CEL-SCI
Empowering Immune Defenses

Corporate Presentation

CEL-SCI Corporation

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-
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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.

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

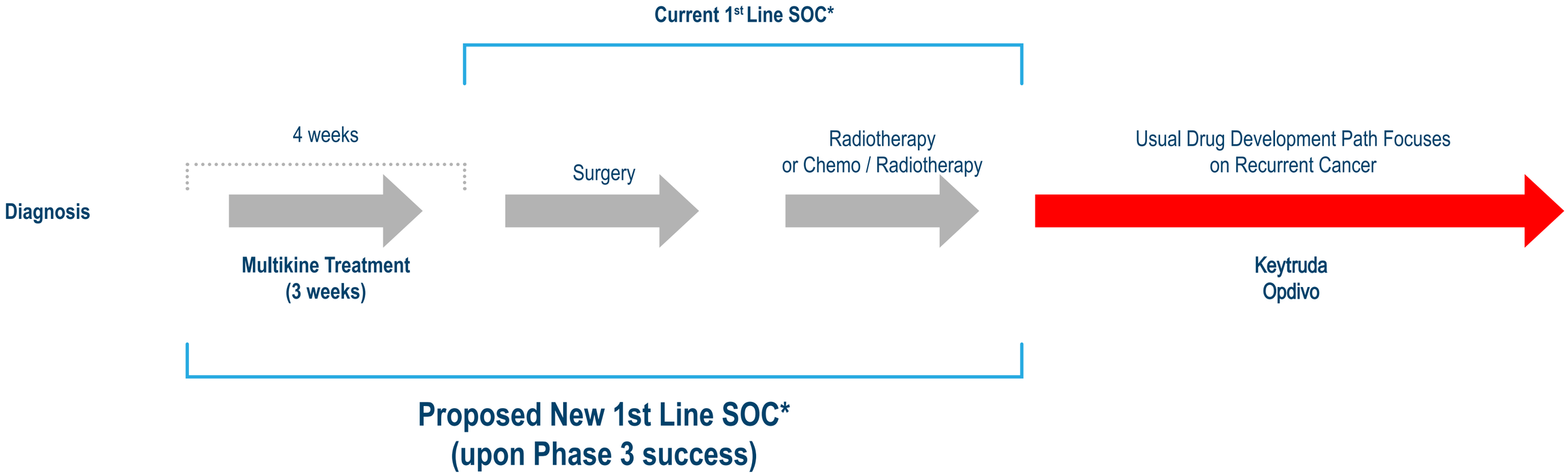
Multikine is administered to previously untreated, newly diagnosed head and neck cancer patients right after diagnosis for three weeks before the current standard of care treatments (surgery followed by radiation or combined radio-chemotherapy). There is no delay of surgery or follow on standard of care 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.

Phase 3 Study Design -Timing of Multikine Treatment Regimen

Advanced Primary Head and Neck Cancer



* Standard of Care

Introducing The Management Team

Geert R. Kersten
Director and CEO

- CEO since 1995; joined in 1987
- 30+ years pioneering field of cancer immunotherapy
- Previously worked at the law firm of Finley & Kumble and Source Capital, an investment bank
- Undergraduate degree Accounting, MBA from George Washington and JD from American University

Eyal Talor, Ph.D.
Chief Scientific Officer

- CSO since 2009; joined in 1993
- 23+ years of managing clinical R&D development for immunotherapy application
- Served as Director of Clinical Laboratories; and as R&D Director at CBL
- Author of over 30 publications
- Ph.D. at University of Ottawa and Post Doc at Johns Hopkins

Introducing The Management Team

	Officer Title	Joined CVM	Years of Exp.	Background
	Patricia B. Prichep SVP of Operations	**1992**	**40+**	• Former Manager of Quality and Productivity for the NASD • BA from the University of Bridgeport
	Daniel Zimmerman, Ph.D. SVP of Cellular Immunology	**1996**	**40+**	• Author of over 40 scientific publications and dozen patents • Former Senior Staff Fellow at NIH • PhD and Masters U. of Florida; BS Emory and Henry College
	John Cipriano SVP of Regulatory Affairs	**2004**	**48+**	• Former FDA Deputy Director of Biologics IND Division • BS Massachusetts College of Pharmacy and MS (Medicinal Chemist) Purdue University
	William Jones VP of Quality Assurance	**1999**	**30+**	• QA positions at Novartis in US and Europe • Former GMP compliance officer at NCI's Frederick facility • BS from George Mason and MS from Hood College
	Todd Burkhart VP of Manufacturing	**2010**	**30+**	• Previously involved in the building and/or running a number of major pharmaceutical facilities at Cephalon, HGS, and Univax • BS from Tusculum College

Product Candidates

Candidate	Preclinical	Phase 1	Phase 2	Phase 3	Marketing approval

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

L.E.A.P.S. Technology

Rheumatoid Arthritis CEL-2000:
Phase 1 enabling Studies CEL-4000 (NIH Grant)

Pandemic Flu treatment:
(NIAID)

Breast Cancer

Boosting the Immune System Before the Ravages of Radiation/Chemotherapy

- Give immune system drugs while the immune system is still strong, before surgery, radiation and chemotherapy
- Increase success rate of first cancer treatment by adding our immune stimulating product candidate Multikine to the current standard of care (SOC) for advanced primary (not yet treated) head and neck cancer
- Help the immune system “see” the tumor
- World’s largest Phase 3 trial in advanced primary head and neck cancer
    - 928 patients are enrolled. Full enrollment was completed in September 2016. We are currently waiting for 298 events (deaths) in the two main groups to prove an overall survival benefit.
- There is one recommended standard of care for advanced primary head and neck cancer. Chance to establish a new first line standard of care.
- Checkpoint inhibitors, CAR T-cell therapy, etc. cannot be used in this patient population. They are used only in recurrent / metastatic head and neck cancer patients.

What is Multikine?

- Multikine is an investigational patented mass produced biological product manufactured following Good Manufacturing Practice (GMP) requirements from ”Source Leukocytes” – an FDA licensed product - at CEL-SCI’s manufacturing facility near Baltimore, MD
- Cytokine Cancer Immunotherapy, contains 14 natural human cytokines, the body’s regulators of the immune system
- This pro-inflammatory cytokine mixture includes interleukins, interferons, chemokines and colony-stimulating factors - elements of the body’s natural mix of defenses against cancer
- Research at the US National Institute of Health has shown that the cytokines in Multikine (shown in **red** in the table) are the ones that are required to reject any tumor

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 for Multikine

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 33rd International Congress of the Society of Gynecological Oncologists
Phase 1/2	HIV	15	U.S.	Antiviral Therapy
	Total Patients	**224**		

Why Head and Neck Cancer as a First Target?

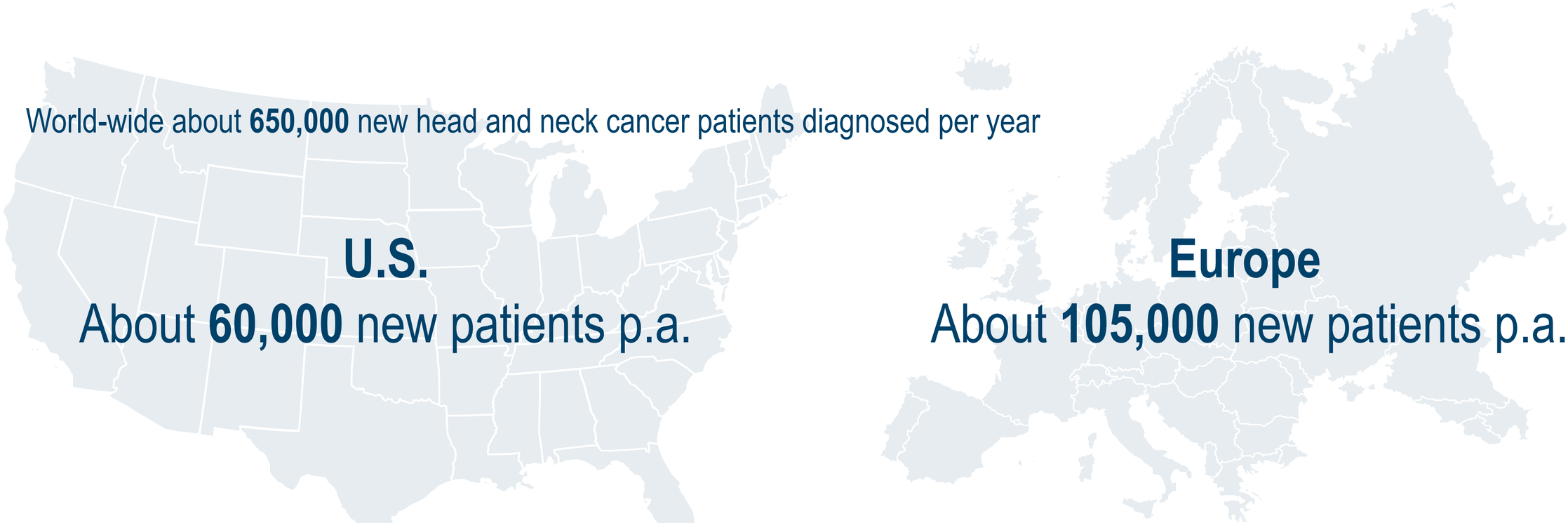
- Advanced (stages 3 and 4) primary (not yet treated) head and neck cancer was selected as the first indication because:
  - Represents an unmet medical need
  - Last FDA approval of a therapy for advanced primary head and neck cancer was about 60 years ago
  - Awarded Orphan Drug Status in the US
  - Head and neck cancer represents a very large cancer
  - Only one standard of care throughout the world

- Multikine administration is well suited as an addition to the established SOC in H&N cancer
  - SOC is surgery followed by either radiation or concurrent radiation/chemotherapy
  - During the 3-4 week preparation & scheduling of surgery, the Multikine investigational treatment regime is administered for 3 weeks, 5 times per week, with no impact on scheduling of and administration of SOC treatment

- Once successful we 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



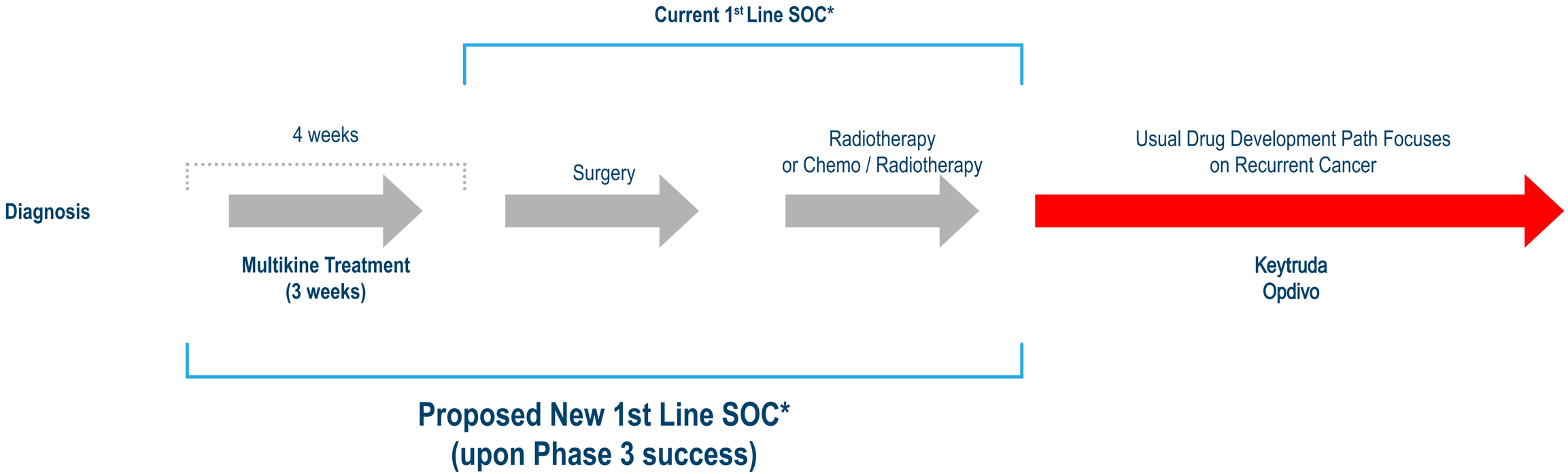
U.S.
About **60,000** new patients p.a.

Europe
About **105,000** new patients p.a.

- Advanced primary head and neck cancer constitutes about 2/3 of all head and neck cancer patients
- Neoadjuvant treatment. Use right after diagnosis, before surgery.
- Improvement in overall survival should result in Multikine becoming part of a new standard of care: Multikine followed by (plus) the ‘old’ SOC

Phase 3 Study Design -Timing of Multikine Treatment Regimen

Advanced Primary Head and Neck Cancer



* Standard of Care

Multikine Showed Measurable Anti-Tumor Responses in 3 Weeks Only

The final “Proof of Concept” Phase 2 study, following multiple Phase 2 studies that tested different treatment regimens, selected the best treatment for patients. The 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 of Multikine alone

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

50% average reduction in the number of cancer cells (by pathology) following 3 weeks of Multikine alone

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

Quality of life 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

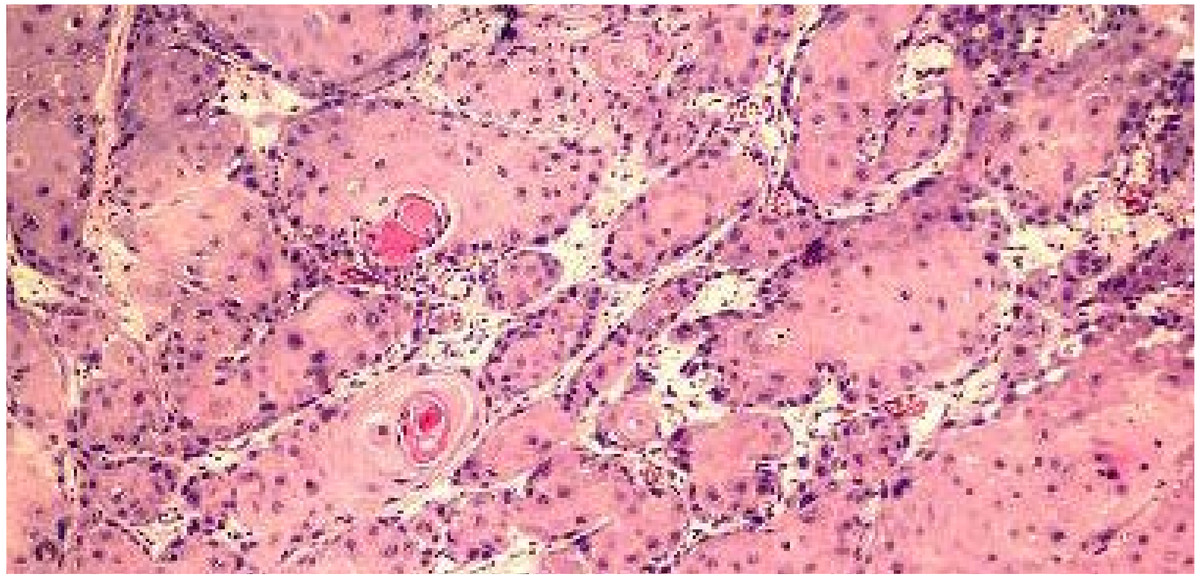
Follow-up Endpoint	Standard of Care (SOC)* +/- All other Treatment Modalities	Multikine** + Standard of Care	% Improvement over SOC***
Overall Survival (at 3.3 years from treatment)	47.5%	63.2%	33.1%

* Survey of 55 clinical trials; advanced primary H&N cancer (published 1987 – 2007)
** Multikine Treatment: 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)

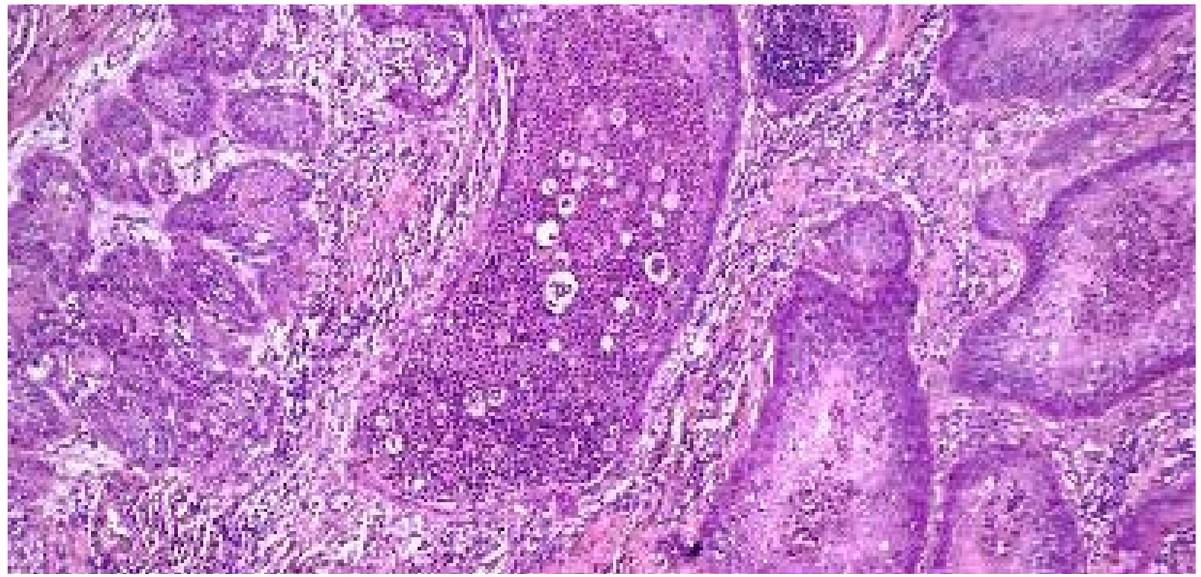
Pathology: Non-Treated – vs. – Multikine Treated (Final Phase 2 study)

Oral Squamous Cell Carcinoma (Locally Advanced Primary H&N Cancer)

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



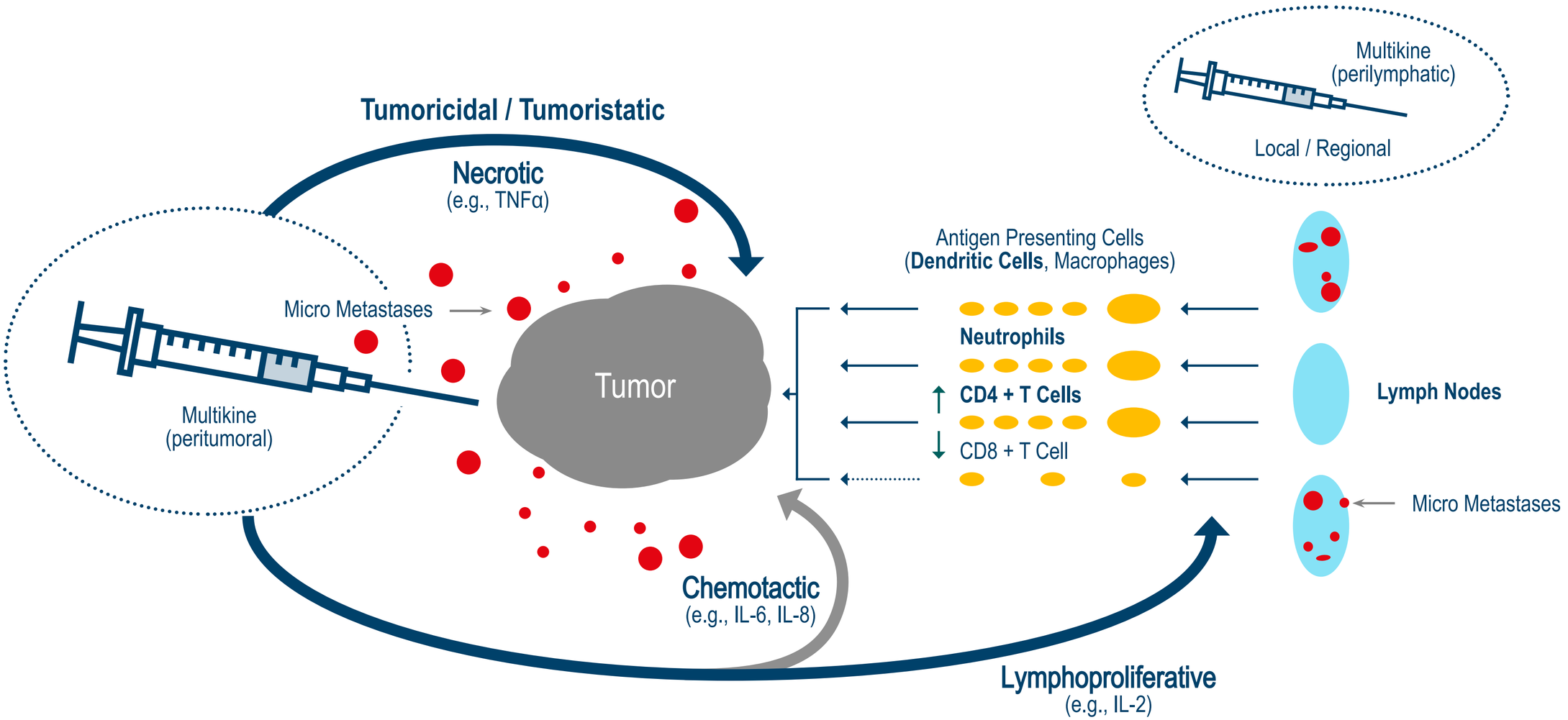
Non-Multikine treated
Lack of necrosis in the epithelial nests of OSCC



Multikine treated
Entire cancer nest is necrotic and filled with debris and leukocytes

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

Mechanism of Action Stimulates an Immune Response at the Injection Site



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

Phase 3 Trial Partners

National Institutes of Health, USA

—

genetic and molecular markers from tumor samples derived from Phase 3 study patients

Teva Pharmaceutical Industries Ltd., Israel (NYSE:TEVA)

—

licensee for several countries

Orient Europharma Co. Ltd., Taiwan

—

licensee for several Far Eastern countries

Ergomed PLC, UK

—

CRO that completed Phase 3 patient enrollment, contributed up to $12 million towards the cost of the Phase 3 study

About 100 top medical research institutes, universities and hospitals around the world participating in the Phase 3 study

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
- 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 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
- 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

Cancer Immunotherapy in Head and Neck Cancer

The best known cancer immunotherapy treatments are checkpoint inhibitors Keytruda (Merck) and Opdivo (BMS). 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 head and neck cancer (not the “advanced primary” population CEL-SCI is targeting for approval).

In October 2018 Merck announced interim data showing that Keytruda produced a survival benefit in first line treatment for patients with recurrent or metastatic head and neck cancer. This proves that a cancer immunotherapy can work for head and neck cancer patients.

Keytruda and Opdivo are not competitors to Multikine since the Multikine patient population is advanced primary head and neck cancer which is scheduled for surgery for its first treatment (intent to cure). It is unethical to delay surgery. Therefore, Multikine is only given for three weeks prior to surgery. Keytruda and Opdivo, requiring months of treatment to work, on the other hand are used in metastatic and recurrent patients, where surgery is not the first treatment.

We know of no Merck or BMS studies in our patient population. All of their studies are run in metastatic or recurring head and neck cancer patients. Our patients are treated prior to surgery, radiation and chemotherapy.

Multikine Compared to Keytruda and Opdivo in SCCHN

	Multikine	Keytruda (Merck)	Opdivo (BMS)
Indication:	Advanced primary previously untreated SCCHN	Recurrent metastatic SCCHN	Recurrent metastatic SCCHN
Dosing:	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
Mechanism of Action:	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
Efficacy:	Phase 2 - 33% increase Overall Survival (OS) vs. literature reports in 55 trials conducted between 1987-2007 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 Phase 3 - results expected early 2019. Endpoint 10% increase in OS in MK + SOC vs SOC. Study design replicates Phase 2 "Proof of Concept"	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
Toxicity Profile:	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

Intellectual Property Protection for Multikine

Patents and other protection for Multikine:

- Composition of matter patent protection until 2024
  - US Patent # 6,896,879
  - European Patent (Germany) # 1,773,395
  - European Patents: #1,753,452; #1,773,368; #1,879,618
  - Chinese Patent # ZL200480025403.6
  - Japanese Patent # 5,122,279
- Additional pending patent applications world-wide
- US FDA granted Orphan drug designation for the “neoadjuvant therapy in patients with squamous cell carcinoma of the head and neck”
  - Gives potential for 7 year market exclusivity upon approval

Proprietary quality control and manufacturing know-how

- This is most important since Multikine is a complex biologic and very hard to copy

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^2 of Manufacturing and R&D space available
  - About 35,000 ft^2 fully developed – room for growth
  - Scaled for commercial use
- We spent over 10 years and approx. $80 million developing and validating the Multikine manufacturing process
- Significant investment has been made (~$25 million) in the Multikine manufacturing plant
- Construction began in August 2007 and Plant and Process validation completed in 2010
- Inspected by European Qualified Persons
  - No Significant Findings
- Significant “know how” developed to manufacture Multikine – Method of Manufacture
  - Trade-secret

LEAPS: A Separate Technology

CEL-SCI's LEAPS technology is a platform technology for therapeutic vaccines

- A patented new class of drug with a novel approach, acting earlier in the pathway of the specific disease
- Efficacy demonstrated in six human diseases by animal challenge models; three autoimmune (two different arthritis models representing Th1 and Th17 conditions, and myocarditis), two infectious (Herpes Simplex Virus and influenza A), and oncology (breast cancer)
- Research has been funded via collaborations with the NIH, U.S. Army, Navy, Universities and has received National Institutes of Health grants (e.g., SBIR)
- Primary focus: development of a therapeutic vaccine for Rheumatoid Arthritis (RA)
- Sept 2017: CEL-SCI was awarded a $1.5 million SBIR grant from NIH to fund GMP manufacturing, IND enabling studies, and additional mechanism of action studies to advance its first LEAPS product candidate for RA towards an IND application

Late Stage Cancer Company Acquisitions in the Past 18 Months

Company	Ticker	Sales price	Phase, Indication(s) and Acquisition
Kite Pharma Bought by Gilead	KITE	**$11.9 B**	• Phase 1&2/3 Solid Tumors, ALL,NHL, Multiple Myeloma, CLL, AML • Acquired by Gilead for $11.9 B (August 2017)
Juno Therapeutics Bought by Celgene	JUNO	**$9.8 B**	• Phase 1 & 2 NHL, ALL, Multiple Myeloma, NSCLC, Mesothelioma, Ovarian, Breast, Lung, Neuroblastoma • Acquired by Celgene for $9 B net of 9.7% already owned (January 2018)
Impact Biomedicines Bought by Celgene	Private	**$7 B**	• Phase 3 myelofibrosis and polycythemia vera • Acquired by Celgene for up to $7 B (January 2018)
Bioverativ Bought by Sanofi	BIVV	**$11.6 B**	• Phase 3 hemophilia • Acquired by Sanofi for $11.6 B(January 2018)
TESARO Bought by GlaxoSmithKline	TSRO	**$5.1 B**	• Acquired by GlaxoSmithKline for $5.1 B (December 2018)
Loxo Oncology Bought by Eli Lilly	LOXO	**$8 B**	• FDA approved first commercial medicine in 2018 • Acquired by Eli Lilly for $8 B (January 2019)

Why is CEL-SCI so Unknown?

- 8 year clinical trial - The Phase 3 trial was supposed to be a 5 year study, instead it has lasted about 8 years so far (lack of enrollment by the former CRO that ran the study from 2011-2013). In the ongoing Phase 3 study we hope to repeat the Phase 2 success that showed Multikine patients living longer. The Phase 3 study requires 298 events to reach its endpoint. A longer time period in reaching 298 events is interpreted by many experts as an indication of potential success

- 4.5 year arbitration - The legal case brought by CEL-SCI against the former CRO created legal uncertainty as it dragged on for 4.5 years. This caused the loss of analyst coverage and many institutional holdings. Now that the legal case has been won by CEL-SCI and the Phase 3 study is nearing its end, both analysts and institutional holders are becoming interested again

- CEL-SCI has had no new clinical data for over 10 years, but ... this should change soon since CEL-SCI is waiting for the final data readout from its massive Phase 3 head and neck cancer study

Who Reviews the Unblinded Data from the Phase 3 Study?

- The study is an open label blinded study. Only the regulators, the Independent Data Monitoring Committee (IDMC) and select members of the CRO have unblinded information
- The FDA and 23 regulators have reviewed detailed annual reports from the Phase 3 study for the last eight years and never had any questions
- The Phase 3 study and its data have been repeatedly reviewed by the IDMC, who have reviewed safety results and efficacy indicators and recommended that the trial continue until 298 events have occurred, as recently as August 2018

Summary

- Multikine is administered before surgery, radiation and chemotherapy because that is the time when the patient's immune system is the strongest. By doing so we hope to either cure the patient or delay the time to recurrence
- Phase 3 overall survival (OS) data results are expected soon
- Endpoint of 10% improvement in OS over comparator arm in Phase 3 study. In our completed Phase 2 we saw a 33.1% improvement over the average OS for the current SOC (from scientific literature) at 3.3 years post-surgery
- No severe toxicity associated with Multikine in Phase 2 studies and in the Phase 3 study
- Head and neck cancer is a major cancer with ~650,000 new cases p.a. worldwide
- Other cancer immunotherapies, e.g., Keytruda, Opdivo, CAR-T, etc., cannot be used before surgery since they require long periods for administration and a delay in surgery is not permitted
- No new FDA approved treatments for advanced primary head and neck cancer in about 60 years (unmet medical need) Multikine granted Orphan Drug designation in U.S.

Closing

The Multikine Phase 3 trial is the largest head and neck cancer study ever. Head and neck cancer is one of the biggest cancers worldwide with about 650,000 new patients per year. CEL-SCI's Phase 3 study enrolled the last of its 928 patients about 2.5 years ago and the final data read out is expected soon. If successful, we believe Multikine has the potential to become the first recommended treatment for patients following diagnosis of head and neck cancer. Advanced primary head and neck cancer represents an unmet medical need because the last FDA approval for this disease was about 60 years ago. The FDA has also granted Orphan Drug designation to Multikine. First line treatments in general command a premium to the market because the market is so much larger than that for a recurrent cancer treatment.

To repeat, other immunotherapies such as Keytruda, Opdivo, CAR-T, etc. are indicated only for patients whose cancers have recurred following standard of care (surgery etc.) therapy 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.

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