CEL-SCI Corporation
8229 Boone Boulevard, Suite 802
Vienna, VA 22182, USA
Phone: (703) 506-9460
gdewindt@cel-sci.com
www.cel-sci.com

Company Overview

Cancer Drug Extends Life—Preparing to file for Approvals

CEL-SCI completed the world's largest Phase 3 study in head and neck cancer and reported data showing a significant survival benefit in patients with advanced primary squamous cell carcinoma of the head and neck (SCCHN) who received Multikine®* immunotherapy prior to a standard of care (SOC) treatment of surgery plus radiotherapy as compared to patients who received SOC alone. Multikine added no toxicity. It reduced and eliminated tumors within 3 weeks before surgery (none were reduced or eliminated in the control group), added almost 4 years of life and tumor responders had 5-year survival of 82% vs. 48% in the control. The Company has a global regulatory filing strategy which includes the U.S., Canada, United Kingdom, and European Union to address a population of about 210,000 patients annually. CEL-SCI treats patients by activating the immune system to fight cancer BEFORE surgery, radiation, and chemotherapy have damaged it, addressing the largest segment of the market. Head and neck cancer is a multi-billion-dollar global market and Multikine has received Orphan Drug designation from the FDA for this cancer, an unmet need for which the FDA has not approved a treatment in 50+ years. CEL-SCI completed the commercial scale buildout of its Multikine manufacturing facility in anticipation of market demand once Multikine receives regulatory approval.

EQUITY OVERVIEW* (as of July 20, 2023)

NYSE American: CVM
Stock Price: ~$2
Trading Volume (90-day average): ~250 K
Shares Outstanding: ~ 47.2 M (clean cap structure)
Market Cap: ~$95 M
Cash on Hand (3/31/23): $10.5 M plus $5 M raised on 7/20/23

ANALYST COVERAGE

EF Hutton

PEER REVIEWED PHASE 3 PRESENTATIONS

- **American Society of Clinical Oncology Conference 2022**
- **European Society for Medical Oncology Annual Congress 2022**
- **European Congress on Head & Neck Oncology 2023**
- **American Head and Neck Cancer Society Conference 2023**

UPCOMING MILESTONES

- **Canada's Conditional Approval Pathway filing**
- **Meeting with EMA (Europe)**
- **Meeting with MHRA (UK)**
- **More presentations and data submissions to top peer reviewed scientific conferences & journals**

IP & MANUFACTURING

- **Robust technology protection for Multikine in the U.S., Europe, China, and Japan**
- **73,000 sq. ft. cGMP manufacturing facility**
- **Over $150 M invested in manufacturing plant, development, and validation**

HEAD & NECK CANCER MARKET

- **890,000 new cases each year**
- **CEL-SCI's target population is 210,000 per year**

Investment Highlights

Multikine Modulates & Mobilizes Intact Immune Response to Kill Cancer

Multikine is a copy of the pro-inflammatory cytokine immune response our bodies produce every day and is designed to empower a person's intact immune system cells to attack their own cancer. Patients are treated with Multikine right after diagnosis, before any other standard of care treatment. The goal is to help the intact immune response detect and kill the tumor and micro-metastases in order to reduce recurrence and improve overall survival.

Phase 3 Trial Reports Positive Results: Preparing to File for Approvals

928 patients were randomized into two treatment arms determined by risk of recurrence post-surgery following National Cancer Comprehensive Network (NCCN)* guidelines. Final results showed that Multikine significantly increased survival, the gold standard for cancer drug testing, in patients who were treated with radiation, but not in patients who were also treated with chemotherapy, representing 380 of the 928 patients enrolled. Results in these patients:

- 14.1% absolute 5-year overall survival benefit (62.7% vs 48.6%)
- 15.2% of patients saw partial or complete tumor response in the 3 weeks prior to surgery which led to much higher survival (82% vs. 48%)
- 5 patients had a complete tumor response vs. zero tumor response in control group
- Tumor response → significantly lower death rate
- No toxicity added

Global Regulatory Approval Strategy Underway

CEL-SCI's global Phase 3 study spanned 20 countries where approvals are expected. The Company's goal is to obtain approval of Multikine worldwide and then make it available to patients as fast as possible. Filings in major markets are planned including:

- **Canada** - Health Canada advised CEL-SCI that it would be appropriate to request advance consideration for approval of Multikine under the Notice of Compliance with Conditions (NOCC) policy. If Health Canada grants the NOCC, then it is possible that CEL-SCI could begin commercialization in Canada as early as 2024.
- **US** – CEL-SCI recently completed a positive meeting with the FDA. A confirmatory clinical trial will be conducted for the FDA based on the agreed upon selection criteria for patients that will be treated with Multikine as assessed by methods including PET-CT/MRI screening. CEL-SCI is collaborating closely with the FDA to design a clinical protocol to generate, as expeditiously as possible, the confirmatory data they require for approval of Multikine.
- **Europe and UK** – Scientific advisory meetings are planned with the European Medicines Agency and the UK's Medicines and Healthcare Products Regulatory Agency to help determine if a conditional approval can be given in those countries with a promise to do confirmatory studies after approval or if it is possible to get a conditional approval with the enrollment of just a small number of patients.