

**IMPORTANT
CORRECTION
OF INVESTIGATIONAL DRUG
INFORMATION
about the
Investigational Therapy
Multikine® (Leukocyte Interleukin,
Injection)**

September 20, 2011

Dear Patients and Healthcare Professionals:

CEL-SCI Corporation announced on August 17, 2011, that the U.S. Food and Drug Administration (FDA) on August 5, 2011, issued a Warning Letter to CEL-SCI Corporation regarding certain pages of CEL-SCI's website, www.cel-sci.com, which FDA identified as containing claims that: promote the Company's investigational therapy Multikine® (Leukocyte Interleukin, Injection) as safe and effective for the purposes for which it is being investigated or that otherwise promote the Investigational drug when the Investigational product has not yet been approved by FDA; suggest the investigational therapy Multikine is safe and/or effective for the treatment of various kinds of cancers, including those of the head and neck, when it has not been approved for these uses; suggest that the drug is "non-toxic" and has demonstrated "impressive" and "extraordinary" improvements in overall survival "over what can be expected from the current therapy".

To the extent patients and healthcare professionals may have been misled by any information on its website, CEL-SCI is providing the following clarifying information about the investigational therapy Multikine (Leukocyte interleukin, Injection).

Claims Identified by FDA that Promote Multikine as Safe and/or Effective for which it is being Investigated or that Otherwise Promote the Investigational Drug

The FDA states the web pages contain claims such as the following that promote the investigational therapy Multikine as safe and effective for the purposes for which it is being investigated, or otherwise promote the Investigational drug: "Multikine is non-toxic because it works with the body's immune system"; "Multikine is the first combination immunotherapy. It is the only immunotherapy that is able to directly affect the tumor cells themselves and activate a robust anti-tumor immune response."; "Multikine® has been shown to be safe and well tolerated and is non-toxic to healthy cells."; "Multikine® unleashes and then harnesses and enhances the immune system's ability to target and kill those tumor cells before they can cause recurrence or metastasize." CEL-SCI wants you to know the following:

- [Multikine \(Leukocyte Interleukin, Injection\) is an investigational new drug, and the product's indication\(s\), warnings, precautions, adverse reactions, and dosage and administration have **not** been established and are unknown at this time.](#)
- [The investigational therapy Multikine has **not** been licensed or approved for sale, barter or exchange by the FDA or by any other regulatory agency.](#)

** 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.*

- The safety or efficacy of the investigational therapy Multikine has **not** been established for any use.
- No definitive conclusions can be drawn from the early-phase, clinical-trials data summarized on CEL-SCI's website involving the investigational therapy Multikine (Leukocyte Interleukin, Injection).
- Further research on the investigational therapy Multikine is required, and early-phase clinical trial results must be confirmed in the well-controlled, Phase III clinical trial of this investigational therapy that is currently in progress.
- Revisions have been made to the various web pages containing information on the investigational therapy Multikine in light of FDA's Warning Letter (dated August 5, 2011), and this Important Correction of Investigational Drug Information is also being posted on the CEL-SCI website.

The FDA states the web pages contain claims such as the following that promote the investigational therapy Multikine as safe and effective for the purposes for which it is being investigated or that otherwise promote the Investigational drug: "Efficacy seen in clinical trials conducted with Multikine®"; "33% improvement in median overall survival: In Phase II studies an impressive 33% improvement in median overall survival at a median 3.5 year past surgery was seen in patients with locally advanced disease treated with Multikine® as first-line therapy (absolute survival rate 63%) over the 3.5 year median overall survival rates of the same cancer patient population determined from a review of 55 clinical trials reported in the scientific literature that were conducted between 1987 and 2007. . . . To put this in context, most cancer blockbusters have been approved on a 10% increase in overall survival, so a 33% improvement over what can be expected from the current therapy is considered extraordinary." CEL-SCI wants you to know the following:

- Multikine (Leukocyte Interleukin, Injection) is an investigational new drug, and the product's indication(s), warnings, precautions, adverse reactions, and dosage and administration have **not** been established and are unknown at this time.
- The investigational therapy Multikine has **not** been licensed or approved for sale, barter or exchange by the FDA or by any other regulatory agency.
- The safety or efficacy of the investigational therapy Multikine has **not** been established for any use.
- No definitive conclusions can be drawn from the early-phase, clinical-trials data summarized on CEL-SCI's website involving the investigational therapy Multikine (Leukocyte Interleukin, Injection).
- Further research on the investigational therapy Multikine is required, and early-phase clinical trial results must be confirmed in the well-controlled, Phase III clinical trial of this investigational therapy that is currently in progress.
- Revisions have been made to the various web pages containing information on the investigational therapy Multikine in light of FDA's Warning Letter (dated August 5, 2011), and this Important Correction of Investigational Drug Information is also being posted on the CEL-SCI website.

The FDA states that what had been posted on the "Multikine® Tumor Pictures" web pages, which were removed from the website in response to FDA's Warning Letter (dated August 5, 2011), present three cases studies using before and after images of patients treated with Multikine for head and neck cancer, and the images depict dramatic improvements in all three cases and are accompanied by claims such as the following that promote the investigational therapy Multikine as safe and effective for the purposes for which it is being investigated or that otherwise promote the Investigational drug: "After 3 months of treatment with Multikine, no evidence of tumor was observed, either visually or by

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palpation"; "During the course of 2 treatment cycles with Multikine in 42 days, the plum sized tumor virtually disappeared". CEL-SCI wants you to know the following:

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- Further research on the investigational therapy Multikine is required, and early-phase clinical trial results must be confirmed in the well-controlled, Phase III clinical trial of this investigational therapy that is currently in progress.
- Revisions have been made to the various web pages containing information on the investigational therapy Multikine in light of FDA's Warning Letter (dated August 5, 2011), and this Important Correction of Investigational Drug Information is also being posted on the CEL-SCI website.

The FDA states the web pages contain claims such as the following that promote the investigational therapy Multikine as safe and effective for the purposes for which it is being investigated or that otherwise promote the Investigational drug: "First Line treatment Advantages: Multikine® (following approval) would be part of **standard of care** for every head and neck cancer patient's initial treatment. This means every patient diagnosed with the disease should receive Multikine®". CEL-SCI wants you to know the following:

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- The investigational therapy Multikine has **not** been licensed or approved for sale, barter or exchange by the FDA or by any other regulatory agency.
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- No definitive conclusions can be drawn from the early-phase, clinical-trials data summarized on CEL-SCI's website involving the investigational therapy Multikine (Leukocyte Interleukin, Injection).
- Further research on the investigational therapy Multikine is required, and early-phase clinical trial results must be confirmed in the well-controlled, Phase III clinical trial of this investigational therapy that is currently in progress.
- As indicated on CEL-SCI's update website, revisions have been made to the various web pages containing information on the investigational therapy Multikine in light of FDA's Warning Letter (August 5, 2011), and this Important Correction of Investigational Drug Information is also being posted on the CEL-SCI website.

The FDA states the web pages contain claims such as the following that promote the investigational therapy Multikine as safe and effective for the purposes for which it is being investigated or that otherwise promote the Investigational drug: "Furthermore, because Multikine® is made from healthy donors' immune system cells and is readily available as a ready-to-use anti-cancer immunotherapy, it can be administered to any patient immediately and without delay." CEL-SCI wants you to know the following:

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If you have any questions about the corrective information in this letter, please contact CEL-SCI's Clinical Development Department, John Cipriano at: 703-506-9460 or Eyal Talor, Ph.D., at 410-358-6866: Please refer to the full Phase III clinical trial information for the investigational therapy Multikine (Leukocyte Interleukin, Injection) which you can link to from this letter at: <http://www.clinicaltrials.gov/ct2/show/NCT01265849?term=multikine&rank=1>.

Sincerely,

Geert Kersten
Chief Executive Officer

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