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THE
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Cancer research news for clinicians

Gastrointestinal Cancers Symposium:

Avastin Improves PFS For Metastatic Colorectal Cancer In Phase III Study

The first study to evaluate the addition of bevacizumab (Avastin) to oxaliplatin-based chemotherapy as a first-line treatment in patients with advanced metastatic colorectal cancer shows that bevacizumab improves progression-free survival, according to research presented at the Gastrointestinal Cancers Symposium last month.

The study was one of the largest ever conducted in metastatic colorectal cancer.

The phase III trial involved 1,401 patients receiving chemotherapy

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Head & Neck Cancer:

Erbitux Plus Radiation, Chemo, Appears To Provide CRs In A Small Phase II Study

Preliminary findings show adding the chemotherapy drug cetuximab (Erbitux) to radiation therapy and chemotherapy may help some patients with head and neck cancer live longer, according to a study presented last month at the plenary session of the Multidisciplinary Head and Neck Cancer Symposium, co-sponsored by the American Society for Therapeutic Radiology and Oncology, the American Society for Clinical Oncology and the American Head and Neck Society.

Researchers are recommending a larger trial to prove definitively if cetuximab combined with radiation helps improve survival for these patients.

Researchers at the University of Maryland Medical Center in Baltimore designed the study to evaluate the efficacy of the addition of cetuximab with concurrent chemotherapy and radiation in patients with locally advanced squamous cell carcinoma of the head and neck in order to improve local regional control and overall survival. Currently 21 patients are enrolled in this study. They received an initial dose of cetuximab followed by weekly doses of the drug. Patients also received daily radiation therapy treatments and weekly doses of chemotherapy.

Of the 21 patients, 18 have completed all therapy and were available for analysis of toxicity and response. No grade 4 toxicities were reported, however 89 percent reported mouth pain and 11 percent reported skin problems. Other toxicities included difficulty swallowing, fever and a drop in white blood cell count. Seventy-two percent achieved a complete response two months after

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Avastin + FOLFOX4 Increased Progression-Free Survival

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with either capecitabine (Xeloda) plus oxaliplatin (Eloxatin) (a regimen known as XELOX) or 5-fluorouracil and leucovorin plus oxaliplatin (a regimen known as FOLFOX4), who were randomized to receive either bevacizumab or a placebo in addition to the chemotherapy. Progression-free survival was 8.0 months in the chemotherapy plus placebo group, compared with 9.4 months in patients who received chemotherapy plus bevacizumab.

Overall side effects for the groups were similar. These effects were due primarily to oxaliplatin-based therapy and included neuropathy (pain, numbness, and tingling), lowered resistance to infection, fatigue, and diarrhea. The only side effect that was clearly increased by bevacizumab was elevated blood pressure, which was easily controlled with medication.

"Although previous studies have not examined its use in the first-line setting, oxaliplatin-based chemotherapy plus bevacizumab is nonetheless currently a widely used first-line treatment regimen in standard practice in the United States for advanced colorectal cancer," said Leonard Saltz, professor of medicine and member of the Gastrointestinal Oncology Service at Memorial Sloan-Kettering Cancer Center, and the study's lead author. "This is the first study to examine this regimen's use as first-line treatment. These data validate its continued use in standard practice."

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Saltz is the U.S. principal investigator for this trial; the European principal investigator is James Cassidy, Cancer Research UK Professor of Oncology at Glasgow University in Scotland.

The symposium was co-sponsored by the American Gastroenterological Association, the American Society of Clinical Oncology, the American Society for Therapeutic Radiology and Oncology, and the Society of Surgical Oncology.

Other highlights from the symposium follow:

Addition of Oxaliplatin to Preoperative Therapy

A multi-institutional Italian study (called Studio Terapia Adiuvante Retto, or STAR) has shown that oxaliplatin (Eloxatin) can be added to a standard preoperative fluorouracil-based chemoradiotherapy regimen for rectal cancer, with increased frequency and severity of acute toxicity but without major unexpected adverse events, and without affecting the dosage of radiotherapy or the ability to perform surgery.

Chemotherapy and radiation are sometimes offered before surgery for colon and rectal cancers to shrink tumors, making them easier to remove. The addition of oxaliplatin has been shown to increase the efficacy of chemotherapy in both early-stage and metastatic colon cancer, either following or as a substitute for surgery, but it was not known whether it was safe and effective to add oxaliplatin to chemotherapy and radiation regimens given prior to surgery.

This study reports preliminary safety data from the first 250 patients, and will ultimately report on the efficacy of the approach. Approximately half of the patients received standard 5FU chemotherapy and radiation before surgery, while the other half received the chemoradiotherapy regimen combined with oxaliplatin therapy. The large majority of patients in both groups had surgery following preoperative treatments. The study was an open-label, multicenter, randomized phase III trial with the primary purpose of comparing the activity (pathological response rate) and efficacy (overall and disease-free survival) of preoperative chemoradiotherapy with and without oxaliplatin.

Although oxaliplatin regularly resulted in more severe acute toxicity, there were no major unexpected adverse events. The most common side effects were diarrhea (59% in the oxaliplatin group versus 47% in the control group), neurosensory problems (40% vs. 0%), nausea (36% vs. 19%), and vomiting (24% vs. 6%). With the exception of a slight increase in severe (grade 3 or 4) diarrhea, none of the side effects were severe enough to result in major changes in the treatment program.

"These data show that adding oxaliplatin to preoperative chemotherapy and radiation for rectal cancer is safe and could, if proven effective, provide an important new tool for treating this disease," said Carlo Aschele, attending physician and lead clinician in colorectal/gastrointestinal cancer in the Department of Medical Oncology and Cancer Prevention, E.O. Ospedali Galliera in Genoa, Italy, and the study's lead author. "The doses of oxaliplatin used in this study are in the same range as those used in the treatment of metastatic cancer, and thus are likely to be active in this population of patients as well. Our group is continuing to enroll patients in the study to determine whether the addition of oxaliplatin improves both tumor response and overall and disease-free survival in these patients."

Need for Improvement in Risk Communication

A survey of patients who had previously received chemotherapy following surgery for colorectal cancer (called "adjuvant" chemotherapy) found that although patients are generally satisfied with their care, better communication between oncologists and patients is needed regarding the benefits and potential side effects of therapy. The study also found that clinical investigators and practicing medical oncologists may underestimate patients' willingness to undergo therapy for even a modest treatment benefit.

The study surveyed 150 patients treated with adjuvant chemotherapy for colorectal cancer within the past five years. Twenty-three clinical investigators and 150 practicing medical oncologists also participated in a corresponding survey. Patients listened to an audio educational program about adjuvant chemotherapy; based on the risks and benefits discussed in the program, patients were asked whether they would be willing to undergo the same adjuvant chemotherapy they received previously for varying reductions in risk of cancer recurrence. The patients were also asked about their experiences with treatment and their clinical care.

Of these patients, 36% said they would choose to be treated again with the same therapy for a 1% absolute reduction in the risk of cancer recurrence and 57% would be treated again for a 3% reduction. By contrast, clinical investigators and medical oncologists predicted that far fewer patients would wish to be treated for those same benefits.

The patient survey also found that the side effects of treatment differed from what patients expected, suggesting that communication from physicians regarding the potential toxicities of therapy were not as clear or accurate as it could have been, or that patients are receiving inaccurate information from other sources. Additionally, the survey found that 60% of patients were not offered the opportunity to participate in a clinical trial, but that 81% of those patients wished they had received such information.

"This survey demonstrates that patients may be far more willing to receive cytotoxic therapy for what others might view as modest potential treatment benefits," said Neil Love, a medical oncologist who is president of Research to Practice, an oncology education company in Miami, and the study's lead author. "The findings underscore the importance of better communication between physicians and patients to ensure that physicians clearly understand patient expectations regarding treatment, and so that patients receive clear and accurate information about the risks and benefits of therapy."

Liver Cancer:
Liver Transplant Associated With 67% 5-Year Survival

A study presented at the Gastrointestinal Cancers Symposium demonstrated that liver cancer survival rates are associated with the type of local treatment patients receive for hepatocellular carcinoma, the most common form of primary liver cancer.

Local treatment for liver cancer is considered the best option for most patients. Types of local treatment include surgery to remove the tumor and part of the liver (resection); complete removal of the liver followed by transplantation; and several types of tumor removal (ablation) that use an electric current, freezing, or lasers.

In this study, researchers analyzed the records of 46,065 patients treated between 1970 and 2003 who were included in the National Cancer Institute's Surveillance Epidemiology and End Results database. A multivariate analysis examined many prognostic factors, including tumor size and grade, extent of disease spread, patient age and gender, and the type of local treatment received. Researchers noted that they were not able to determine whether patients had liver disease (such as cirrhosis or hepatitis B or C), how well patients' livers functioned, and their overall health, factors that can strongly influence both the type of treatment patients are offered and overall survival rates.

The investigators found that after adjusting for other known factors, patient survival rates were linked to the type of local treatment received. The

five-year overall survival rate was 67% for patients who underwent liver transplants, 38% for patients who underwent surgery, 19% for patients who underwent ablation, and 3% for patients who received no treatment. The researchers noted that the superior outcomes seen after transplantation and surgery are due in part to the fact that patients receiving these treatments generally have less advanced disease, higher-functioning livers, and few additional health complications.

"These data suggest that transplantation and resection should still be preferentially considered for all hepatocellular carcinoma patients," said Roderich Schwarz, director of the Pancreatic Cancer Program and associate professor of surgery at the Cancer Institute of New Jersey, and the study's lead author. "However, because many patients cannot undergo these procedures, it is important to continue to explore less invasive options in order to find the optimal treatment for these patients."

Pancreatic Cancer:
Therapeutic Vaccine May Fight Pancreatic Cancer

A phase II trial presented at the Gastrointestinal Cancers Symposium shows that a therapeutic vaccine may be effective at fighting pancreatic cancer when given in combination with chemoradiotherapy following surgery.

Therapeutic cancer vaccines do not prevent cancer, but boost the body's own immune system to help it recognize and attack cancer cells.

The study involved 60 patients, all of whom were treated at Johns Hopkins University School of Medicine and had operable disease that had spread beyond the pancreas to nearby tissue and organs, blood vessels, or lymph nodes. All patients received their first vaccine 8 to 10 weeks after surgery, followed by chemotherapy combined with radiation therapy. Patients who were disease-free one month after chemoradiotherapy received three additional vaccine doses one month apart, followed by a fifth booster six months later. For patients in the study, the one-year survival rate was 88%, and the two-year survival rate was 76%. After a median follow-up of three years, the median overall survival of patients in the current study was 26 months. The researchers compared survival rates to past studies of patients treated with surgery alone, which showed average one-year survival of 63% and two-year survival of 42%.

"We are now comparing the patients in this study to a separate database of patients who received adjuvant chemoradiation therapy alone after surgery," said Daniel Laheru, assistant professor at Johns Hopkins and the study's lead author. "Our initial review suggests that the vaccine could provide additional benefit over chemoradiotherapy, but prospective randomized trials are needed to confirm this observation."

The investigators are also evaluating whether the vaccine is most effective in combination with chemotherapy alone or with chemotherapy and radiation together.

The vaccine was made using cells derived from pancreatic cancer cells that were irradiated and engineered to secrete the molecule GM-CSF. GM-CSF attracts immune cells to the vaccine site, where the immune cells encounter pancreas cancer antigens. They then patrol the rest of the patient's body to destroy pancreas tumor cells with the same antigen profile. Vaccine side effects were limited to local reactions at the injection site—including itching, redness, and swelling—and typically went away within a week to 10 days.

Avastin Doesn't Improve Survival

The preliminary results of a multi-institutional phase III trial for advanced pancreatic cancer showed that addition of bevacizumab (Avastin), a vascular endothelial growth factor (VEGF) inhibitor, to the standard treatment gemcitabine (Gemzar) did not improve survival when compared with gemcitabine alone.

"These results were quite disappointing. Our prior phase II study suggested that bevacizumab in combination with gemcitabine is an active combination in pancreatic cancer patients," said Hedy Lee Kindler, associate professor of medicine and director of the Gastrointestinal Oncology Program at the University of Chicago, and the study's lead author. "Unfortunately, given the number of negative phase III trials that have followed promising phase II trials in this disease, this result is not altogether surprising."

This randomized, double-blind placebo-controlled trial enrolled 602 patients with metastatic or locally advanced pancreatic cancer, with 302 patients receiving gemcitabine and bevacizumab, and 300 patients receiving gemcitabine and a placebo. The two groups were balanced in terms of gender, age, stage of disease, and performance status.

Median overall survival was 5.7 months for the bevacizumab group versus 6.0 months for the placebo group, a difference that was not statistically significant. Both groups experienced the same side effects, including

lowered blood counts, blood clots, and stroke. Patients who received bevacizumab had higher rates of high blood pressure and slightly higher rates of bowel perforation and gastrointestinal bleeding.

"This trial definitively shows that bevacizumab does not improve survival in patients with advanced pancreatic cancer," Kindler said. "The many laboratory correlative studies that were a part of this study may help us determine if there is a subset of patients who might still benefit from bevacizumab, and further insights may be obtained in ongoing studies in advanced disease in which bevacizumab is being combined with EGFR inhibitors, and in the adjuvant setting where it is being combined with radiation."

The current standard of care for advanced pancreatic cancer is gemcitabine or gemcitabine with erlotinib (Tarceva), but these drugs have a very modest impact on survival. Given the difficulty of successfully treating pancreatic cancer, other agents are being actively investigated. The trial was conducted by Cancer and Leukemia Group B, a national clinical trials cooperative group.

Stomach Cancer:
S-1 After Surgery Improves Survival, Japanese Trial Finds

A phase III Japanese trial has found that administration of an experimental chemotherapy agent called S-1 following surgery in patients with stomach cancer improves overall survival when compared with surgery alone.

"This is the first phase III study to compare S-1 chemotherapy following surgery to surgery alone," said Mitsuro Sasako, professor of surgery and deputy director of the National Cancer Center Hospital in Tokyo, Japan and the study's lead author who presented the results at the Gastroinestinal Cancers Symposium. "The findings are significant because they showed improved survival with a single chemotherapy agent—one that is cheaper and has lower toxicity than adjuvant chemotherapy regimens commonly used in North America and Europe."

Standard treatment for gastric cancer, or cancer of the stomach, is surgery to remove the tumor, part or all of the stomach, and the affected lymph nodes, sometimes followed by chemotherapy, radiation, or a combination of the two. Although chemotherapy following surgery has shown benefit in some patients, it is unclear which chemotherapy drugs are the most effective.

In the current study, 1,059 patients were randomized to receive S-1 chemotherapy following surgery (529 patients) or surgery alone (530 patients), the current standard treatment in Japan. All patients had stage II or III disease, meaning that the tumors had spread locally, but had not spread to other parts of the body. At three years, the overall survival for patients who received S-1 was 80.5%, compared with 70.1% of patients who received surgery alone. Side effects were rare and included anorexia (6.0% in the S-1 group had severe symptoms, versus 2.1% in the surgery group) and some blood-related toxicities.

S-1 belongs to a class of drugs called oral fluoropyrimidines. It is also being evaluated in clinical trials as a treatment for other gastrointestinal cancers including colorectal and pancreatic tumors.

New Findings Being Put into Practice

A new study shows that the proportion of patients with stomach cancer who receive radiation therapy after surgery more than doubled after results from the Intergroup 0116 trial were presented at the 2000 American Society of Clinical Oncology annual meeting.

The Intergroup trial showed that patients receiving radiation treatment following surgery ("adjuvant" therapy) had significantly better overall survival (36 months versus 27 months) and disease-free survival (30 months versus 19 months) compared with those treated with surgery alone. The findings were important for patients, since five-year survival rate across all stages of stomach cancer is low, at approximately 23%.

The current study examined records from 9,528 patients who underwent surgery for stomach cancer between 1996 and 2003, divided into two groups: those treated before and after the presentation of the Intergroup study results at the 2000 ASCO Annual Meeting. Patients were identified using the Surveillance Epidemiology and End Results cancer registry, a National Cancer Institute-sponsored population-based database that provides detailed information on cancer statistics.

The study found that prior to the presentation of the 0116 results, only 15% of gastric cancer patients received adjuvant radiation therapy, compared with 30.4% of patients in the three years following presentation of the study. Researchers reviewed several demographic categories (such as age, gender, race, and marital status), finding increases of at least 10% in the rate of adjuvant therapy in each of these groups in the three years following the presentation of the 0116 data. However, younger patients, married patients, patients with higher tumor stage and higher grade, and patients

from whom more lymph nodes were assessed were significantly more likely to receive radiation therapy after surgery. Moreover, there were important variations in the use of adjuvant radiation therapy between different regions of the U.S.

"The increasing use of radiation treatment following surgery for gastric cancer is highly significant. However, the percentage of patients getting such treatment is still low, and further efforts are needed to ensure that the results of the Intergroup 0116 trial are put into practice for the appropriate patients," said Ulrich Guller, a surgical oncology fellow at the University of Toronto and the study's lead author.

Head & Neck Cancer:

Combination Therapy Helps Patients Avoid Surgery

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completion of therapy. Ultimately, 95 percent were disease free after all therapy.

"Given the advanced stages of disease that patients have on this study, these results point to the potential of increasing the therapeutic gain for patients. We now need a phase III study to determine if adding this drug is better than the current standard of care," said Mohan Suntharalingam, lead author of the study and a radiation oncologist at the University of Maryland. "I encourage people with disease and their family members to ask their doctors about participating in this clinical trial."

Combination Therapy Helps Avoid Surgery

Giving patients with head and neck cancer a combination of chemotherapy and radiation therapy controls the cancer and allows many patients to avoid additional surgery to the neck, according to a study presented at the plenary session.

"Our goal is to cure the cancer as effectively as we can while using as few treatments as possible," said Ramesh Rengan, lead author of the study and an assistant professor at University of Pennsylvania in Philadelphia. "This study is so exciting because it demonstrates that giving patients with head and neck cancer a non-invasive regimen of cisplatin-based chemotherapy and radiation therapy effectively treats many advanced head and neck cancers, meaning some patients can safely avoid an invasive surgery."

A standard of care for patients with advanced head and neck cancer is chemotherapy and radiation followed by surgery to the neck. This study, performed at Memorial Sloan-Kettering Cancer Center, instead focused on treating the patients with chemotherapy and radiation and then measuring the patients' response to the therapy to see if they still needed the follow-up neck surgery.

Eighty percent of the patients with advanced head and neck cancer who participated in this study had a complete response to chemoradiation alone with elimination of any detectable disease in the neck. Of these patients who achieved eradication of neck disease, 85 percent were able to maintain long-term remission without the need for additional invasive neck surgery.

Oral Cancer:

Advanced Screening Provides More Accurate Diagnosis

Patients with early stage oral cancer may benefit from a more advanced screening process allowing for a more accurate diagnosis, according to a study presented at the plenary session of the Multidisciplinary Head and Neck Cancer Symposium last month.

"By combining conventional techniques with more modern techniques, we were able to better diagnose and determine the best options for patients with oral cancer," said J.B. Epstein, lead author of the study and professor at the University of Illinois at Chicago. "This approach to diagnosing oral cancer may lead to easier identification of serious pathology, significantly lessening the need for unnecessary biopsies without additional risk of false negatives."

Patients with early stage oral cancer are typically examined by their doctor for suspicious areas in the mouth and throat area. Doctors in this study wanted to test the value of two diagnostic aids in evaluating lesions in the oral cavity. Chemiluminescent light, or brand name Vizilite and toluidine blue, a pharmaceutical grade dye, were used in addition to the conventional, visual and manual observations of the patient.

Patients were given routine visual examinations under incandescent light for suspicious lesions. The lesions that were deemed suspicious were then assessed with Vizilite, followed by the toluidine blue dye and then biopsied. Doctors then compared the findings from the conventional exam to the advanced, illumination and stain exam.

This study found that of the 84 patients studied, Vizilite improved either the brightness or sharpness of the identified lesions by 61 percent. Only biopsing lesions which retained the toluidine blue stain reduced the false positive rate by nearly 59 percent while maintaining zero false negatives.

Leukemia:

Arsenic Compound Improves Survival Of Adults With APL

Adult patients with previously untreated acute promyelocytic leukemia who had standard chemotherapy to induce remission of their disease, and then received the chemotherapy drug arsenic trioxide to maintain remission, had a significantly better event-free survival and better overall survival than those who received only standard chemotherapy, according to results of a phase III trial.

This type of leukemia is often accompanied by life-threatening bleeding at diagnosis that typically worsens, even as initial treatment is administered. Treatment has improved dramatically in recent years with the addition of all-trans retinoic acid (ATRA, or tretinoin) to chemotherapy.

More recently, arsenic trioxide (Trisenox) was shown to be effective for producing a second remission in patients who had a relapse or recurrence of their APL after initial treatment. Both ATRA and arsenic trioxide are approved by FDA for the treatment of APL.

Standard chemotherapy regimens produce complete remission rates of approximately 70 percent and show a five-year survival without the recurrence of disease in 35 to 45 percent of patients.

The study, sponsored by NCI and let by the Cancer and Leukemia Group B, tested the effectiveness and side effects from adding two 25-day courses of intravenous arsenic trioxide to the combination of ATRA and chemotherapy.

Patients with newly diagnosed APL were randomly assigned to receive either the standard remission treatment with ATRA twice daily, daunorubicin for four days, and cytarabine for seven days, both of which are standard chemotherapy drugs for this disease, followed by a standard post-remission regimen with two more courses of ATRA plus daunorubicin, or the experimental treatment where patients received the same standard treatment with the addition of two courses of arsenic trioxide given immediately after the patient entered a complete or partial remission and before the standard post-remission regimen.

The arsenic trioxide course was a two hour intravenous infusion, Monday through Friday, on an outpatient schedule for five weeks. Patients who remained free of visible leukemia after completion of the remission therapy then received an additional year of treatment with oral chemotherapy drugs to prevent the leukemia from relapsing.

Between June 1999 and March 2005, 582 patients enrolled on this study. Patients participated through one of five NCI-sponsored cooperative groups. By study design, patients less than 15 years of age (11 percent of the entire group) were not assigned to the treatment that contained arsenic trioxide.

The percentage of adult patients who remained alive and in remission three years after diagnosis was 77 percent on the treatment arm that included arsenic trioxide compared to 59 percent on the standard treatment arm. This difference was highly statistically significant. The greater effectiveness of the experimental combination also resulted in better overall survival after three years of 86 percent for the patients who received the arsenic trioxide, compared to 77 percent for patients on the standard treatment arm.

Patients were followed for a median period of 29 months. After reviewing the study results, a data safety monitoring board notified the investigators and the NCI of the positive results and the findings are being released so that all APL patients will have a chance to benefit from this therapy.

"The willingness of patients with leukemia and their physicians to participate in this important clinical trial has markedly improved the outcome for these and future patients with APL," said Bayard Powell, of Wake Forest University and principal investigator of the study.

The side-effects from treatment were reported at the annual meeting of the American Society of Hematology last December. There was no difference in hematologic toxicities between the group who received arsenic and those who did not, but there was a slightly higher incidence of headache and infection in the group who received arsenic trioxide. A complete scientific presentation of these study results is planned for the annual meeting of the American Society of Clinical Oncology in June.

"These results indicate that arsenic trioxide should be considered as part of the initial treatment of patients with acute promyelocytic leukemia," said Richard Larson, of University of Chicago and a co-investigator of the study.

"Achieving success in a clinical trial for a rare cancer is a difficult task due to the limited number of patients eligible to enroll in the trial, so this is very encouraging news for all patients with this form of leukemia," said NCI Director John Niederhuber. "This positive outcome demonstrates, yet again, the benefits of clinical trials and will hopefully serve as encouragement for others to join such trials."

Cancer Statistics:

Cancer Death Rates Improving, But Still Higher, In Blacks

Although the overall cancer death rate in African Americans has continued to decrease since the early 1990s, the rate was 35 percent higher in African American men and 18 percent higher in African American women than in white men and women in the most recent time period (2003). However, the disparity among men has narrowed over the past 10 years because rates have decreased faster in African Americans than whites.

These data appear in the newly released Cancer Facts & Figures for African Americans 2007-2008. The report estimates that approximately 153,000 of the 1.4 million cases of invasive cancer diagnosed in the US in 2007 will be among African Americans, as well as almost 63,000 of the estimated 560,000 deaths from cancer.

The most common cancers diagnosed in African American men are prostate, lung and bronchus, and colon and rectum; among African American women, cancers of the breast, lung and bronchus, and colon and rectum are the most commonly diagnosed. Cancer of the lung is the most common cause of cancer death in both African American men and women, followed by prostate cancer in men and breast cancer in women.

NCI-Approved Clinical Trials

The National Cancer Institute's Cancer Therapy Program approved the following clinical research studies last month. For further information about a study, contact the principal investigator listed.

Phase I/II

Phase I/II Study of Flavopiridol in Relapsed or Refractory Mantle Cell Lymphoma and Diffuse Large B-cell Lymphoma. NCI Medicine Branch protocol 7844, Dunleavy, Kieron, phone 301-435-1007.

Phase II Study of VEGF Trap for the Treatment of Relapsed or Refractory Multiple Myeloma. Weill Medical College of Cornell University, protocol 7521, Niesvizky-Iszaevich, Ruben, phone 212-746-3964.

Phase II

Phase II Trial of Erlotinib (OSI-774) and Sorafenib (BAY 43-9006) for Patients with Progression or Recurrent Glioblastoma Multiforme. New Approaches to Brain Tumor Therapy Consortium, NABTT-0502, Peereboom, David Mare, phone 216-445-6068.

Prospective Phase II Trial of Transperineal Ultrasound-Guided Brachytherapy for Locally Recurrent Prostate Adenocarcinoma Following External Beam Radiotherapy. Radiation Therapy Oncology Group, RTOG-0526, Crook, Juanita, phone 416-946-2919.

Phase II Trial of the Combination of OSI-774 (Erlotinib; NSC-718781) and Bevacizumab (rhuMAb VEGF; NSC-704865) in Never-Smokers with Stage IIIB and IV Primary NSCLC Adenocarcinomas. Southwest Oncology Group, SO636, West, Howard, phone 206-386-2424.

Phase III

Phase III Blinded Study of Immediate Post-TURBT Instillation of Gemcitabine Versus Saline in Patients With Newly Grade I/II Superficial Bladder Cancer. SWOG, S0337, Messing, Edward, phone 585-275-3345.

Other

Evaluation of the Association Between DNA Methylation and Shortened Survival in Patients with Advanced Colorectal Cancer Treated with 5-FU/Oxaliplatin-Based Regimens in E3200. Eastern Oncology Cooperative Group, E3200T1, Hamilton, Stanley, phone 713-792-2040.

Assessment of MUM1 Expression, Lymphoma-Associated Macrophages, and Regulatory T-Cells in Follicular Lymphoma: Prognostic Markers in SWOG S8809 and S9800/S9911 Trials Representing Pre-and Post-Monoclonal Antibody Therapy Protocols. SWOG, S8809-S9800, Sweetenham, John, phone 216-445-6707.

SWOG Closes Prostate Cancer Trial With Mitoxantrone

The NCI-sponsored Southwest Oncology Group last month announced that it has closed a phase III prostate cancer treatment clinical trial because the new treatment under investigation was associated with a rare but dangerous side effect.

The trial, called S9921, was designed to see whether hormone-deprivation therapy combined with the chemotherapy drug mitoxantrone was superior to hormone-deprivation therapy alone in men with "poor risk" prostate cancer - that is, cancer that had spread beyond the prostate and was at high risk of recurring after surgery or radiation therapy.

Mitoxantrone has been approved by FDA for the treatment of advanced prostate cancer. Of the 983 patients enrolled in the trial, 488 had received mitoxantrone as part of their treatment. In the most recent review of survival and side-effect data from the trial, SWOG explained in a statement, trial leaders noted three cases of acute myelogenous leukemia among the patients who had received mitoxantrone. No patients in the hormone deprivation-only group developed leukemia.

Following a review and recommendation from SWOG's Data Safety Monitoring Committee, the trial was closed.