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New Imaging Agent Enables Better Cancer Detection, More Accurate Staging

Drug Designed and Developed at UC San Diego School of Medicine

Researchers at the University of California, San Diego School of Medicine have shown that a new imaging dye, designed and developed at UC San Diego Moores Cancer Center, 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 published online today in the *Annals of Surgical Oncology*.

Anne Wallace MD, chief of plastic surgery, UC San Diego Health System

“Tilmanocept is a novel engineered radiopharmaceutical specifically designed for sentinel lymph node detection,” said David R. Vera, PhD, 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 March 13, 2013, tilmanocept received U.S. Food and Drug Administration (FDA) approval.

After a cancer diagnosis, surgeons want to be sure that the disease has not spread to a patient’s lymph nodes, especially the sentinel nodes that may be the first place that a cancer reaches. The lymphatic system is a network of vessels and ducts that carry disease-fighting cells throughout the body, but can also act as a way for cancer cells to access the bloodstream. By surgically removing and examining the sentinel nodes that drain a tumor, doctors can better determine if a cancer has spread.

“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. “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 tumor area. Then, using a handheld radiation detector, they found the lymph nodes that had taken up the drugs 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 standardize 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.

Study collaborators include: Linda Han, MD, Indiana University Simon Breast Center; Stephen P. Povoski, MD, Wexner Medical Center; Kenneth Deck, MD, South Orange County Medical; Schlomo Schneebaum, MD, Sourasky Medical Center; Nathan Hall, MD, PhD, Wexner Medical Center; Carl K. Hoh, MD, and Karl Limmer, MD, UC San Diego; Helen Krontiras, MD, University of Alabama; Thomas Frazier, MD, Bryn Mawr Hospital; Charles Cox, MD, University of South

Florida; Eli Avisar, Sylvester Comprehensive Cancer Center at University of Miami; Mark Faries, MD, John Wayne Cancer Institute; and Dennis King, PhD, and Lori Christman, PhD, STATKING Clinical Services.

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