CEL-SCI Corporation
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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 and reduced or eliminated tumors within 3 weeks before surgery (none were reduced or eliminated in the control group). In the target population of patients with low PD-L1 (a cancer biomarker) Multikine increased 5-year survival from 45% to 73% compared to control, cutting the risk of death by half. 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 145,000 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 November 27, 2023)

NYSE American: CVM
Stock Price: about $2.60
Trading Volume (90-day average): ~1.2 m
Shares Outstanding: ~ 50 M (clean cap structure)
Market Cap: ~$130 M

ANALYST COVERAGE

EF Hutton
ThinkEquity
Zacks

PEER REVIEWED PHASE 3 PRESENTATIONS

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

UPCOMING MILESTONES

- **File in Canada for conditional approval pathway**
- **Present new data to U.S. FDA**
- **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 $200 M invested in manufacturing plant, development, and validation**

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 since that is when the immune system is strongest. 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.

Clear Efficacy in Target Population: Preparing to File for Approvals

In the target patient population, Multikine showed the following in clinical trials:

- ***Risk of death cut in half at 5 years*** versus the control;
- 5-year survival Multikine 73% vs. control 45%;
- 28.6% absolute 5-year overall survival benefit versus control (p=0.0015);
- 0.349 hazard ratio vs control (95% CIs [0.18, 0.66], Wald p=0.0012);
- >35% rate of pre-surgery tumor reductions and/or downstages (p<0.01);
- Low PD-L1 tumor expression (vs high PD-L1 where Keytruda and Opdivo work best);
- No Multikine-related deaths or excess toxicity/adverse event incidence vs control;
- **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. Based on the target population findings recently presented at ESMO, CEL-SCI believes the Phase 3 data present a compelling case for immediate patient access to Multiline since a confirmatory trial is statistically more than 95% sure to be successful. Requests have been filed with United Kingdom and European Union regulators. Requests and filings based on the new data will be made with the U.S. FDA and with Health Canada, which had already 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 late 2024.