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THE
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Cancer research news for clinicians

Clinical Guidelines:

ASCO Expanding Tools To Improve Coordination Of Cancer Treatment

The American Society of Clinical Oncology is expanding its tools to improve documentation and coordination of cancer treatment and survivorship care by developing a chemotherapy treatment plan and summary template for breast cancer patients.

The goal of the breast cancer treatment plan and summary (available at www.asco.org/treatmentsummary) is to improve communication among oncologists, patients and other care providers to better manage breast cancer patients' treatment across health care settings. It will also make gathering

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Cervical Cancer:

PET Three Months After Therapy Provides Early Warning Of Need For Intervention

Whole-body positron emission tomography scans done three months after completion of cervical cancer therapy can ensure that patients are disease-free or warn that further interventions are needed, according to a study at Washington University School of Medicine in St. Louis.

"This is the first time we can say that we have a reliable test to follow cervical cancer patients after therapy," said Julie Schwarz, a Barnes-Jewish Hospital resident in the Department of Radiation Oncology. "We ask them to come back for a follow-up visit about three months after treatment is finished, and we perform a PET scan. If the scan shows a complete response to treatment, we can say with confidence that they are going to do extremely well. That's really powerful."

Schwarz and colleagues published their study in the Nov. 21 issue of JAMA.

Without a test like PET, it can be difficult to tell whether treatment has eliminated cervical tumors, Schwarz said. Small tumors are hard to detect with pelvic exams, and overt symptoms, such as leg swelling, don't occur until tumors grow quite large.

CT and MRI scans often don't differentiate tumor tissue from surrounding tissues, Pap tests can be inaccurate because of tissue changes induced by radiation therapy, and no blood test exists to detect the presence of cervical cancer.

Cancerous tumors glow brightly in the PET scans used in the study, called FDG-PET scans, which detect emissions from radioactively tagged

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ASCO Offers Treatment Plans To Aid Documentation, Care

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data to evaluate and improve quality of care and patient outcomes more accurate and efficient.

The new breast cancer treatment plan and summary template joins a colorectal treatment template published online earlier this year. ASCO is continuing to develop and test treatment plans and summaries for additional cancer diagnoses, including lung cancer.

The chemotherapy treatment plan, which the oncologist is to fill out before the patient begins receiving chemotherapy, maps out the patient's planned treatment. The treatment summary, developed after treatment is complete, describes what care the patient actually received. Some of the core elements of the treatment plan and summary include:

- Diagnosis, including the cancer site, histology and stage
- A summary of the chemotherapy and other treatment that is planned and actually delivered
- The reason treatment was stopped or modified
- Information on appropriate follow-up care and relevant providers
- Evidence-based survivorship and surveillance guidelines from ASCO

To improve care for the increasing number of cancer survivors, ASCO developed the Breast Cancer Survivorship Plan that can be added to the treatment summary to provide clarification on necessary follow-up care, including physical exams, post-treatment mammography, breast self-examination, and pelvic examinations.

"The adjuvant treatment plan and summaries and the breast cancer survivorship plan are not only tools for oncologists, but also an educational resource for patients," said Patricia Ganz, professor of health services and medicine at the UCLA School of Public Health and director of the Division of Cancer Prevention and Control Research at the Jonsson Comprehensive Cancer Center. "We expect that discussion of the plan with the patient, and sharing of the information with her primary care provider, will improve coordination of follow-up care after primary breast cancer treatment."

The breast cancer treatment plan and summary have been field tested by practices to ensure that the most useful information is being tracked and patients are consistently receiving quality care. All ASCO treatment plan and summary templates are published in modifiable forms, allowing oncologists to customize and adapt them to suit their own practices.

ASCO also is promoting integration of the treatment plan and summaries into oncology electronic health records.

"After Hurricane Katrina, the need for durable, transportable medical records became increasingly obvious," said ASCO President Nancy Davidson, director of the Breast Cancer Program at the Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins University.

"Cancer patients in particular need to have access to their medical records," Davidson added. "ASCO developed these templates as a standard for an oncology patient's EHR. It would be very complicated if every oncology office is out there designing their own version of an EHR."

The treatment plan and summary are not intended to replace detailed chart documentation, including complete patient histories or chemotherapy flow sheets. No single treatment plan can be appropriate for all patients; treating oncologists assume responsibility for tailoring the treatment summary to meet individual patient's needs.

ASCO has posted or updated several clinical guidelines in the past month:

Use of ESAs in Cancer Treatment

ASCO and the American Society of Hematology will release an updated joint guideline on the use of erythropoiesis-stimulating agents, a class of drugs that stimulate the bone marrow to produce more red blood

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cells, to treat chemotherapy-related anemia.

"One goal of these guidelines is to inform clinicians with the most up-to-date evidence from high-quality studies regarding the risks and benefits of ESAs in patients with cancer," said J. Douglas Rizzo, co-chair of the guideline panel and associate professor of medicine, Medical College of Wisconsin.

This updated guideline, originally published in 2002, was derived from systematic reviews and analysis of published clinical trials. It outlines the clotting risks of ESAs, makes recommendations on usage, and provides insights on disease progression and patient survival.

Specifically, the guideline:

—Declares epoetin and darbepoetin equally safe and effective.

—Recommends the use of ESAs as a treatment option for cancer patients who become anemic as a result of chemotherapy when their hemoglobin approaches or falls below 10 g/dL, as well as for patients with low-risk myelodysplasia.

—Suggests that when using ESAs, hemoglobin can be raised to (or near) a concentration of 12 g/dL at which point the dosage should be titrated to maintain that level. Dose reductions are also recommended when hemoglobin rise exceeds 1 g/dL in any two-week period or when the hemoglobin level exceeds 11 g/dL.

—Recommends discontinuing use of ESAs beyond six to eight weeks if a patient has not responded to the drug.

—Recommends monitoring the iron levels of patients being treated with ESAs and providing supplements accordingly.

—Cautions against using ESAs for cancer patients not receiving chemotherapy since recent trials have shown increased thromboembolic risks and decreased survival under these circumstances.

"As new data become available, it is important to update clinical practice guidelines to ensure that physicians make treatment decisions based upon the most up-to-date available evidence," said Alan Lichtin, guideline panel co-chair and associate professor of medicine at the Cleveland Clinic Lerner College of Medicine. "However, new evidence can also reinforce previous recommendations, as it did in this guideline."

ESAs carry an increased risk for blood clots, strokes, and heart attacks in some patients under certain conditions, spurring the FDA to call for new drug warning labels this past March. Following the FDA's warning, the Centers for Medicare & Medicaid Services issued a National Coverage Decision this summer, outlining the specific conditions under which use of ESAs would be reimbursed for cancer patients.

"We hope that these evidence-based recommendations will influence practice standards and result in better care for patients," said Samuel Silver, ASH Executive Committee councillor, chair of the ASH Subcommittee on Reimbursement, and professor of internal medicine at the University of Michigan.

In developing the guideline update, panel members considered two meta-analyses that reviewed close to 60 randomized clinical trials. Additional evidence was considered when it was considered pertinent to each section of the updated guideline.

Adjuvant Therapy For NSCLC

ASCO and Cancer Care of Ontario issued a new collaborative clinical practice guideline on adjuvant therapy, or the use of chemotherapy or radiation after surgery, for treating non-small cell lung cancer. The guideline provides new evidence that treatment with chemotherapy can increase survival for people with stages II and III lung cancer.

Almost 85 percent of all lung cancer cases are of the non-small cell type. Treatment for stages I, II, and IIIA of NSCLC includes surgery to remove the tumor as well as the surrounding lung tissue and lymph nodes, if necessary. By stage IV, the lung cancer has spread throughout the body and is no longer treatable with surgery.

The guideline strongly recommends chemotherapy following successful surgery (when the tumor is completely removed) for patients with stages IIA, IIB, and IIIA lung cancer. The data show that chemotherapy increased the five-year survival rate of patients with stage II by 10 percent or stage IIIA cancers by 13 percent.

"As someone who been in the oncology field for a long time, I have seen how oncologists have labored through the days of relatively ineffective adjuvant therapy," said guideline panel co-chair Katherine Pisters, with the Department of Thoracic Head & Neck Medical Oncology at the M.D. Anderson Cancer Center. "Now, evidence is showing that chemotherapy after surgery can help patients with stage II and III NSCLC live longer."

Of people diagnosed with stage IA and IB lung cancer, an estimated 74 percent will be alive 5 years after diagnosis, according to the Surveillance, Epidemiology, and End Results Program Statistical Database. Currently, there is not enough evidence to demonstrate that chemotherapy helps patients with stage I NSCLC

live longer. Chemotherapy may be an option for some patients with stage IB NSCLC, particularly patients with tumors larger than 4 centimeters, but current data do not support recommending it for routine use for patients with stage IB NSCLC and not at all for stage IA.

Evidence on the use of radiotherapy in treating patients with lung cancer was not sufficient for the panel to recommend it as an adjuvant therapy and is detrimental at stages I and II. However, research is underway on possible benefits from adjuvant radiotherapy for patients with stage IIIA lung cancer.

In conjunction with this guideline, ASCO developed a Decision Aid Tool, which uses straightforward charts and additional diagrams to explain the risks and benefits of adjuvant therapy to patients and their families. One section, called "Thinking It Over," poses questions about what risks and benefits matter most to the individual patient. It also asks patients to think about how they are making their treatment decisions, including questions about their support system and whether or not they feel pressured to undergo additional treatment.

The goal of the tool is to help doctors better communicate with their patients about their treatment options and prognosis.

"It is really important for doctors and patients to discuss whether or not adjuvant therapy is an appropriate treatment for the patient," said guideline co-author William Evans, one of CCO's regional vice presidents and an oncologist at the Juravinski Cancer Centre in Ontario. "The Decision Aid Tool helps explain patients' options and potential outcomes in a clear way, to help the patient and their loved ones make more informed decisions."

Tumor Markers In Breast Cancer

ASCO updated its clinical practice guideline on the use of tumor markers in breast cancer. The guideline authors observed that although researchers have made progress in developing tumor markers in areas such as diagnosis and treatment planning, mammography remains the gold standard in screening for breast cancer.

A tumor marker is a substance found in a person's blood, urine, or body tissue. The presence of a tumor marker, or higher- or lower-than-normal levels of a tumor marker, may indicate an abnormal process in the body, such as cancer, and can provide further information if cancer is diagnosed. Doctors may suggest tumor marker tests at various stages in the diagnosis or treatment of cancer. These tests can provide helpful information about both the cancer and the treatment.

"Increased use of tumor markers represents a shift in our understanding of the basic biology of breast cancer, which will affect how we treat patients," said guideline co-author Lyndsay Harris, vice chair of ASCO's Tumor Markers Expert Panel and associate professor and director of the Breast Cancer Disease Unit at Yale University. "The cancer research community needs to continue to conduct more clinical trials to examine exactly how tumor markers can help with the early detection of breast cancer."

To update its clinical practice guideline, first published in 1996 and subsequently updated in 2001, the ASCO expert committee reviewed the use of tumor markers in breast cancer and made recommendations based on their effectiveness for early detection of the disease, as well as their benefit in helping to plan treatment, monitoring response to treatment, and determining a patient's prognosis.

Much progress has been made in the area of tumor markers over the past 10 years. Since the 2001 guideline, researchers have identified six new categories of tumor markers. Although currently there are insufficient data to recommend the use of any of these new tumor markers in diagnosing breast cancer, both ER/PR and HER 2 testing are still recommended for diagnosis, as noted in previous versions of this guideline. However, two new tumor marker tests were recommended for their use in determining a breast cancer patient's treatment or whether or not breast cancer is likely to return after initial treatment.

The updated recommendations covered two new tumor marker tests for patients with newly diagnosed node-negative breast cancer, or cancer that has not spread to the lymph nodes.

The Oncotype DX tumor marker test is recommended for patients with node-negative breast cancer that is ER-positive and/or PR-positive, which is the case for 20 percent of breast cancer patients. The test measures multiple genes at once to estimate the risk of breast cancer recurrence. Patients with a low recurrence score may be able to receive only hormone therapy and avoid chemotherapy. Sparing patients from unnecessary treatment may not only improve their quality of life, but it also will reduce overall health care costs.

Other tumor markers that doctors can test are urokinase plasminogen activator (uPA) and plasminogen activator inhibitor (PAI-1) markers. Testing these tumor markers can help estimate a patient's prognosis. Patients with tumors that do not have uPA and PAI-1 have a good prognosis and may not need chemotherapy. However, the test is not currently commercially available in the

United States, but it is in Europe. More studies of this tumor marker are currently under way.

The guideline also encourages patients to enroll in clinical trials that focus on the use of additional tumor markers as a surveillance tool for breast cancer.

"Tumor markers can predict whether or not a patient will respond to treatment," Harris said. "The goal of these guidelines is to help doctors provide their patients with the best possible care. Patients will benefit from knowing whether or not a treatment will help them before beginning the treatment regimen."

Preventing And Treating Blood Clots

ASCO will release new clinical guideline recommendations on the use of anticoagulants to treat venous thromboembolism (VTE), or blood clots, in people with cancer.

Blood clots and their complications are a leading cause of death in patients with cancer and may affect 4 to 20 percent of people with cancer at some point in their treatment. Major risk factors for developing a blood clot include age, primary site of cancer, hospitalization, a history of VTE, and active therapy such as chemotherapy, antiangiogenic drugs, and hormonal therapy.

The primary treatment for blood clots in cancer patients is an anticoagulant, a drug that helps to break up the blood clot. Anticoagulants may raise a patient's risk of bleeding and treatment often requires a short hospital stay, but, in virtually every case, the benefits of treatment with anticoagulants outweigh the risks, according to Gary Lyman, co-chair of the guideline panel and director, Health Services and Outcomes Research Program-Oncology at Duke University Medical Center.

The key recommendations include:

—All hospitalized patients with cancer should receive preventive anticoagulation.

—All patients with cancer who develop a blood clot should be treated with an anticoagulant for at least six months and possibly longer in those who continue treatment for active cancer.

—Doctors should evaluate all patients with cancer receiving major surgery, for administering anticoagulation, beginning before the operation or as soon afterwards as possible.

—Regular use of an anticoagulant for patients with cancer who are not hospitalized and receiving chemotherapy is not recommended, except for patients with multiple myeloma receiving thalidomide or lenalidomide with chemotherapy or dexamethasone (a steroid).

"The frequency of diagnosed blood clots in cancer patients has been rising yearly. On the other hand, several studies suggest that anticoagulants are underused, particularly in hospitalized cancer patients who are at increased risk," Lyman said.

"More research is also urgently needed to identify better markers of who is most likely to develop VTE among ambulatory cancer patients," Lyman said. "People with cancer should be encouraged to ask their oncologist about their risk of VTE and to participate in clinical trials designed to evaluate anticoagulant therapy as an adjunct to standard anticancer therapies."

Cervical Cancer:
PET Scans Predict Long-Term Survival Of Cervical Cancer

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blood sugar, or glucose. Tumor tissue traps more of the glucose than does normal tissue, making tumors readily discernable.

Not only can post-treatment PET scans reassure those patients whose tumors respond well to therapy, they can also identify those patients whose tumors have not responded so that their physicians can explore other treatment options before the cancer advances further. These options can include surgery to remove tissue, standard chemotherapy or experimental therapies available through clinical trials.

"Follow-up PET scans can also be very useful tools for physicians conducting clinical trials of new therapies," Schwarz said. "Our study has shown that the scans are predictive of long-term survival. Using PET scans, clinical researchers can get an early readout of how effective experimental treatments might be."

Schwarz and colleagues also have a project to compare follow-up PET results with tumor biology to find out why some tumors don't respond well to therapy. In a study that won her a Resident Clinical Basic Science Research Award from the American Society for Therapeutic Radiation and Oncology, a global organization of medical professionals, Schwarz found differences in gene activity between tumors from patients that responded well and those that had persistent disease. Ongoing research will look for the significance of these differences.

The study's senior author, Perry Grigsby, professor of radiation oncology, of nuclear medicine and of obstetrics and gynecology and a radiation oncologist with the Siteman Cancer Center at Washington University School of Medicine and Barnes-Jewish

Hospital, has overseen a patient database that now has PET images and tumor samples from hundreds of cervical cancer patients.

"We have a tremendous database of PET images collected from patients in the department since 1998," Schwarz said. "We want to combine these results with analyses of tumor biopsies so that we can more effectively choose additional therapies for patients who haven't responded to the initial treatment."

The research was supported by Washington University School of Medicine.

FDA Approvals:

Nexavar Approved For Patients With Inoperable Liver Cancer

FDA approved Nexavar (sorafenib) for use in patients with a form of liver cancer known as hepatocellular carcinoma, when the cancer is inoperable. Nexavar was originally approved in 2005 for the treatment of patients with advanced renal cell carcinoma, a form of kidney cancer.

"In a randomized clinical trial, the group of patients with inoperable hepatocellular carcinoma who received Nexavar survived 2.8 months longer than the group of patients who didn't receive the drug," said Robert Justice, director of FDA's division of drug oncology products. "This is an important new treatment option for patients who are fighting this very difficult form of cancer."

FDA's approval of Nexavar was based on the results of an international randomized placebo-controlled trial in patients with inoperable hepatocellular carcinoma. The study was designed to compare the survival of a group of patients who received the drug against a group of similar patients who did not.

A total of 602 patients were studied. Each patient received Nexavar or a placebo. Both groups were comparable with regard to age, gender, race, the stage and other characteristics of their cancer, and the types of cancer treatment they had received before entering the clinical trial.

The trial was stopped after a planned interim analysis showed a statistically significant advantage in overall survival for the patients who had received Nexavar. Patients who received Nexavar survived a median of 10.7 months while patients who received placebo survived a median of 7.9 months.

A separate analysis showed that tumors progressed more slowly in patients who received Nexavar compared to patients who had received placebo.

The most common adverse reactions that have been observed in patients taking Nexavar (for hepatocellular carcinoma or renal cell carcinoma) are fatigue, weight loss, rash or superficial skin shedding, hand or foot skin reaction, hair loss, diarrhea, anorexia, nausea and abdominal pain.

Twenty percent or more of patients had experienced at least one of these reactions. In patients with hepatocellular carcinoma, diarrhea was reported in 55 percent of patients who received Nexavar. Inadequate blood supply to the heart or heart attack were reported in 2.7 percent of patients who received Nexavar, compared to 1.3 percent for patients who received placebo. New high blood pressure was reported in 9 percent of patients who received Nexavar, compared to 4 percent of patients who received placebo.

Elevated serum lipase, an enzyme that measures liver function, occurred in 40 percent of patients who received Nexavar, compared to 37 percent of patients who received placebo, and hypophosphatemia, or low blood levels of phosphate, occurred in 35 percent of patients who received Nexavar, compared to 11 percent of patients who received placebo.

Nexavar is manufactured by Bayer HealthCare AG, Leverkusen, Germany for Bayer Pharmaceuticals Corporation, West Haven, Conn. and by Onyx Pharmaceuticals, Inc., Emeryville, Calif.

Colorectal Cancer:

Erbitux Improves Survival In Advanced Colorectal Cancer

Erbitux (cetuximab) as a single agent demonstrated a significant improvement in overall survival in patients with metastatic colorectal cancer refractory to approved chemotherapy agents in a randomized phase III trial.

The study (NCIC CTG CO.17), conducted by the National Cancer Institute of Canada Clinical Trials Group in collaboration with the Australasian Gastro-Intestinal Trials Group, involved 572 patients and demonstrated that treating patients with Erbitux as a monotherapy plus best supportive care significantly increased overall survival compared to BSC alone.

BSC included palliative therapies designed to alleviate pain and treat other effects caused by metastatic colorectal cancer (mCRC).

The study was published in the New England Journal of Medicine earlier this month.

The study enrolled patients with epidermal growth factor receptor (EGFR)-expressing metastatic colorectal cancer who had been previously treated. Erbitux was

administered at the recommended dose and schedule: 400 mg/m2 initial dose, followed by 250 mg/m2 weekly until disease progression or unacceptable toxicity.

Median survival was 6.1 months for patients treated with Erbitux plus BSC versus 4.6 months for patients on BSC alone (Hazard Ratio: 0.77, P=0.005).

Treatment with Erbitux monotherapy resulted in a significant improvement in progression-free survival versus BSC alone (Hazard Ratio: 0.68, P<0.001). Twenty-three patients (8.0%) treated with Erbitux and no patients on BSC alone had partial responses (P<0.001).

Grade 3/4 adverse events (occurring in ≥10% of patients in either group) reported more frequently in the Erbitux plus BSC treatment arm compared with the BSC only arm included fatigue (33% vs 26%), other pain (16% vs 7%), dyspnea (16% vs 12%), infection without neutropenia (13% vs 6%) rash/desquamantion (12% vs <1%), and other gastrointestinal (10% vs 8%). Grade 3/4 infusion reactions (hypersensitivity) occurred in 5% of patients in the Erbitux plus BSC arm.

The most common (occurring in ≥25% of patients in either group) adverse events of any grade were rash/desquamation, fatigue, abdominal pain, other pain, dry skin, dyspnea, constipation, pruritus, diarrhea, vomiting, infection without neutropenia, headache, fever, insomnia, cough, other dermatology, and stomatitis.

This study supported the recent label change for Erbitux—approved by FDA on Oct. 2—to include overall survival data as a monotherapy agent in patients with EGFR-expressing mCRC after failure of irinotecan- and oxaliplatin-based chemotherapy regimens.

Multiple Myeloma:

Revlimid Plus Steroid Effective In Clinical Trial

Pairing a new thalidomide derivative with a steroid slows progress of multiple myeloma, an incurable bone marrow cancer, and prolongs the lives of patients who have relapsed from previous treatment, researchers report in the Nov. 22 New England Journal of Medicine.

In the study conducted at 44 centers in the U.S. and Canada, 353 patients with myeloma received either a combination of lenalidomide (Revlimid) and the steroid dexamethasone or dexamethasone plus a placebo.

"Those taking the lenalidomide combination had a median time to disease progression of 11.1 months compared with 4.7 months in the placebo-dexamethasone group and an improved median overall survival time of 29.6 months compared with 20.2 months," said lead author Donna Weber, associate professor in the Department of Lymphoma and Myeloma at the University of Texas M. D. Anderson Cancer Center.

The results were impressive enough that in December 2005, an independent interim data analysis resulted in the trial being halted early so those on placebo-dexamethasone could also benefit from the addition of lenalidomide.

The collaborative study by North American Multiple Myeloma Study investigators, and an international trial also reported in the New England Journal of Medicine, led to the approval of lenalidomide and dexamethasone for previously treated patients by FDA.

"These trials highlight how large-scale cooperation in a team effort by myeloma investigators can quickly confirm benefits and introduce new active agents for patients with this disease," Weber said. "We also owe a debt to the willing patients who participated in this study."

Thalidomide is produced and marketed by Celgene Corp. as Thalomid. The company chemically altered thalidomide to make lenalidomide, known commercially as Revlimid, in hopes of reducing side effects and improving efficacy against the disease. The drugs attack both the malignant cells and the cellular environment that nurtures them.

Of 177 patients who received the lenalidomide combination therapy, 108 (61%) had complete, near-complete or partial responses to the medication compared with 35 patients out of 176 (19.9%) in the placebo-dexamethasone group.

An analysis by Michael Wang, assistant professor in the Department of Lymphoma and Myeloma at M. D. Anderson, found 56.8% of patients who had prior treatment with thalidomide before receiving the lenalidomide combination had a response, compared with 64.1% with no previous thalidomide treatment.

"That suggests that the drugs differ enough to get a separate response, not just a refinement of side effects," Weber said.

The superior results for the combination also held up among patients previously treated with another new drug, bortezomib, a proteasome inhibitor known commercially as Velcade and marketed by Millennium Pharmaceuticals.

Combinations of drugs are important in ongoing treatment as a patient's disease becomes resistant to one therapy. "It's great that this research gave us a new drug," Weber said. "But what we also find with new

drugs is that they work well with older therapies, which gives us many combinations to offer our patients."

Lenalidomide is being tested as a front-line therapy and in combination with other medications in a variety of clinical trials.

Overall, 85.3% of those receiving the combination therapy experienced side effects compared with 73.1% of the placebo-dexamethasone group. Some of the side effects were serious enough to cause 19.8% of the combination group and 10.2% of the placebo group to quit the trial.

Major side effects from the combination were suppression of patients' white blood cells, making them vulnerable to infection, and formation of blood clots. In most cases, these side effects were countered by decreasing the lenalidomide dose, or administering antibiotics or anticoagulants.

One of the major side effects of thalidomide—significant nerve pain and numbness in the limbs known as peripheral neuropathy—was nearly absent in the lenalidomide group.

The research was funded by Celgene.

NCI-Approved Clinical Trials Begun At Groups, Centers

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 Evaluation of Everolimus (RAD001), Radiation and Temozolomide Followed by Adjuvant Temozolomide and Everolimus in Newly Diagnosed Glioblastoma. North Central Cancer Treatment Group, protocol N057K, Sarkaria, Jann, phone 507-284-3559.

Phase II

Phase II Study of AZD0530 in Hormone Receptor-Negative Metastatic Breast Cancer. Memorial Sloan-Kettering Cancer Center, protocol 7567, Hudis, Clifford, phone 646-888-4551.

Phase II Study of AZD6244 in Iodine-131 Refractory Papillary Thyroid Carcinoma with Follicular Elements. Mofitt Cancer Center and Research Institute, protocol 7918, Hayes, David, 919-966-3786.

Phase II Study of AZD6244 in Biliary Cancers. Ohio State University Hospital, protocol 7932, Bekaii-Saab, Tanios, phone 614-293-9863.

Phase II Study of Positron Emission Tomography Imaging with [18F]-Fluoromisonidazole and[18F]-Fluorodeoxyglucose for Assessment of Tumor Hypoxia in Cervical Cancer. University of Washington Medical center, protocol 7958, Rajendran, Joseph, phone 206-598-4248.

Phase II Study of 3'-deoxy-3'-18F Fluorothymidine in Invasive Breast Cancer. Virginia Commonwealth University, protocol 8029, Kurdziel, Karen, phone 804-827-4984.

Intergroup Phase II Trial for Adolescents and Young Adults with Untreated Acute Lymphoblastic Leukemia. Cancer and Leukemia Group B, protocol CALGB-10403, Larson, Richard, phone 773-702-6783.

Phase II Trial of Bortezomib) + Lenalidomide (Revlimidô, CC-5013) for Relapsed/Refractory Mantle Cell Lymphoma. Cancer and Leukemia Group B, protocol CALGB-50501, Morrison, Vicki, phone 612-467-4135.

Phase II Study of ATRA, Arsenic Trioxide and Gemtuzumab Ozogamicin in Patients with Previously Untreated High-Risk Acute Promyelocytic Leukemia. Southwest Oncology Group, protocol S0535. Lancet, Jeffrey, phone 813-745-6841.

Phase III

Phase III Study of Risk Directed Therapy for Infants with Acute Lymphoblastic Leukemia: Randomization of Highest Risk Infants to Intensive Chemotherapy +/-FLT3 Inhibition. Children's Oncology Group, protocol AALL0631, Hilden, Joanne, phone 317-338-3466.

Trial of Intensive Multi-Modality Therapy for Extra-Ocular Retinoblastoma. Children's Oncology Group, protocol ARET0321, Dunkel, Ira, phone 212-639-2153.

Phase III Randomized Controlled Clinical Trial of Carboplatin and Paclitaxel Alone or in Combination with Bevacizumab Followed by Bevacizumab and Secondary Cytoreductive Surgery in Platinum-Sensitive, Recurrent Ovarian, Peritoneal Primary and Fallopian Tube Cancer. NCI-Supplied Agents: Bevacizumab. Gynecologic Oncology Group, protocol GOG-0213, Coleman, Robert, phone 713-745-3357.

Other

COG Study for Collecting and Banking Ewing Sarcoma Specimens. Children's Oncology Group, protocol AEWS07B1, Lessnick, Stephen, 801-585-9268.