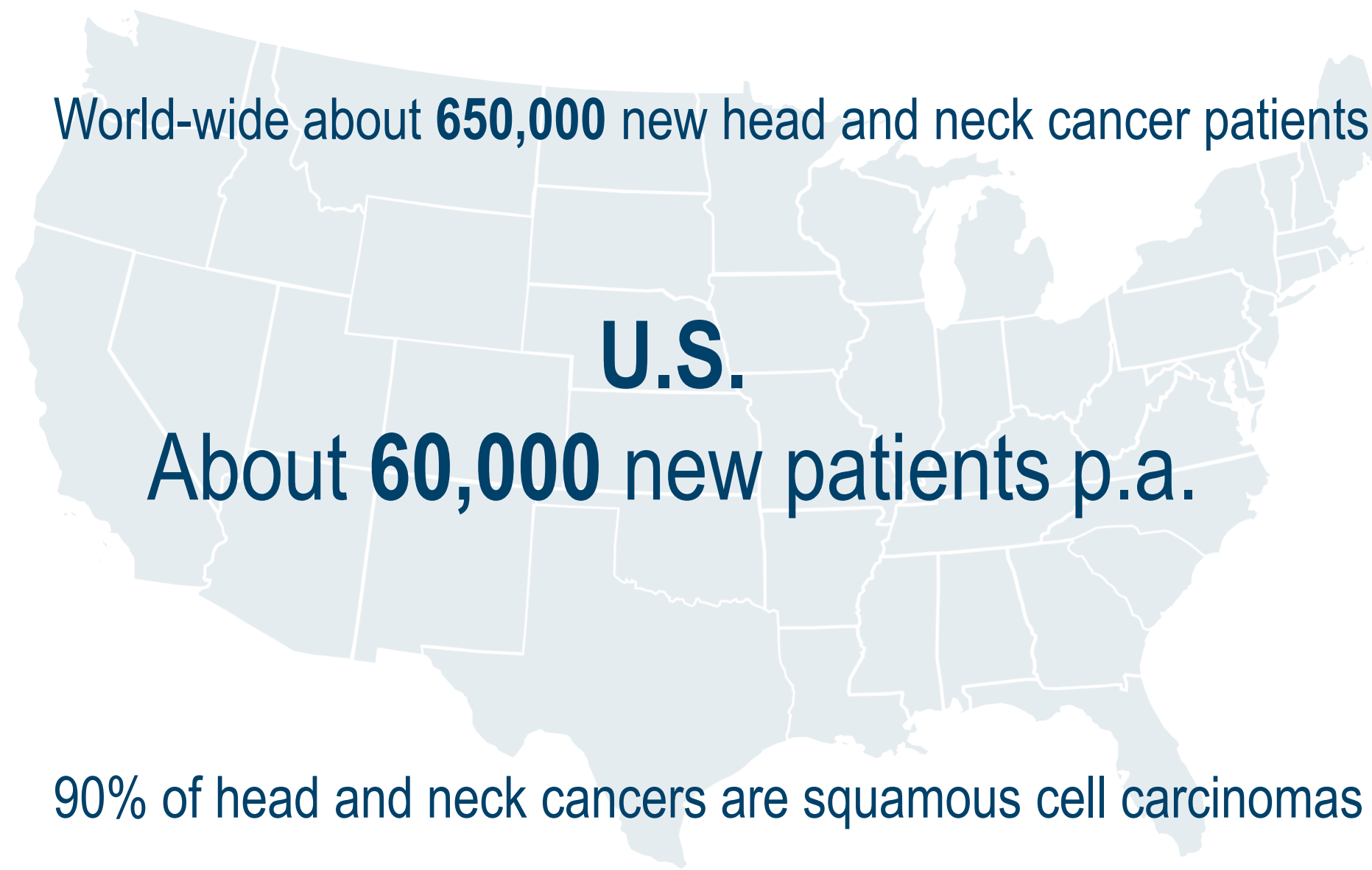
# Why Head and Neck Cancer as a First Target?

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 approx. 60 years 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



- 90% of head and neck cancers are squamous cell carcinomas
- Following approval, Multikine would be used in newly diagnosed squamous cell carcinoma of the head and neck patients 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

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# 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 <sup>(1)</sup>
- 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 ft<sup>2</sup> of Manufacturing and R&D space available
  - About 35,000 ft<sup>2</sup> 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 Persons
  - Certified (by the QP) for the Manufacture 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 <sup>rd</sup> 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

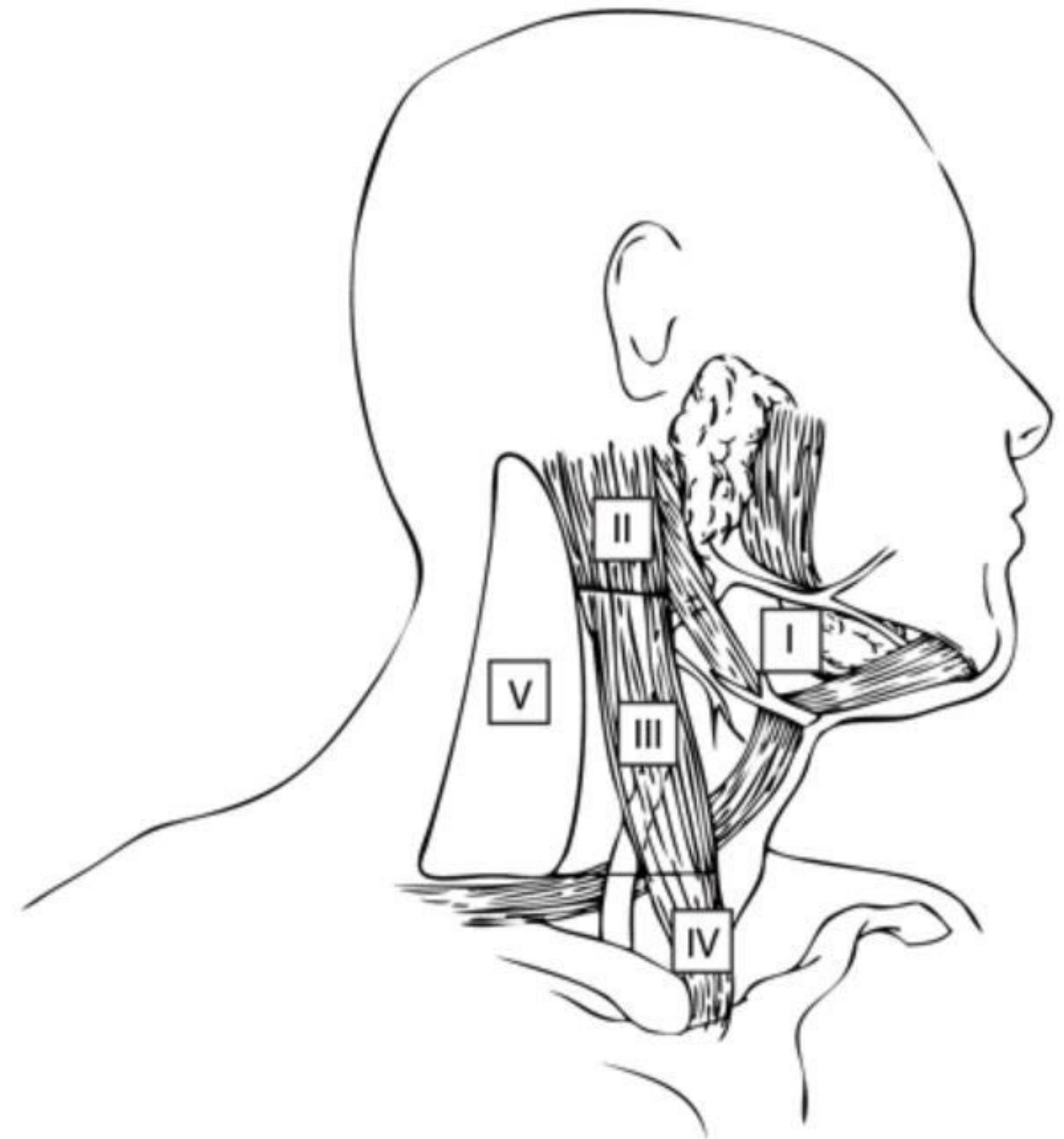
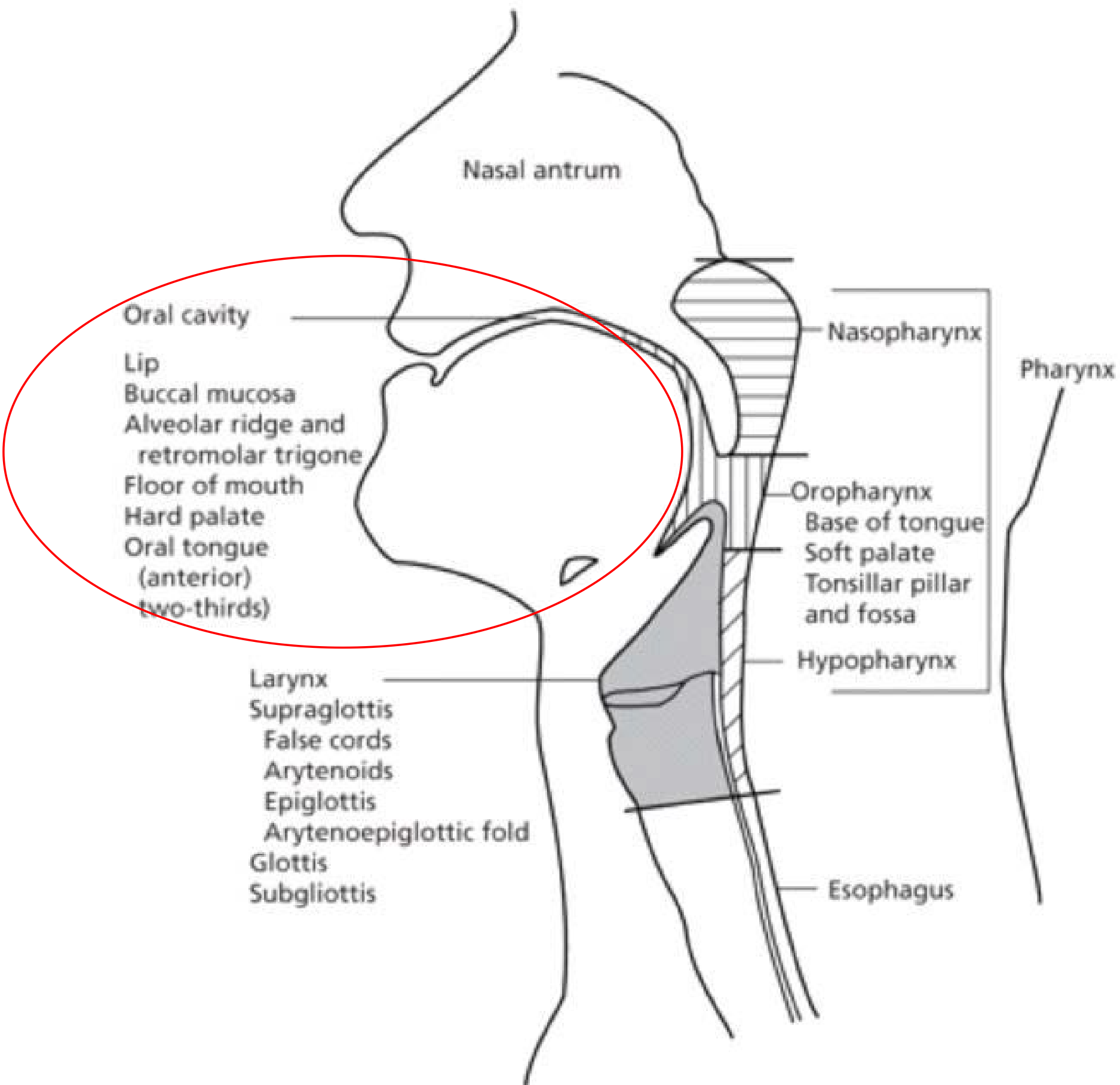
- Multikine is administered in supra-physiological doses locally (near or close) to the tumor and the adjacent lymph nodes. The known cytokines contained in Multikine are present in amounts well below any published levels that would impart toxicity.
- **Phase 1 and Phase 2 clinical trials with Multikine:** 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

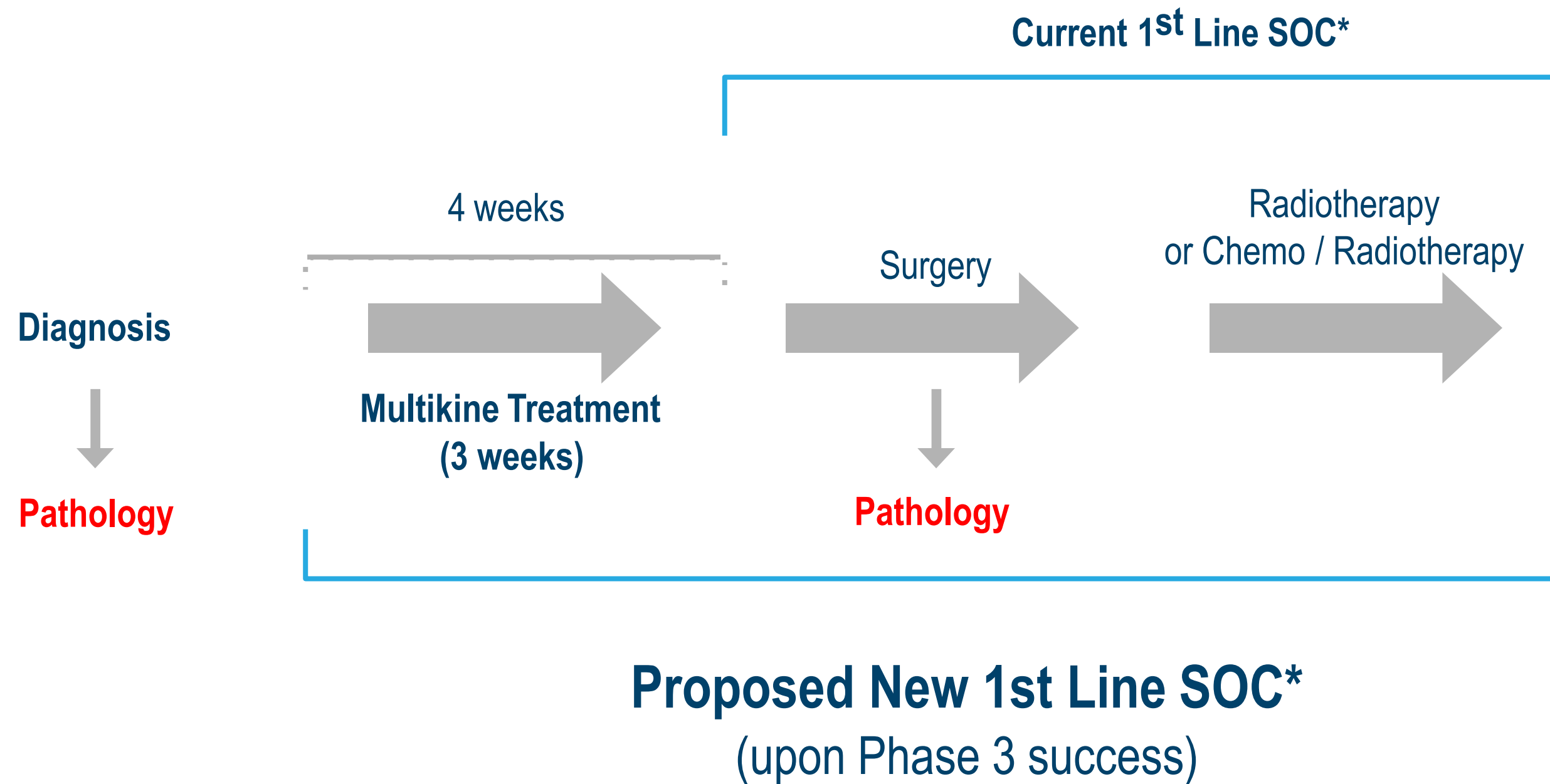
# NCCN Guidelines – Standard of Care



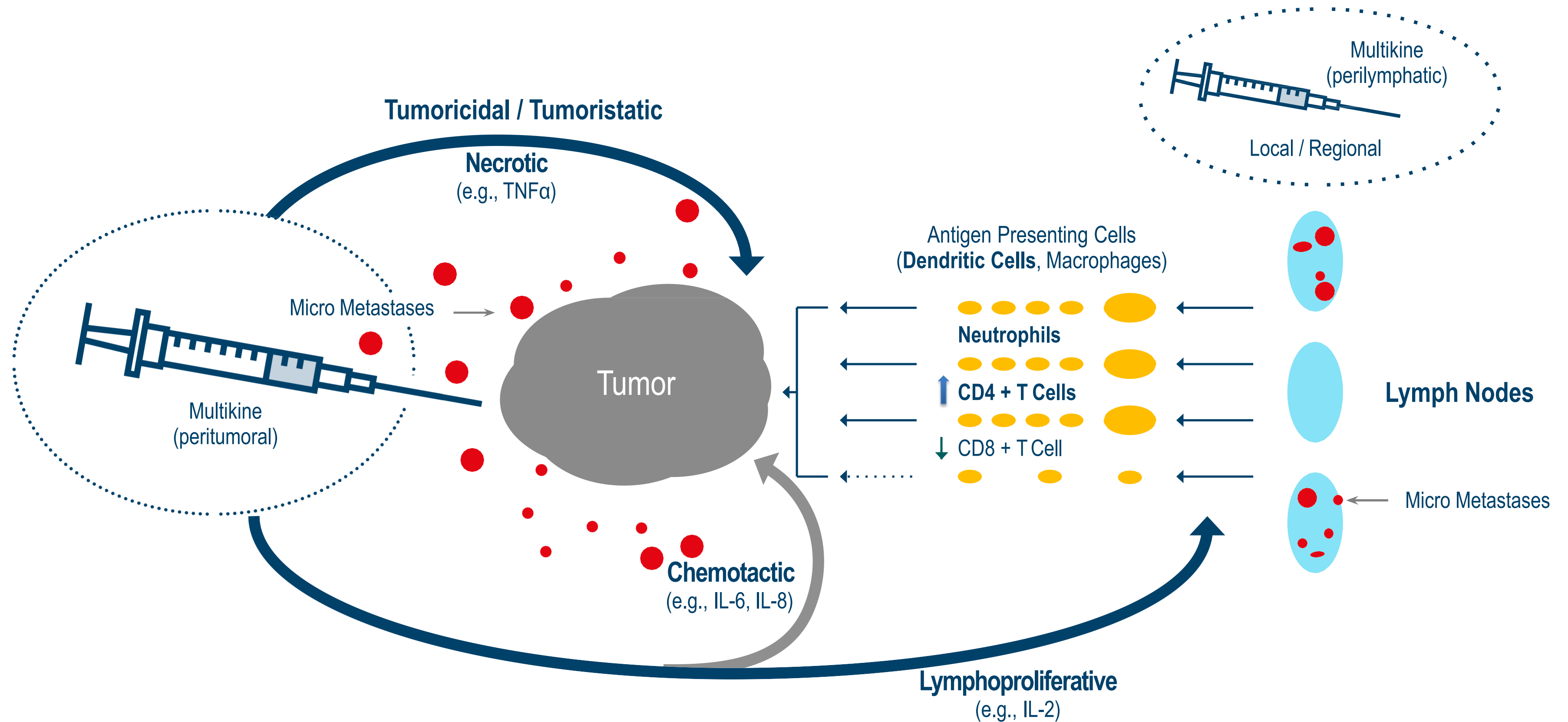


# The Timing of Multikine Treatment Regimen Phase 2

Advanced Primary Head and Neck Cancer



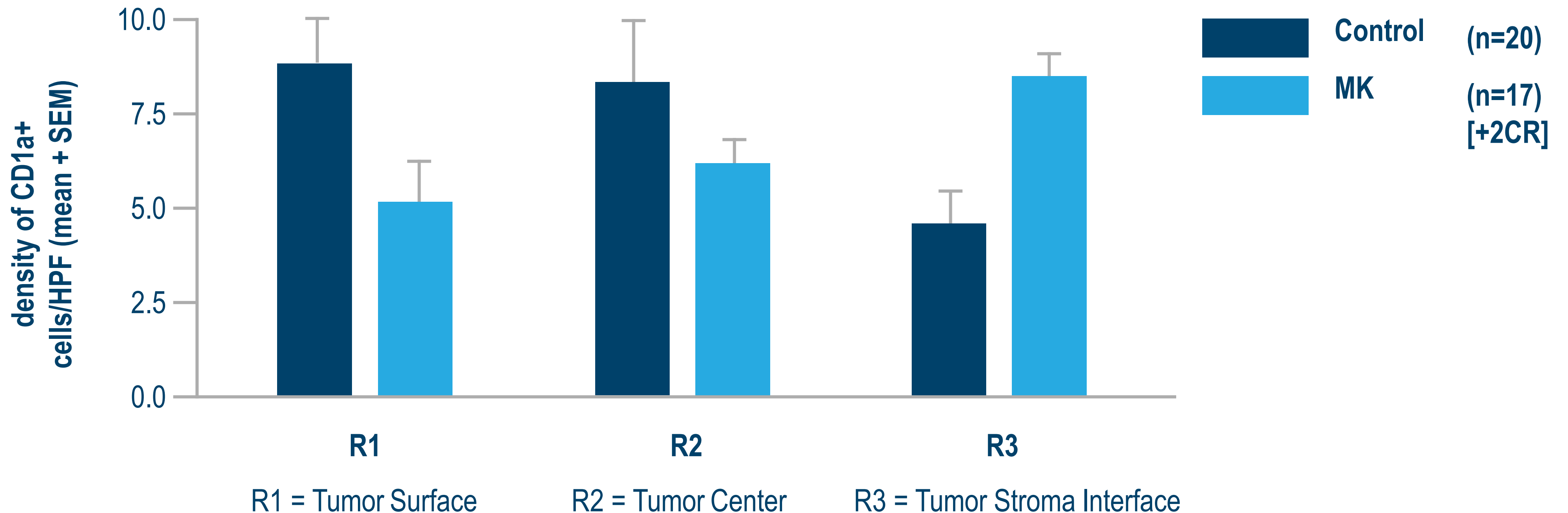
# Mechanism of Action Stimulates an Immune Response at the Injection Site



# Observed Effects Following Multikine Treatment Regimen – Phase 2

## Dendritic cells (CD1a) Infiltrate Redistribution\*

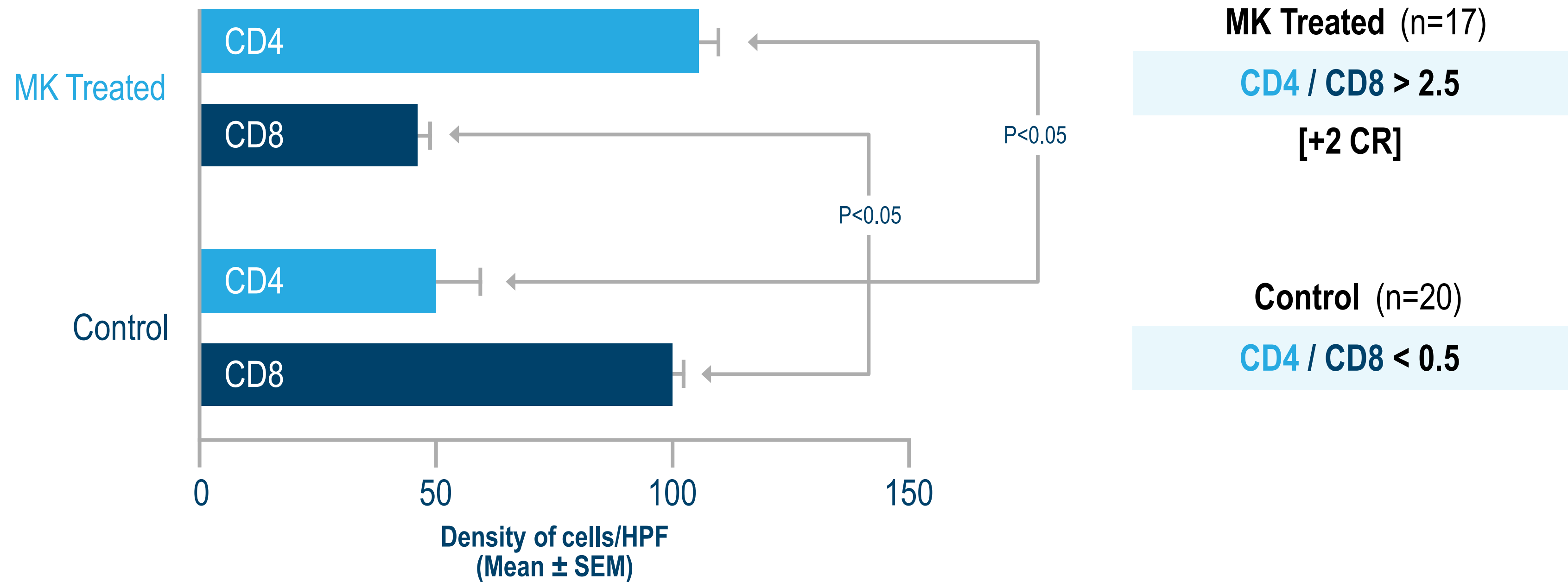
[Locally Advanced Primary H&N Cancer]



\* Timar et al: Journal of Clinical Oncology 2005

# Observed Effects Following Multikine Treatment Regimen – Phase 2

## An Apparent Shift in Tumor Microenvironment

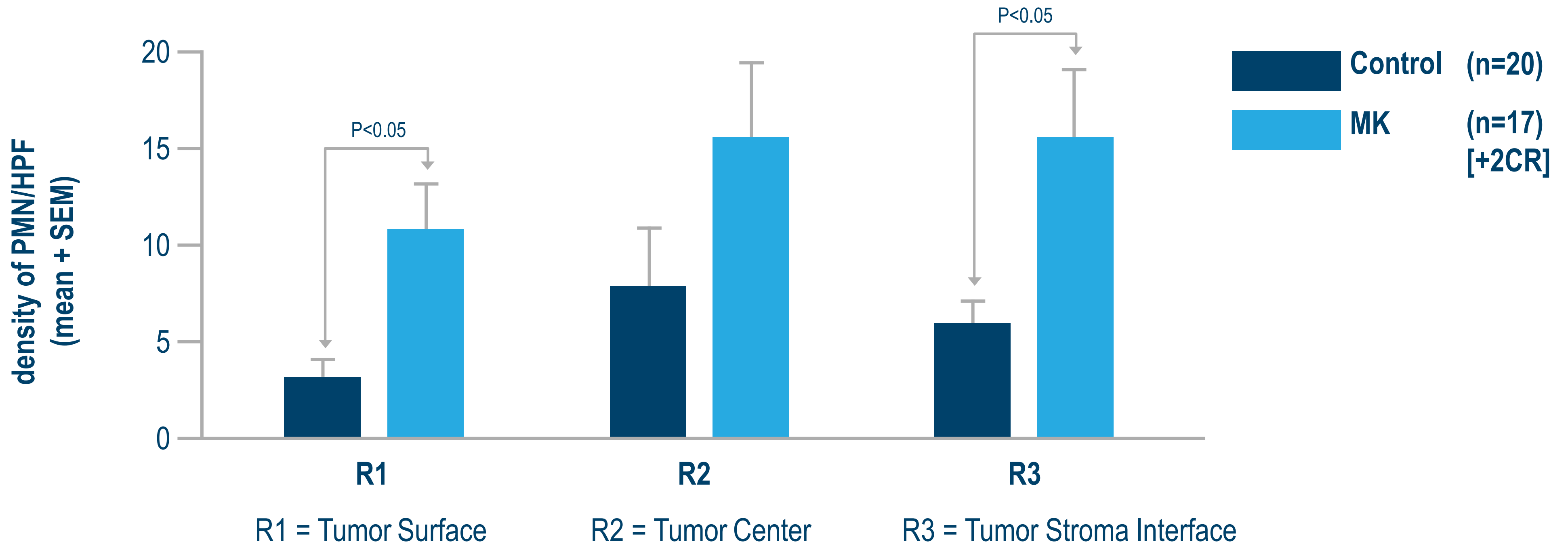


**Multikine Treatment Effect on Host CD4 and CD8 Tumor Infiltrating Cell Density in OSCC**  
(Locally Advanced Primary H&N Cancer)

\* 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

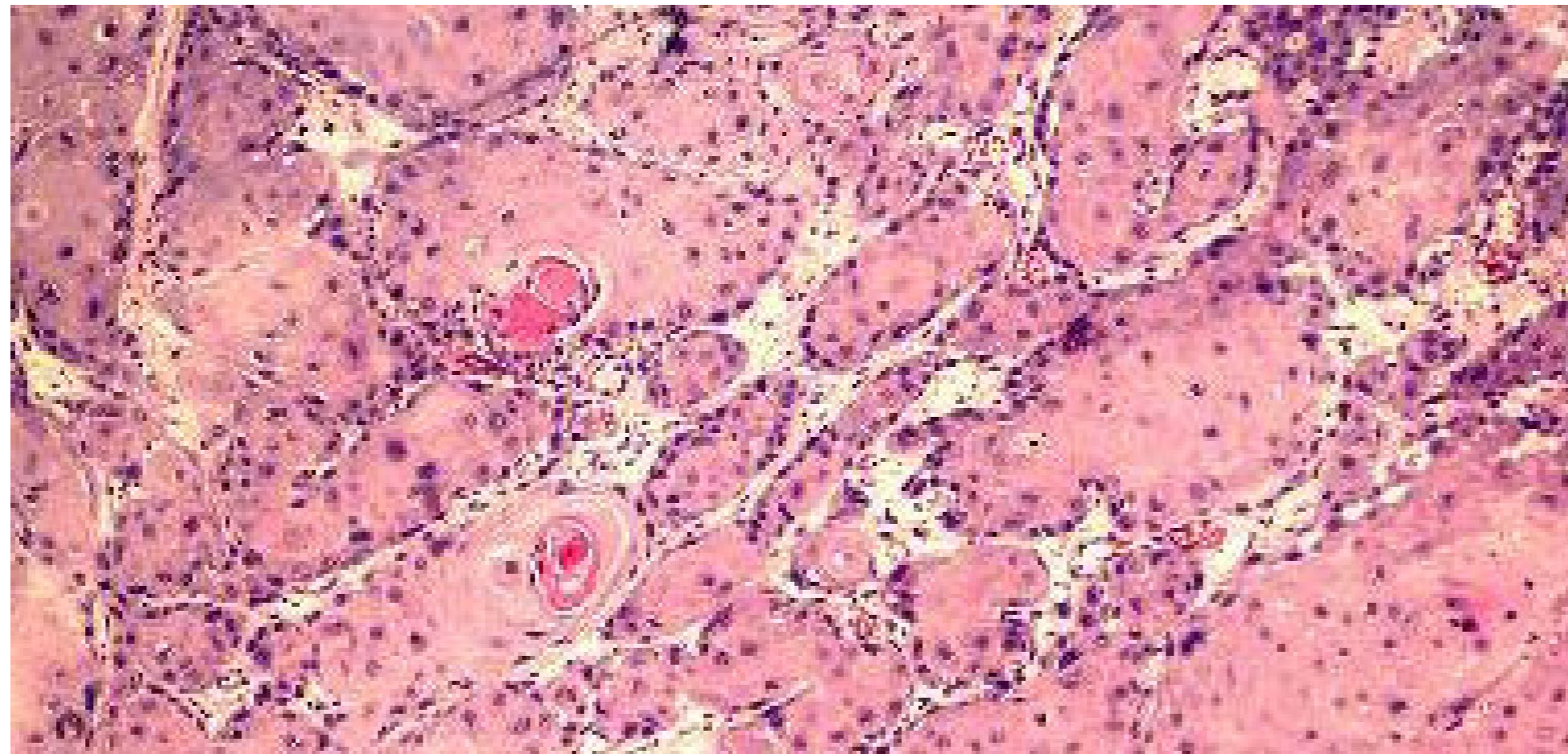


# Non-Multikine Treated vs. Multikine Regimen Treated – Phase 2 Results

## Oral Squamous Cell Carcinoma

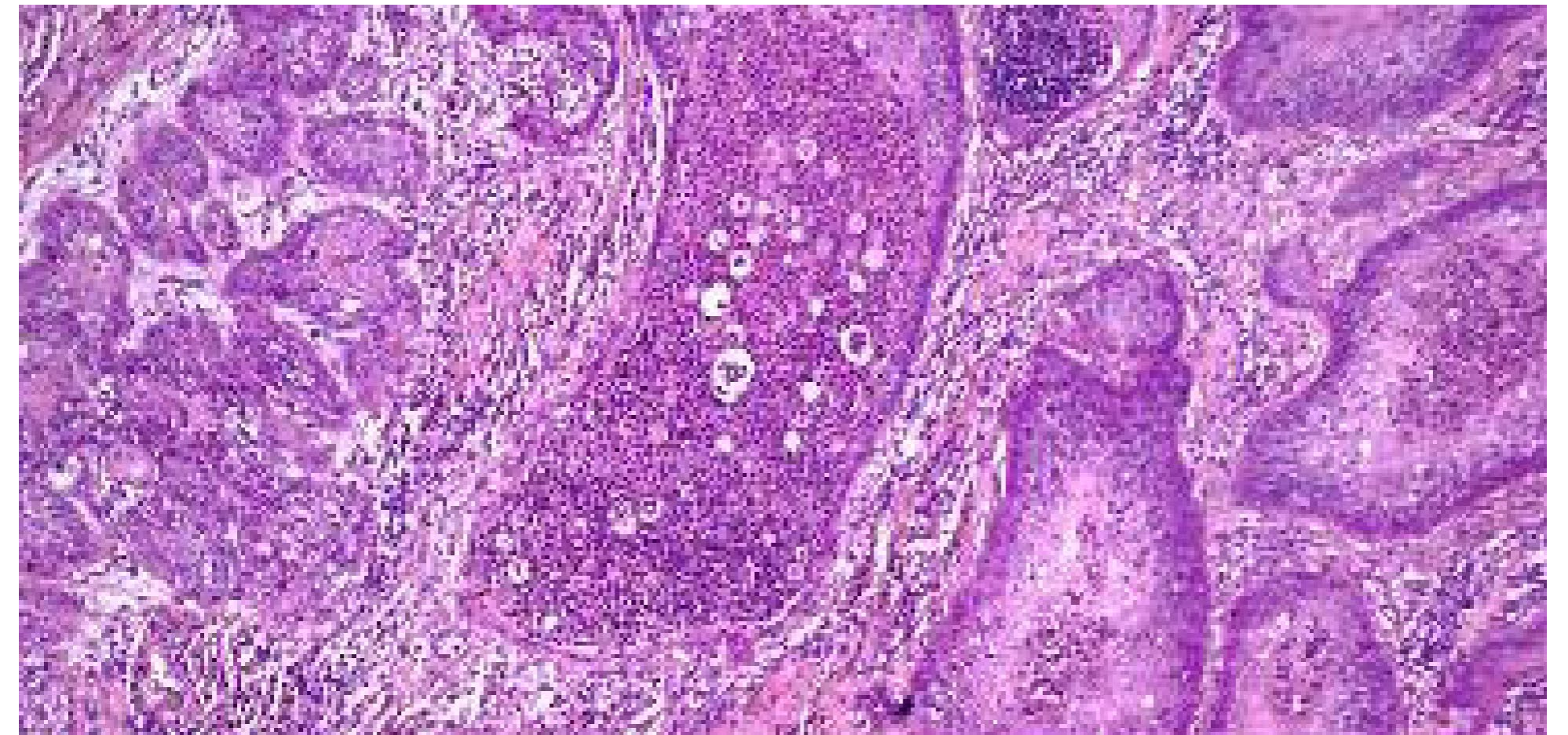
(Locally Advanced Primary H&N Cancer)

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

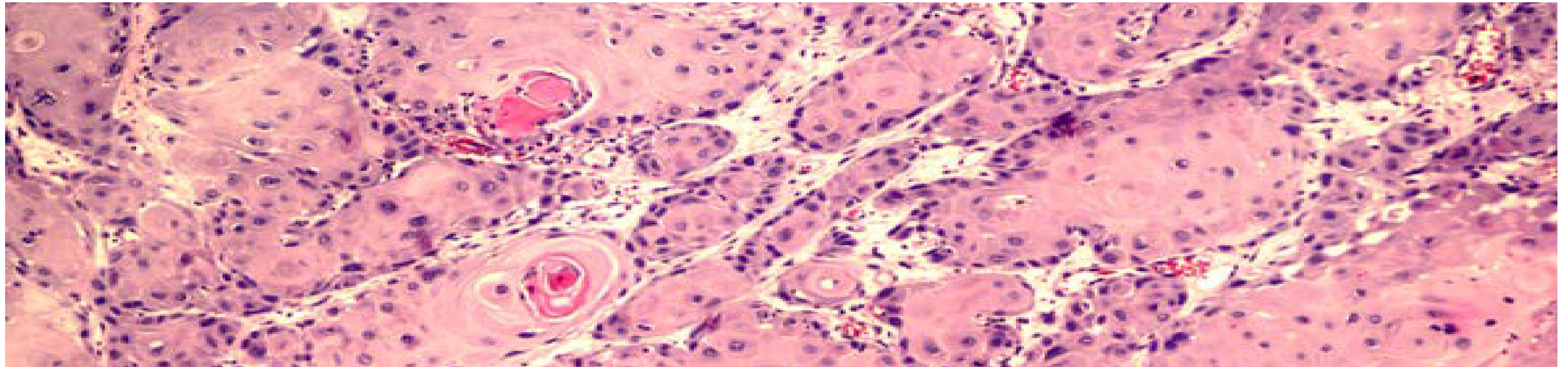


# Conventional Treatment (SOC)

## 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

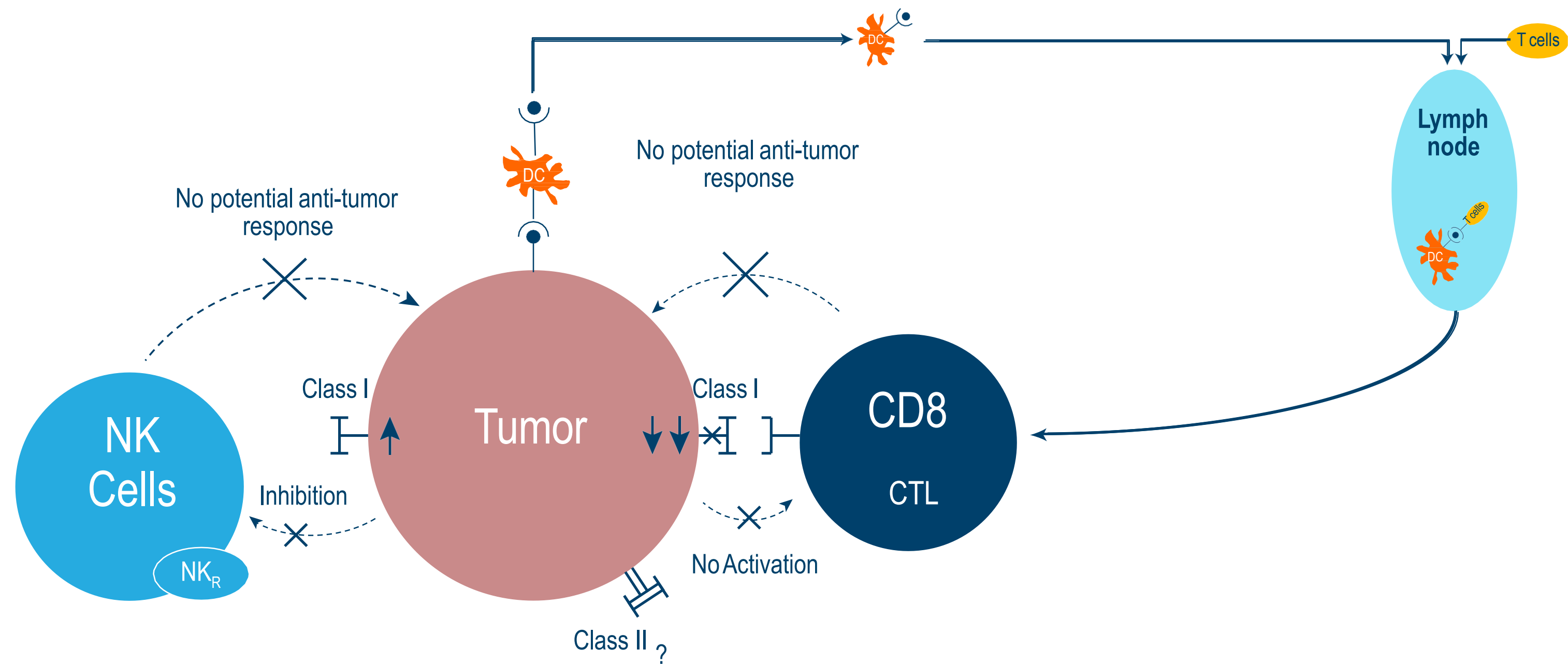
Lack of necrosis in the epithelial nests of OSCC



# 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.



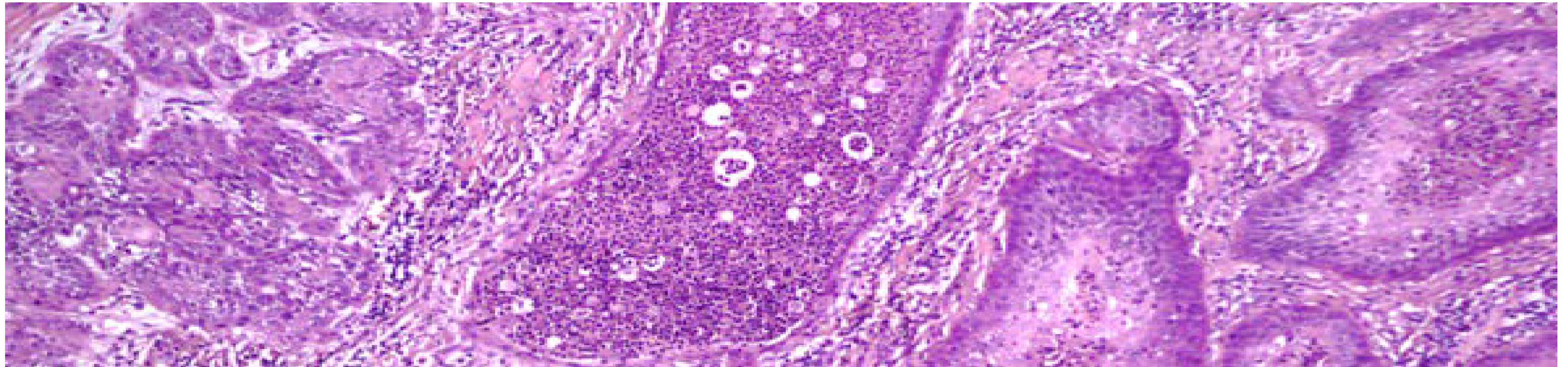


# Multikine Treatment Regimen

## 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

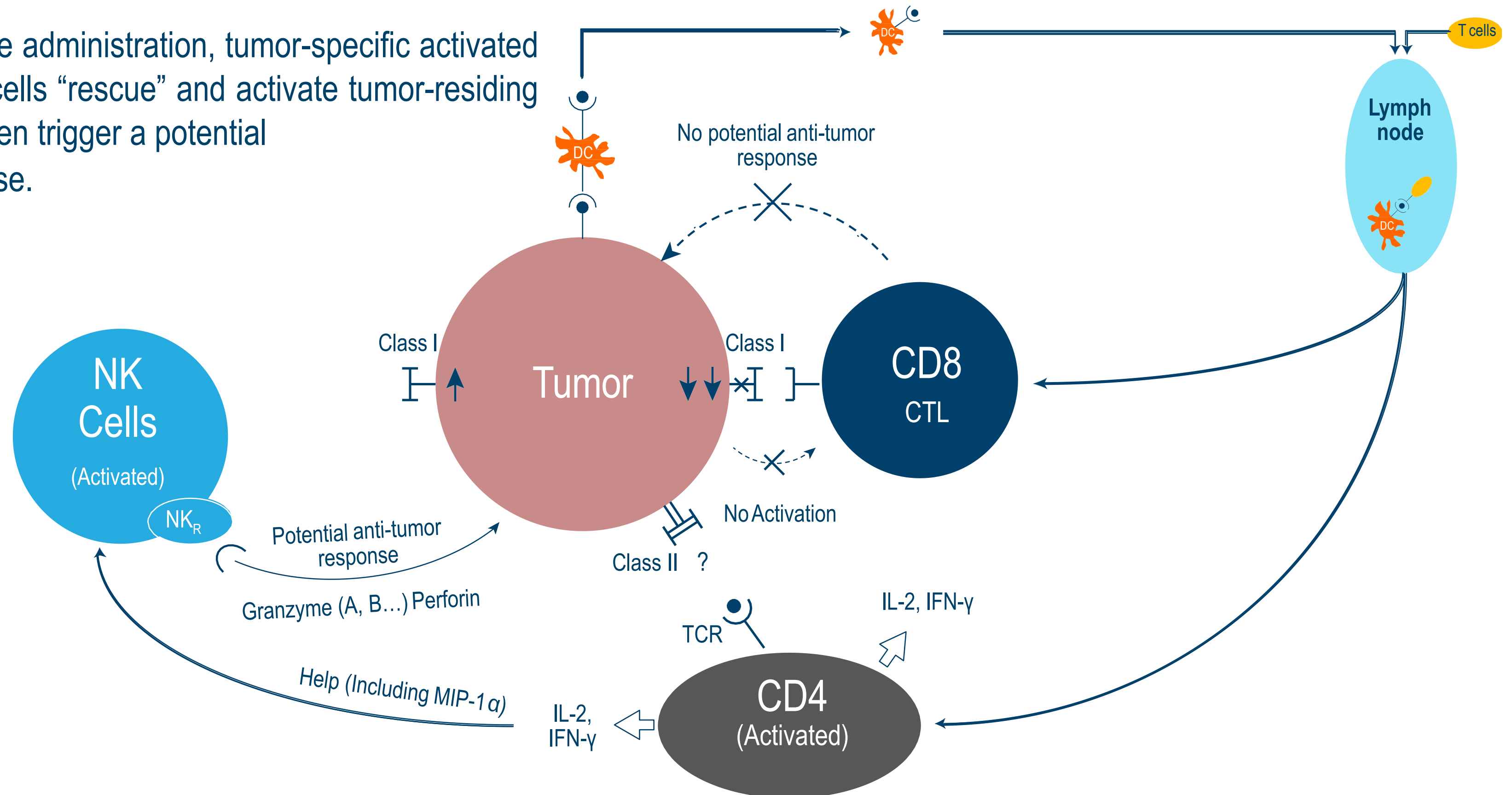
Entire cancer nest is necrotic and filled with debris and leukocytes



# 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<sup>+</sup> (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

<p>Of the evaluable patients - <b>10.5%</b> of patients had no remaining cancer cells (by pathology) following 3 weeks (x5/wk) of Multikine treatment regimen</p> <p>Timar et al: Journal of Clinical Oncology 23 (15) May 20, 2005 and Talor et al, Oral Oncology Supplement (2) No. 1, May 2007</p>	<p><b>50%</b> average reduction in the number of cancer cells (by pathology) following 3 weeks (x5/wk) of Multikine treatment regimen</p> <p>Timar et al: Journal of Clinical Oncology 23 (15) May 20, 2005</p>	<p><b>42.1%</b> Overall Response Rate (RECIST) in Phase 2 study</p> <p>Timar et al: Journal of Clinical Oncology 23 (15) May 20, 2005</p>
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## 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 Multikine Differ from Checkpoint Inhibitors?

The best known cancer immunotherapy treatments, to date, are checkpoint inhibitors Opdivo (BMS) and Keytruda (Merck). These two drugs have been rapidly approved for sale, in many cases on the basis of small studies only, in multiple cancer indications. They are also approved for sale in head and neck cancer (squamous cell carcinoma of the head and neck), but only for metastatic or recurrent disease - not the “advanced primary” population CEL-SCI is targeting for approval.

Keytruda and Opdivo are not competitors to Multikine since the Multikine patient population is the advanced primary head and neck cancer which per the standard of care is scheduled for surgery as its first treatment (“intent to cure”). As it is unethical to delay surgery, Multikine is only given for three weeks prior to surgery. Keytruda and Opdivo, requiring months of treatment to work, cannot be used in a patient population where surgery is currently the first recommended treatment.

These two checkpoint inhibitors appear to work well in lung cancer and in malignant melanoma, as well as in some patient populations in head and neck cancer. They also have many toxicities that preclude using them in the curative intent setting - as is currently being investigated in the Multikine Phase 3 study.

# Multikine Compared to Keytruda and Opdivo in SCCHN

	Multikine	Keytruda (Merck)	Opdivo (BMS)
<b>Indication:</b>	Advanced primary previously untreated SCCHN	Recurrent metastatic SCCHN	Recurrent metastatic SCCHN
<b>Dosing:</b>	Intracutaneous (IC) one course injected 5 times a week x 3 weeks around tumor and draining lymph nodes prior to surgery radio and chemotherapy	Intravenous (IV) every 2 weeks until toxicity	Intravenous (IV) every 2 weeks until toxicity
<b>Mechanism of Action:</b>	Multicomponent cytokine mixture. Acts locally on tumor and draining nodes. Multi-targeted.	Monoclonal antibody targeting PDL 1, a single target present in only 43% of SCCHN patients	Monoclonal antibody targeting PDL 1, a single target present in only 43% of SCCHN patients
<b>Efficacy:</b>	<p>Phase 2 - 33% increase Overall Survival (OS) vs. literature reports in 55 trials conducted between 1987-2007.</p> <p>Pathology - complete disappearance of tumor cells in tumor removed at surgery in 10% of patients. Remaining patients had only 50% of tumor cells remaining, following 3 week treatment.</p> <p>Phase 3 - results expected early 2019. Endpoint 10% increase in OS in MK + SOC vs SOC. Study design replicates Phase 2 "Proof of Concept"</p>	Phase 3 - Endpoint was Overall Response Rate (ORR) endpoint. ORR 16%. Complete Response (CR) 5%	Phase 3 - 8.7 and 4.6 months median survival in the Opdivo & chemo arms respectively in the PDL 1 positive group
<b>Toxicity Profile:</b>	Investigators reported Multikine safe and well-tolerated in > 750 patients	Serious adverse reactions in 45% of patients	Can be life threatening affecting a variety of organ systems



# IT-MATTERS

## Global Phase 3 Head & Neck Cancer Study

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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

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# Multikine H&N Cancer Phase 3 Study Summary

- Open-label Phase 3 Study
- 784 locally advanced SCCHN evaluable subjects
- Combined 298 events in the 2 main comparator groups

## Enrollment:

- Last patient enrolled September 2016
- Total enrolled patients in Phase 3 H&N Cancer Study 928

# Multikine Phase 3 Trial Design

## Study Enrollment 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/m<sup>2</sup> (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).

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# Head and Neck Tumors of Interest for this Phase 3 Study

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

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# 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
N0	NE	NE	Stage III	Stage IVa
N1	Stage III	Stage III	Stage III	Stage IVa
N2	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 Endpoints:**
  - Progression Free Survival
  - Local/Regional Control
  - Safety
  - Histopathology of Tumor infiltrate
  - Quality of Life

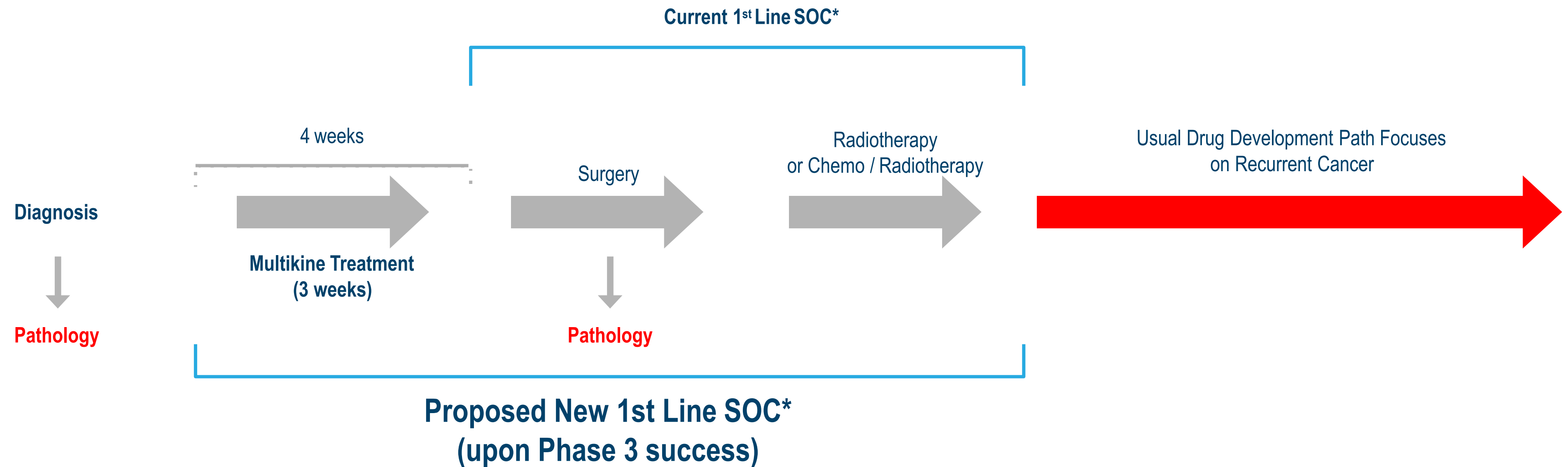
Note: Tumor Response - Tertiary outcome

# When Will the Phase 3 Study End?

- The study is fully enrolled with 928 patients
- 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 last patient was enrolled in the study in September 2016
- The study took 6 years to enroll instead of the planned 2 years. The original CRO did not perform, was sued by CEL-SCI and CEL-SCI won the arbitration. The CRO was found to be guilty of material breach of contract
- The study protocol assumes an overall survival rate of about 55% at 3 years for the SOC treatment group alone
- 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 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

# Phase 3 Study Design -Timing of Multikine Treatment Regimen

## Advanced Primary Head and Neck Cancer





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