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New Imaging Agent Enables Better Cancer Detection and Staging

Researchers at the University of California, San Diego School of Medicine have shown that a new imaging dye is an effective agent in detecting and mapping cancers that have reached the lymph nodes. The radioactive dye, called Technetium Tc-99m tilmanocept, successfully identified cancerous lymph nodes and did a better job of marking cancers than the current standard dye. Results of the Phase III clinical trial are published online in the Annals of Surgical Oncology.

“Tilmanocept is a novel engineered radiopharmaceutical specifically designed for sentinel lymph node detection,” said David R. Vera, the drug’s inventor, who is a professor in the UCSD Department of Radiology. “The molecule, developed at UC San Diego School of Medicine, offers surgeons a new tool to accurately detect and stage melanoma and breast cancers while in the operating room.”

On 13 March 2013 tilmanocept received U.S. Food and Drug Administration (FDA) approval.

“Tilmanocept advances the molecular targeting in breast cancer. It’s the first agent that is binding to a lymph node because it is a lymph node that plays an important role in metastasis,” said Anne Wallace, MD, professor of surgery, UC San Diego School of Medicine and principal investigator of the study (pictured above). “Tilmanocept’s ability to identify more cancer containing nodes will lead to better post-operative care for patients, especially those patients who had more than one positive sentinel node.”

Doctors compared injections of tilmanocept, also called Lymphoseek, and the standard blue dye into the tumour area. Then, using a handheld radiation detector, they found the lymph nodes that had taken up the drug's radioactivity. The researchers found that more than 99 percent of sentinel lymph nodes containing blue dye also contained tilmanocept. Of these nodes, 18 percent were positive for cancer. Ninety-four percent of the malignancies were detected by the new radiopharmaceutical whereas the blue dye only detected 76 percent.

“Tilmanocept is just as accurate as current techniques, simple to use, takes less time to find lymph nodes and is cleared faster from the body. This could standardise the process of lymph node mapping and make the process easier, particularly for less experienced surgeons,” said Wallace, chief of plastic surgery at UC San Diego Health System and director of the Breast Care Unit at UC San Diego Moores Cancer Center.

Tilmanocept was originally developed at UC San Diego by Vera. Wallace advanced the agent through Phase 1 clinical trials with funding provided by the Susan G. Komen Breast Cancer Foundation and the American Cancer Society. The Phase III study was supported by Navidea Biopharmaceuticals, Inc. based in Dublin, Ohio.

Lymphoseek's safety and effectiveness were established in two clinical trials of 332 patients with melanoma or breast cancer. The Phase III clinical trial took place at 13 medical centers involving 148 patients who had both melanoma and breast cancer. The most common side effects identified in clinical trials was pain or irritation at the injection site reported by two patients.

Reference:
Comparative Evaluation of [99mTc]Tilmanocept for Sentinel Lymph Node Mapping in Breast Cancer Patients: Results of Two Phase 3 Trials. Anne M. Wallace, Linda K. Han, Stephen P. Povoski et al. Annals of Surgical Oncology. Published online March 2013. DOI 10.1245/s10434-013-2887-8

Published on : Wed, 24 Apr 2013