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Fox Chase Cancer Center

New tool for pre-surgical detection of kidney cancers may help patients avoid unnecessary surgeries

SAN FRANCISCO, CA. (June 1, 2010)—Kidney cancer is a radiographic diagnosis which means treatment decisions are often made based on the findings of a solid mass on CT or MRI. Unfortunately these tests cannot distinguish the different types of kidney cancers which have variable risks. As more Americans continue to be scanned as part of their evaluation for various ailments and symptoms, the number of kidney tumors found serendipitously has increased such that now up to 70 percent of kidney cancers are discovered incidentally.

Kidney cancer is a surgical disease which means that many patients with incidentally detected masses will be offered surgery. Often, however, the tumors are shown post-surgically to have been benign or indolent, and many would not have required immediate surgical intervention. In the absence of a definitive pre-surgical diagnosis, surgeons generally must opt for surgery.

The results of a prospective multicenter phase III study being presented at the 2010 annual meeting of the American Urological Association demonstrate that the use of an antibody called 124I-girentuximab with PET/CT imaging can help to distinguish clear-cell renal cell carcinoma (RCC), the predominant variant of kidney cancer, from other types of benign or malignant kidney masses. If approved by the FDA, this will be one of the first diagnostic scans which can distinguish not only identify a tumor's origin and location, but also provide data on the type (histology) of that tumor. Armed with this information, physicians and patients will be able to make more informed treatment choices.

Robert G. Uzzo, M.D., F.A.C.S., chairman of Fox Chase Cancer Center's department of surgery, will present the results of this Phase III study entitled Multicenter Phase III REDECT trial with 124 I-girentuximab-PET/CT for the pre-surgical Detection of Clear Cell Renal Carcinoma (cc(RCC)" at the "Late Breaking" session of the AUA in San Francisco on Tuesday, June 1.

124I-girentuximab is a monoclonal antibody that binds to a unique protein expressed highly on the most common and lethal type of kidney cancer (clear cell renal cell carcinoma). When injected intravenously as part of a PET/CT scan, it gives histological information providing useful non-invasive clinical insights to a renal masses biologic properties. The PET imaging with 124I-girentuximab (REDECTANE) is a cutting-edge type of molecular imaging tool. Researchers at Fox Chase Cancer Center have led accrual nationally to this important Phase III trial.

"The ability to distinguish pre-operatively between aggressive and less aggressive kidney masses is a critical clinical challenge," says Uzzo, who is also co-director of Fox Chase's Keystone Program in Personalized Kidney Cancer Therapy. "Such information makes a direct impact on patient management, giving physicians the ability to match tumor biology to appropriate treatment strategies."

The 124I-girentuximab PET/CT is performed similarly to any PET or CT - the antibody is injected intravenously and the patient is then imaged. In the case of kidney cancer, REDECTANE provides oncologists with superior imaging, allowing them to distinguish the aggressive RCC phenotype from other renal cell subtypes and benign tumor much better than current tests. Furthermore, the technology may aid in more precise diagnosis of tumor stage, detecting early, otherwise undetectable, metastatic deposits.

Researchers identified and enrolled 226 patients in the multi-center study and found that the antibody 124I-girentuximab (cG250) binds to an aggressive phenotype, which is expressed in more than 95 percent of clear cell RCC—the most common form of kidney cancer, accounting for up to 90 percent of all kidney cancer deaths.

In this study, Dr. Uzzo and his team used PET/CT scans with 124I-girentuximab to reliably distinguish the aggressive RCC phenotype from less aggressive subtypes prior to surgery. The sensitivity and specificity of the test were 86% and 87% respectively with a positive predictive value of 95% for clear cell Renal cancer. Such strategies potentially can help reduce the number of unnecessary surgeries and guide individualized patient management.

This multi-center Phase III REDECT trial was conducted at 14 centers across the US and sponsored by Wilex AG, Munich, Germany.

The full final data set, including diagnostic endpoints and sample patient images, will be presented at the AUA meeting.

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The Keystone Program in Personalized Kidney Cancer Therapy, co-directed by Robert G. Uzzo, M.D., F.A.C.S., Gary Hudes, M.D., and Joseph R. Testa, Ph.D., investigates the biological mechanisms that

lead to kidney cancer metastasis and aims to uncover the molecular signals that predict how an individual patient's kidney tumor will respond to therapies.

Fox Chase Cancer Center is one of the leading cancer research and treatment centers in the United States. Founded in 1904 in Philadelphia as one of the nation's first cancer hospitals, Fox Chase was also among the first institutions to be designated a National Cancer Institute Comprehensive Cancer Center in 1974. Fox Chase researchers have won the highest awards in their fields, including two Nobel Prizes. Fox Chase physicians are also routinely recognized in national rankings, and the Center's nursing program has received the Magnet status for excellence three consecutive times. Today, Fox Chase conducts a broad array of nationally competitive basic, translational, and clinical research, with special programs in cancer prevention, detection, survivorship, and community outreach. For more information, visit Fox Chase's Web site at www.fccc.org or call 1-888-FOX CHASE or (1-888-369-2427).

Abstract: "Multicenter Phase III REDECT trial with 124 I-girentuximab-PET/CT for the pre-surgical Detection of Clear Cell Renal Carcinoma (cc(RCC)"

Presentation Time: Tuesday, June 1, 2010 at 3:40 p.m. CST
