NEWS RELEASE

CEL-SCI Files Request With the UK's MHRA Regarding Path to Approval for Multikine in the Treatment of Head & Neck Cancer

10/5/2023

- CEL-SCI will present the MHRA with new results that demonstrate pre-surgical response rates and overall survival advantages that are superior to those published by CEL-SCI previously, as a result of an improved selection algorithm that more accurately predicts the patients who would benefit most from the Multikine therapy
- UK has about 12,500 new head & neck cancer cases each year

VIENNA, Va.--(BUSINESS WIRE)-- CEL-SCI Corporation (NYSE American: CVM) today reported it has filed a request with the United Kingdom's Medicines and Healthcare Products Regulatory Agency (MHRA) to discuss a pathway for approval of Multikine* (Leukocyte Interleukin, Injection) immunotherapy for the treatment of newly diagnosed head and neck cancer.

At the meeting, CEL-SCI will present MHRA with new results that demonstrate pre-surgical response rates and overall survival advantages that are superior to those published by CEL-SCI previously. These new results arose from an improved selection algorithm of the Multikine target population. The improvements in the selection algorithm were based on discussions and feedback from regulators and consultants. This improved selection algorithm is able to more accurately predict the patients who would benefit most from the Multikine therapy.

A statistical validation of outcomes in the new target population, based on the Phase 3 study data, was recently concluded and will be presented at the Conference of the European Society for Medical Oncology (ESMO) which takes place October 20-24, 2023 in Madrid, Spain.

CEL-SCI is seeking a pathway towards approval of Multikine throughout the UK. CEL-SCI's goal is to apply for marketing authorization in the UK as soon as possible, based on the data already generated. Just two weeks ago CEL-SCI filed a similar submission with the European Medicines Agency (EMA).

"We have a comprehensive global regulatory approval strategy," stated CEL-SCI's CEO Geert Kersten. "Having received encouraging submission guidance from Health Canada, we plan to file for a NOC/C conditional approval there. This pathway would allow CEL-SCI to request immediate approval based on the data generated to date, and any additional studies if needed would be done post-market. With the European Medicines Agency and the MHRA, we hope to do the same. We are extremely excited about the results seen in the newly defined Multikine target population."

CEL-SCI's pivotal Phase 3 study tested Multikine in newly diagnosed locally advanced head and neck cancer patients. The study demonstrated a nearly 4-year median overall survival benefit for Multikine treated patients who were treated with surgery and radiotherapy versus the control group who did not receive Multikine. The dire need for a new and effective treatment for newly diagnosed locally advanced primary head and neck cancer is widely recognized in the medical community.

About CEL-SCI Corporation

CEL-SCI believes that boosting a patient's immune system while it is still intact should provide the greatest possible impact on survival. Therefore, in the Phase 3 study, CEL-SCI studied patients who were newly diagnosed with locally advanced primary squamous cell carcinoma of the head and neck (oral cavity and soft-palate) with the investigational product Multikine first, before they received the standard of care, which involved surgery followed by either radiation or chemoradiation. Our approach is unique because most other cancer immunotherapies are administered only after conventional therapies have been tried and/or failed.

Multikine is designed to help the immune system "target" the tumor at a time when the immune system is still relatively intact and thereby thought to be better able to mount an attack on the tumor. The Phase 3 study enrolled 928 patients.

Multikine (Leukocyte Interleukin, Injection) received Orphan Drug designation from the FDA for neoadjuvant therapy in patients with squamous cell carcinoma (cancer) of the head and neck.

The Company has operations in Vienna, Virginia, and near/in Baltimore, Maryland.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. When used in this press release, the words "intends," "believes," "anticipated," "plans" and "expects," and similar expressions, are intended to identify forward-looking statements. Such statements are subject to risks and uncertainties that could cause actual results to differ materially from those projected. Such statements include, but are not limited to, statements about the terms, expected proceeds, use of proceeds and closing of the offering. Factors that could cause or contribute to such differences include an inability to duplicate the clinical results demonstrated in clinical studies, timely development of any potential products that can be shown to be safe and effective, receiving necessary regulatory approvals, difficulties in manufacturing any of the Company's potential products, inability to raise the necessary capital and the risk factors set forth from time to time in CEL-SCI's filings with the Securities and Exchange Commission, including but not limited to its report on Form 10-K for the year ended September 30, 2022. The Company undertakes no obligation to publicly release the result of any revision to these forward-looking statements which may be made to reflect the events or circumstances after the date hereof or to reflect the occurrence of unanticipated events.

* Multikine (Leukocyte Interleukin, Injection) is the trademark that CEL-SCI has registered for this investigational therapy. This proprietary name is subject to FDA review in connection with the Company's 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.

Gavin de Windt
CEL-SCI Corporation
(703) 506-9460

Source: CEL-SCI Corporation