Lymphoseek®, also known as Technetium Tc 99m Tilmanocept, is an injectable radio-labelled tracer that has been designed for lymphatic mapping and sentinel lymph node location in breast cancer, head and neck cancer and melanoma. It has been developed by Navidea™ Biopharmaceuticals.

Lymphoseek® is injected into a primary tumour, and is designed to accumulate in any lymph nodes that drain from it. The radioactive label, technetium-99, can be detected using a hand-held gamma detector and helps to locate these lymph nodes either before or during surgery (lymphatic mapping). The first nodes to which a tumour drains can be located using this technique (sentinel node location). The spread of cancer can often be detected earliest in the lymph nodes and locating these can help to assess and stage the disease, and in planning further treatments. Currently in the NHS, the location, removal and testing of sentinel lymph nodes is carried out routinely for breast cancer and melanoma.

Lymphoseek® is made of a radio-labelled tracer molecule called tilmanocept which is approximately 7 nanometers in size and contains many units of a sugar called mannose. The mannose units bind to a specific receptor, CD-206, which is found in high concentrations on the surface of immune cells called macrophages and dendritic cells which are present in the lymph nodes. The company state on their website that the tracer accumulates within the lymph nodes within 10 minutes of injection and remains there up to 30 hours afterwards. Although no serious hypersensitivity reactions have been reported in clinical trials, Lymphoseek® may pose a risk of reactions due to its chemical similarity to dextran. The tracer is synthetic and not derived from animal or human products.
A marketing authorisation application was submitted to the EMA in December 2012 and the company anticipate that Lymphoseek® will be launched in the UK by April 2014 for use in breast cancer, head and neck cancer and melanoma. It is also in trials for use in other cancers. The tracer was approved by the FDA for use in breast cancer and melanoma in March 2013.

**POTENTIAL FOR IMPACT**

Sentinel lymph node localisation and lymphatic mapping are currently performed using vital blue dye in combination with a non-binding radioactive tracer (sulphur colloid tagged with technetium), although increasingly the tracer is being used alone.

The company suggest that the innovative features of this tracer are its ability to bind to specific receptors in order to label and locate lymph nodes and its small size, which allows faster clearance of the tracer from the injection site than currently available methods. The FDA announcement when this tracer was approved suggests that use of this tracer may increase the number of lymph nodes identified during lymphatic mapping.

If proven to be more effective than current methods of lymphatic mapping and sentinel lymph node detection, this tracer may enable a more comprehensive assessment of melanoma, breast cancer and head and neck cancer. This will depend upon the number of additional lymph nodes correctly identified using this technique as compared with current UK practice.

The impact on patient outcomes of using this tracer will depend on the accuracy of any tests conducted on the identified lymph nodes and the efficacy of any treatments offered in response to these test results.

**EVIDENCE**

**PUBLISHED PAPERS**


**COMPLETE UNPUBLISHED STUDIES**


Final results are awaiting submission for publication and published interim results are listed below:


Comparison of false negative rates (FNR) & overall accuracy (AC) of sentinel lymph node biopsy (SLNB) in phase 3 99mTc-Tilmanocept (TcTM) vs ACOSOG Z-0360 99mTc-sulfur colloid (TcSC) in head/neck squamous cell cancer (SCC). Society of Nuclear Medicine and Molecular Imaging. June 2013. Abstract No. 512. http://jnumedmtg.snmjournals.org/cgi/content/meeting_abstract/54/2_MeetingAbstracts/512

**ONGOING STUDIES**

No ongoing studies in breast cancer, head and neck cancer or melanoma were identified for this alert.

**INFORMATION FROM**

This Alert is based on information from the company and a time-limited internet search.