

## PHARMALUCENCE ANNOUNCES FDA APPROVAL AND ORPHAN DRUG DESIGNATION FOR USE OF SULFUR COLLOID INJECTION TO LOCATE LYMPH NODES IN MALIGNANT MELANOMA PATIENTS

BILLERICA MA – Pharmalucence, Inc. ([www.pharmalucence.com](http://www.pharmalucence.com)) has received FDA approval expanding the indication for use of its Sulfur Colloid Injection (SCI) to include localization of lymph nodes in malignant melanoma patients.

Sulfur Colloid Injection (SCI) is a diagnostic imaging agent manufactured by Pharmalucence which labels lymph nodes with a radioactive signal. Then, using a hand held radioactivity sensing probe, the SCI-labeled lymph nodes are located, surgically removed and analyzed to determine if tumor cells are present.

The American Cancer Society reports that over 75,000 cases of melanoma are diagnosed annually in the United States. Melanoma patient care typically includes assessment of whether or not tumor has spread to the lymph nodes. Clinical studies from reference literature indicate that patients who show no evidence of lymph node involvement may be candidates for less extensive surgical treatment than are patients whose lymph nodes are positive for the presence of tumor.

To gain FDA approval for its new drug indication, Pharmalucence conducted a systematic literature review of published scientific articles that describe the efficacy and safety of SCI used in lymph node localization. For the malignant melanoma indication, Pharmalucence examined 8 publications that reported use of both SCI and blue dye in melanoma patients having lymph node localization studies. From this set of 8 publications, 4 studies were used for a meta-analysis.

In all, 249 patients were evaluated. SCI was present in at least one lymph node in 96.4% of procedures versus blue dye being present in at least one lymph node in 83.6% of procedures, demonstrating the effectiveness of SCI in localizing lymph nodes in malignant melanoma patients. In addition, excellent safety related to the subcutaneous injection route was also demonstrated.

***David Krag, M.D., S. D. Ireland Professor of Surgery, University of Vermont and Study Chair of the National Cancer Institute's NSABP B-32 trial, stated the following;***

*“Lymph node localization studies utilizing Sulfur Colloid in breast cancer and now melanoma patients have been well documented as safe and effective in numerous publications over the past 20 years. It is gratifying to see that FDA has recognized the clinical importance of using Sulfur Colloid in managing patients with these types of cancers.”*

Glenn Alto, Pharmalucence President and CEO stated, “We are very pleased to receive this new FDA approval for the use of SCI in malignant melanoma patients. It comes just a year after we received FDA approval for the use of SCI in breast cancer patients. Lymph node localization with SCI has emerged as the standard of care to help surgeons locate and remove lymph nodes

for testing. Surgeons have come to rely on SCI's demonstrated efficacy and well established track record of patient safety."

The systematic literature review and meta-analysis conducted by Pharmalucence is the most extensive study of its kind demonstrating the use of a radiopharmaceutical for lymph node location in breast cancer and malignant melanoma cancer patients. Over 9,400 patient studies and their results were examined.

About Pharmalucence, Inc.

Pharmalucence is a privately-held company specializing in the production and marketing of radiopharmaceuticals. The company also provides fill and finish manufacturing services for human injectables, as well as contract formulation development and analytical methods development services.

For full prescribing information on Sulfur Colloid and for more information on Pharmalucence products and contract services, please visit [www.pharmalucence.com](http://www.pharmalucence.com).

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