ECOG-ACRIN cancer research group

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Press Release

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# Sunitinib, sorafenib of no benefit in ECOG-ACRIN renal cell trial

**Philadelphia, Pa., February 23, 2015, 5:00 PM** – Research results highlighted today at the press conference of a major medical meeting report no benefit from the use of either Sutent® (sunitinib) or Nexavar® (sorafenib) among patients with locally advanced renal cell carcinoma at high risk of recurrence, the ECOG-ACRIN Cancer Research Group (ECOG-ACRIN) announced. Both of these oral drugs are widely used in helping patients with metastatic renal cell carcinoma, commonly called kidney cancer, live longer with their disease.

The research finding is based upon a phase three trial designed and led by ECOG-ACRIN with funding provided by the National Cancer Institute. This is the first and largest trial reporting on the effectiveness of giving sunitinib or sorafenib, both small molecule vascular endothelial growth factor (VEGF) tyrosine kinase inhibitors, to patients after surgery to remove the tumor.

"Unfortunately we found that the use of sunitinib or sorafenib in this setting did not reduce the incidence of recurrence as compared to standard care," said lead researcher Naomi B. Haas, MD, a medical oncologist at the University of Pennsylvania's Abramson Cancer Center in Philadelphia and a member of ECOG-ACRIN.

Kidney cancer is the sixth most common cancer in the United States, where 63,900 people were diagnosed with the disease in 2014. The current standard of care for patients with locally advanced (non-metastatic) kidney cancer is complete surgical removal of the primary kidney tumor followed by close observation with imaging scans at regular intervals. However, patients are not uniformly cured by surgery alone. Researchers' pursuit of tolerable and effective drugs led to this trial because approximately one-third of patients develop metastatic kidney cancer and ultimately die of the disease.

The primary endpoint for this trial was disease-free survival at five years following treatment. There were no significant differences in disease-free survival or overall survival between either the patients taking a drug or the ones receiving the placebo, which was equal to standard care (observation). Median disease-free survival was 5.6 years for sunitinib, 5.6 years for sorafenib, and 5.7 years for placebo. The full results from the trial will be presented later this week to attendees of the 2015 Genitourinary Cancers Symposium in Orlando.

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In this trial, 1943 patients in the U.S. and Canada who were considered at high risk of recurrence were randomized equally to receive sunitinib or sorafenib or placebo for one year. The three groups of patients were balanced using known or suspected risk factors for recurrence, including the stage and grade of kidney cancer, overall patient health, histology and type of surgery.

“The results of other ongoing adjuvant trials investigating different lengths of therapy and using different VEGF tyrosine kinase inhibitors are not yet available and could have different results than our study,” said Dr. Haas.

Patients in this trial contributed what has become one of the largest repositories of tumor tissue, blood, and urine specimens, with associated treatment and outcomes data, in renal cell carcinoma.

“Analyses of these samples may tell us who might still benefit or definitely not benefit from these therapies in the treatment of their kidney cancer following surgery, and possibly in advanced disease,” said ECOG-ACRIN Genitourinary Cancer Committee chair Michael A. Carducci, MD, FACP, a medical oncologist at The Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins in Baltimore.

“Furthermore we will learn from these specimens about resistance to therapies and also molecular clues as to why disease recurs—an invaluable resource essential to furthering the mission to cure kidney cancer,” said Dr. Carducci. “Conceivably, if the results of this trial hold up in other ongoing trials, patients in the future could be spared unnecessary toxicities.”

**About the Trial**

The trial, identified as E2805, is known by its acronym ASSURE, for **A**djuvant **S**orafenib or **S**unitinib for **U**nfavorable **Re**nal Carcinoma. The trial is federally registered at https://clinicaltrials.gov/ct2/show/NCT00326898.

**About the ECOG-ACRIN Cancer Research Group**

The ECOG-ACRIN Cancer Research Group is a membership-based scientific organization that designs and conducts cancer research involving adults who have or are at risk of developing cancer. ECOG-ACRIN comprises nearly 1100 member institutions in the United States and around the world. Approximately 12,000 physicians, translational scientists and associated research professionals from the member institutions are involved in Group research, which is organized into three scientific programs: Cancer Control and Outcomes, Therapeutic Studies and Biomarker Sciences. ECOG-ACRIN is supported primarily through National Cancer Institute research grant funding, but also receives funding from private sector organizations through philanthropy and collaborations. It is headquartered in Philadelphia, Pa. For more information, visit http://ecog-acrin.org or call 215.789.3631**.**

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