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Company Overview

Immunotherapy Drug Extends Life for Head & Neck Cancer Patients

CEL-SCI presents a unique, derisked investment opportunity into a Phase 3 cancer company that has robust efficacy and safety data for its immunotherapy drug, Multikine, which is set to be confirmed in its upcoming FDA Registration Study. The Company completed the world's largest Phase 3 study in head and neck cancer with 928 patients. Multikine significantly extended life in a target patient population demonstrating a 73% survival rate with Multikine vs. only 45% without at 5 years after treatment. Based on this very strong data, the FDA agreed to CEL-SCI's target patient selection criteria and gave the go-ahead to conduct a small, focused, confirmatory Registration Study which will enroll only 212 patients. CEL-SCI will enroll newly diagnosed advanced primary head & neck cancer patients with no lymph node involvement (determined via PET scan) and with low PD-L1 tumor expression (determined via biopsy), representing over 100,000 patients annually. If, as the Company expects, the Registration study confirms the findings of the Phase 3 study, Multikine should be added to the standard of care. Even a small penetration into treating the target population would mean billions of dollars in annual revenue for CEL-SCI.

EQUITY OVERVIEW (as of May 8, 2024)

NYSE American: CVM
Stock Price: about $1.40
Trading Volume (90-day average): ~300K
Shares Outstanding: ~ 54 M (clean cap structure)
Market Cap: ~$76 M

ANALYST COVERAGE

EF Hutton ⋮ ThinkEquity ⋮ Zacks ⋮ FirstBerlin

UPCOMING MILESTONES

- **Start FDA confirmatory Registration Study for Marketing Approval in the U.S.**
- **More presentations and data submissions to top peer reviewed scientific conferences & journals**

READY FOR COMMERCIAL PRODUCTION

- **73,000 sq. ft. cGMP manufacturing facility**
- **Over $200 M invested in manufacturing plant, development, and validation**

ROBUST IP, KNOW-HOW, TRADE SECRETS

- **Technology protection for Multikine in the U.S., Europe, China, and Japan**

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**

MULTIKINE HAS SHOWN TUMOR RESPONSES IN NUMEROUS OTHER SOLID TUMOR CANCERS

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 (surgery and radiation therapy) 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. The Phase 3 study proved that in the target population, patients had a pre-surgical response (during the 3 weeks while being treated with Multikine prior to surgery) including a reduction in tumor size and a downstaging of disease. Those responses were highly correlated to increased survival.

Clear Efficacy in Target Population: Potential New Standard of Care

In the target patient population, for the FDA confirmatory Registration Study and for potential conditional approval in other countries, Multikine demonstrated the following:

- ***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);
- >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 toxicity*** added.

Confirmatory FDA Registration Study Likely to Succeed

Success in the Registration Study requires an absolute 10% improvement in overall survival (OS) of patients treated with Multikine vs the control group. In the completed Phase 3 trial, the target population had an absolute 28.5% improvement in OS, which is much higher than the absolute 10% needed for success.

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. Based on the target population finding, CEL-SCI believes the Phase 3 data present a compelling case for rapid patient access to Multikine. Once the patients are enrolled in the confirmatory study, CEL-SCI plans to present the tumor response and downstaging data (closely related to survival) to regulators for a potential early approval.