

**PHARMALUCENCE ANNOUNCES FDA APPROVAL FOR USE OF SULFUR COLLOID INJECTION TO LOCATE LYMPH NODES IN BREAST CANCER PATIENTS ;  
Sulfur Colloid Injection Proved Superior to Blue Dye Method**

BEDFORD, MA – Pharmalucence, Inc. ([www.pharmalucence.com](http://www.pharmalucence.com)) has received FDA approval expanding the route of administration and use of its Sulfur Colloid Injection (SCI) to include location of lymph nodes in breast cancer patients.

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

The American Cancer Society reports that over 250,000 cases of breast cancer are diagnosed annually in the United States. Breast cancer patient care typically includes assessment of whether or not tumor has spread to the lymph nodes. Clinical studies 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 the new drug indication, Pharmalucence conducted a systematic literature review of published scientific articles that describe the efficacy and safety of SCI versus a blue dye used in lymph node localization. All cancer types were evaluated in the study. For the breast cancer indication, Pharmalucence examined 43 publications that reported use of both SCI and a blue dye in breast cancer patients having lymph node localization. From this set of 43 publications, 15 prospectively designed studies reporting results from at least 50 patients were used for meta-analysis. Procedure numbers reported in the meta-analyzed publications ranged from a low of 62 to a high of 6,197, where one procedure typically reflected one patient.

In all, 9,213 procedures were evaluated. SCI was present in at least one lymph node in 94.1% of procedures versus blue dye being present in at least one lymph node in 85.1% of procedures. Pharmalucence statistical analysis determined that SCI is superior to blue dye when used alone. In addition, SCI in conjunction with blue dye is also shown to be superior to blue dye alone.

In addition to establishing the clinical effectiveness of the indication, the Pharmalucence study consolidated information regarding SCI preparation parameters including injection volume and radioactive dose as well as describing performance stratified by injection site. Safety data related to the subcutaneous injection route were also collected. Related recommendations are included in updated drug labeling.

Glenn Alto, Pharmalucence President and CEO stated, “We are pleased to receive FDA approval for the use of SCI in locating lymph nodes in breast cancer patients. SCI has emerged as an important tool helping surgeons to locate and remove lymph nodes for testing. This has

supported a trend toward less extensive breast cancer surgery, leading to the alleviation of certain surgical side effects. As follow up, Pharmalucence will soon submit another filing we believe supports use of SCI in lymph node localization in melanoma patients. We are grateful to the many clinical investigators that validated use of SCI in breast cancer and are proud to be part of the advancement of cancer care.”

The Pharmalucence systematic literature review and meta-analysis is the most extensive study conducted to date on the use of a radiopharmaceutical in lymph node localization in cancer patients.

About Pharmalucence, Inc.

Pharmalucence is a privately-held company specializing in the production and marketing of radiopharmaceuticals and the furnishing of contract drug formulation, analytical methods development and production services. In early 2011, Pharmalucence initiated construction of a new, state-of-the-art drug production center and corporate headquarters in Billerica, MA.

For more information on Pharmalucence products and services, visit [www.pharmalucence.com](http://www.pharmalucence.com).

Media contact:

Glenn Alto

[galto@pharmalucence.com](mailto:galto@pharmalucence.com)

Phone: 781-687-1204