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THE
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Cancer research news for clinicians

FDA Approvals:

FDA Approves Silicone Gel Breast Implants, Requires 10 Years Of Patient Follow-Up

FDA approved the marketing of silicone gel-filled breast implants made by two companies for breast reconstruction in women of all ages and breast augmentation in women ages 22 and older. The decision was announced Nov. 17.

The products are manufactured by Allergan Corp. (formerly Inamed Corp.), Irvine, Calif., and Mentor Corp., Santa Barbara, Calif.

"FDA has reviewed an extensive amount of data from clinical trials of women studied for up to four years, as well as a wealth of other information to

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Breast Cancer:

Study Identifies Women Likely To Benefit From Therapy With Aromatase Inhibitors

While some breast cancer survivors could benefit from adding aromatase inhibitors to the standard five years of tamoxifen, a new study shows the additional therapy should be weighed carefully for each individual.

Writing in the Dec. 1, issue of CANCER, a peer-reviewed journal of the American Cancer Society, the study's authors say potential improvement in cancer-free survival beyond 5 years with the added therapy may be less than 2 percent for most patients.

For decades, clinicians have given breast cancer patients tamoxifen, which has been shown to improve survival when given for five years. More recently, aromatase inhibitors, another class of estrogen modulating drugs, have been used to prevent estrogen formation.

A large randomized study has shown that use of aromatase inhibitors after tamoxifen may further improve survival and is recommended for postmenopausal women. Led by Gary Freedman, of the Fox Chase Cancer Center in Philadelphia, researchers investigated which sub-groups of breast cancer patients treated with tamoxifen may benefit the most from this extended therapy with aromatase inhibitors.

The researchers found that in this study population of 471 women, the potential addition of an aromatase inhibitor would have provided only marginal benefits. Premenopausal women and patients with at least four positive lymph nodes would experience the greatest 10-year cancer-free survival benefits. Patients with none or fewer positive lymph nodes, advanced age, or other medical problems that would limit their life expectancy would not have the

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Implant Approval Based On Thorough Review, FDA Says

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determine the benefits and risks of these products," said Daniel Schultz, director of the FDA Center for Devices and Radiological Health. "The extensive body of scientific evidence provides reasonable assurance of the benefits and risks of these devices. This information is available in the product labeling and will enable women and their physicians to make informed decisions."

FDA said it will continue to monitor the devices by requiring each company to conduct a large post-approval study following about 40,000 women for 10 years after receiving breast implants.

The agency said the decision to approve the implants was based on a thorough review of each company's clinical and preclinical studies, a review of studies by independent scientific bodies, and deliberations of advisory panels of outside experts that heard public comment from hundreds of individuals. FDA also conducted inspections of each company's manufacturing facilities to determine that they comply with FDA's Good Manufacturing Practices.

Some of the complications reported in the clinical studies included hardening of the area around the implant, breast pain, change in nipple sensation, implant rupture, and the need for additional surgery. However, the majority of women in these studies reported being satisfied with their implants.

In the past decade, a number of independent studies have examined whether silicone gel-filled breast implants are associated with connective tissue disease or cancer. The studies, including a report by the Institute of Medicine, have concluded there is no convincing evidence that breast implants are associated with either of these diseases.

"The silicone breast implant is one of the most extensively studied medical devices," said Schultz. "We now have a good understanding of what complications can occur and at what rates. We also know that women who get these devices will probably need to have additional breast implant surgery at least once. This is valuable information for women who may be considering these products."

Full information about the risks and benefits of the devices can be found in the package and patient labeling mandated by FDA. The patient labeling outlines some of the important factors women should consider when deciding whether to get silicone gel-filled breast implants. Some of these factors are: breast implants are not lifetime devices and a woman will likely need additional surgeries on her breast at least once over her lifetime; many of the changes to a woman's breast following implantation are irreversible; rupture of a silicone gel-filled breast implant is most often silent, which means that usually neither the woman nor her surgeon will know that her implants have ruptured; and a woman will need regular screening MRI examinations over her lifetime to determine if silent rupture has occurred.

The device labeling states that a woman should have her first MRI three years after her initial implant surgery and then every two years thereafter. The cost of MRI screening over a woman's lifetime may exceed the cost of her initial surgery and may not be covered by medical insurance. The labeling also states that if implant rupture is noted on an MRI, the implant should be removed and replaced, if needed.

FDA approved the silicone gel-filled breast implants with a number of conditions, including requiring each company to: conduct a large post-approval study; continue its core study through 10 years; conduct a focus group study of the patient labeling; continue laboratory studies to further characterize types of device failure; and track each implant in the event, for example, that health professionals and patients need to be notified of updated product information.

The post-approval studies will continue to gather information about the safety and effectiveness of the implants. Information will be collected about rates of local complications, rates of connective tissue disease

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and its signs and symptoms, rates of neurological disease and its signs and symptoms, potential effects on offspring of women with breast implants, potential effects on reproduction and lactation, rates of cancer, rates of suicide, potential interference of breast implants with mammography, and MRI compliance and rupture rates.

Further information is available at www.fda.gov/cdrh/breastimplants.

* * *

FDA Expands Use Of Herceptin

FDA expanded the approved use of Herceptin (trastuzumab, Genentech Inc.) for use in combination with other cancer drugs for the treatment of HER2 positive breast cancer after surgery (lumpectomy or mastectomy).

FDA granted priority review to the supplemental application for Herceptin.

Herceptin is a targeted therapy against the HER2 protein on cancer cells. When an excessive amount of HER2 protein is present, it causes cancer cells to grow more rapidly and standard chemotherapy may be less effective. In 1998, FDA approved Herceptin for the treatment of metastatic breast cancer. The new approval expands its use to women with cancer only in the breast or lymph nodes which has been removed with surgery. Herceptin should only be prescribed for women diagnosed with HER2 positive breast cancer.

"This is especially good news for women who have breast cancer caused by excessive amounts of the HER-2 protein because this cancer typically has a poor prognosis," said Steven Galson, director of the FDA Center for Drug Evaluation and Research.

The two studies leading to this new approved indication were conducted by the National Cancer Institute-sponsored Cooperative Groups, a multicenter clinical trials group. Patients in both trials received standard chemotherapy after surgery for breast cancer; approximately half the patients were also given Herceptin. he results from both trials, which included information on nearly 4,000 women, were combined and analyzed in 2005.

Due to positive results, NCI ended the studies early. The results showed that women who received Herceptin combined with chemotherapy had fewer relapses (return of breast cancer) for up to three years after surgery. The estimated three-year disease-free rates were 87 percent in women receiving Herceptin and chemotherapy and 75 percent in those receiving chemotherapy alone. It is too soon to know whether Herceptin combined with chemotherapy will increase the cure rate or lower the risk of death from breast cancer.

"Today's approval is wonderful news for women with early-stage HER2-positive breast cancer and another significant milestone in the Herceptin story," said Fran Visco, president of the National Breast Cancer Coalition. "Thanks to the thousands of breast cancer patients, clinical investigators, the FDA, Genentech and advocates, who have all played critical roles in Herceptin's development, we now have a treatment option that represents a major advance for women with HER2-positive breast cancer before the disease has metastasized. We look forward to continuing our collaboration with Genentech on future Herceptin research."

The most serious side effect of Herceptin is heart failure that requires medical treatment. Due to the risk of heart disease, only certain patients should receive the drug, including:

—Only patients whose tumors are HER2 positive.

—Patients who do not have heart failure or weak heart muscle (cardiomyopathy).

—Patients must be screened for heart function before beginning and during Herceptin treatment.

Less common but serious side effects include infusion reactions (chills, fever, shortness of breath) that rarely are accompanied by lung problems, low white blood counts, and low red blood cell counts.

* * *

FDA Approves Generic Ondansetron

FDA approved first generic versions of Zofran (Ondansetron) Injection and Zofran (Ondansetron) Injection Premixed.

Ondansetron is indicated for the prevention of nausea and vomiting associated with initial and repeat courses of emetogenic cancer chemotherapy and prevention of postoperative nausea and vomiting.

According to the online magazine Drug Topics, Zofran was the 20th most expensive brand-name drug used in hospitals in the U.S., in 2005, with total costs of $839.26 million.

"These approvals will result in significant savings for the American public," said Gary Buehler, director, FDA Office of Generic Drugs. "Generic drugs undergo a thorough scientific and regulatory review, and are safe and effective alternatives to brand name drugs."

Ondansetron Injection packaged in single (4 mg/2 mL) and multi-dose (40 mg/20 mL) vials are manufactured by Teva Pharmaceuticals USA in North Wales, Penn. Ondansetron Injection Premixed, 32 mg/50 mL in 5 percent dextrose is manufactured by SICOR

Pharmaceuticals, Inc. in Irvine, CA. GlaxoSmithKline, the manufacturer of the innovator drug, has agreed to waive the remainder of a six-month exclusivity period to permit approval of the applications submitted by Teva and SICOR Pharmaceuticals.

Breast Cancer:
Study Identifies Those Likely To Benefit From Anti-Estrogens

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same benefit from 5 more years of therapy.

"Based upon our findings, women who are premenopausal at the time of initial therapy and patients who have 4 or more positive lymph nodes will have the greatest potential benefit from the addition of extended adjuvant anti-estrogen therapy," the study concluded. For patients over 60 years old, "the decision needs to be individualized based upon their initial nodal status and presence of comorbidities that would reduce their 5-year life expectancy."

* * *

Racial Disparity Linked To Aggressive Tumors

Malignancies of the breast can be more aggressive and associated with poorer outcome in African-Americans than other races, according to a new study.

Published in the Dec. 1 issue of CANCER, the study reviewed patient data from two different clinical trial protocols and found that African-Americans have tumors with poorer prognostic cellular characteristics and more aggressive clinical presentations, pointing to the possibility that racially influenced tumor biology may contribute to observed racial disparities in breast cancer outcome.

Population-based studies have demonstrated significant differences in breast cancer survival rates based on race, particularly among African-Americans who are more likely to die of their disease than Caucasians. However, other races have been poorly studied. An often hypothesized explanation is socioeconomic differences that impact healthcare and access. Recent data suggest, however, that there may be differences in the tumors at the cellular level that may contribute to poor clinical presentations and outcomes.

Led by Wendy Woodward of the University of Texas M. D. Anderson Cancer Center, researchers reviewed medical records and outcome data from 2,140 Caucasian, Hispanic and African-American breast cancer patients enrolled in clinical trials, controlling for differences in treatment that compromise other studies. Patients were either treated with chemotherapy before (neoadjuvant) or after (adjuvant) mastectomy.

The researchers found that in both treatment groups African-American race was independently associated with poor tumor and clinical characteristics and low survival rates compared to both Caucasian-Hispanic cohorts. For example, African-Americans presented with more advanced disease and were likely to have estrogen-receptor negative tumors. Analysis to control for other confounding factors confirmed that African-American race by itself was associated with lower survival in both treatment groups.

This study, conclude the authors, supports previous data "that African-American women more frequently had ER-negative disease and high-grade tumors and that African-American race was associated with a poorer survival rate."

* * *

Proton Beam Therapy For Early Stage Cancer

Women with early-stage breast cancer may benefit from a new, accelerated approach to radiation therapy making their course of treatment shorter, according to a study in the International Journal for Radiation Oncology-Biology-Physics.

With traditional radiation therapy, patients can expect daily radiation treatments for a period of 6 to 6 1/2 weeks. Doctors in this study, however, wanted to examine the use of proton beam therapy, in an accelerated regimen to determine how well this treatment would be tolerated. This approach to breast cancer treatment would essentially shorten the course of treatment to less than one week while also delivering radiation to only a portion of the breast, thereby sparing the surrounding healthy tissue and organs.

This study was conducted at the Francis H. Burr Proton Therapy Center at Massachusetts General Hospital in Boston with 20 female participants. The women in the study were being treated for stage I breast cancer and received proton beam partial breast irradiation twice a day for four days. There were no given limitations on the type of additional treatment options available for participants. Consequently, patients were allowed to be treated with hormone therapy and chemotherapy at the discretion of their treating oncologists. The majority of the women in this study received hormonal therapy and a few of the patients received chemotherapy.

Patients were then evaluated at different stages of follow-up, at 3 to 4 weeks, 6 to 8 weeks, 6 months and every 6 months after that. Patients were required to undergo annual mammograms after the treatment period and the patients were asked to grade their cosmetic outcome, or their breast's aesthetic appearance.

Early side effects from radiation therapy can include skin irritation at the site of the radiation beam, skin discoloration or thickening of the skin; accelerating the amount of radiation during treatment could increase the instance of side effects.

Patients judged their own breasts under the criteria given to them and the doctors who supervised this study in turn graded the condition of the participants' breasts as well. Patients were also asked to describe their overall satisfaction with the accelerated proton beam partial breast irradiation.

The results showed that all 20 women were found without any evidence of recurrent disease. The initial response to the cosmetic appearance of the patients' breasts, however, was not ideal. Both patients and doctors reported fair to poor cosmesis, but the appearance of the patients' breasts substantially improved in most patients by the 6 month follow-up. According to the study, 95 percent of patients reported total satisfaction with the proton treatments at their latest follow-up visit.

"We hope our team and others will build on these results to ensure breast cancer patients will maximally benefit from the recent, and dramatic, technological advances in our field," said Kevin Kozak, lead author of the study.

Colon Cancer:
Report Urges Heated Chemo To Optimize Patient Survival

Surgery followed by heated chemotherapy delivered through the lower abdomen of the patient before leaving the operating room may significantly increase the life expectancy for patients with stage IV colorectal cancer, according to a consensus statement by 72 oncology surgeons.

HIPEC involves the use of conventional chemotherapy drugs heated to such a high temperature as to kill cancer cells. By bathing the abdomen with heated chemotherapy immediately following surgery, a higher dose of medication can be used than would normally be tolerated by a patient if given intravenously.

According to the report by the Peritoneal Surface Malignancy Group, the published data on the treatment of patients with stage IV colorectal cancer, with combinations of tumor removal surgery and chemotherapy, showed a median survival of greater than 20 months, compared to six-month survival with traditional intravenous chemotherapy alone.

"HIPEC is an aggressive surgical treatment for end-stage cancer patients, with promising results," said Jesus Esquivel, lead author of the consensus statement and director of the peritoneal surface malignancy program at St. Agnes Healthcare in Baltimore. "This innovative therapy, with surgery, is helping to significantly improve, and extend the lives of patients who are in desperate need."

Patients whose colon cancer recurs, and those with cancer that has spread to other parts of the body, involving the abdomen or peritoneal cavity, are the patients who benefited most from the combination of surgery followed by HIPEC.

The consensus statement, "Cytoreductive Surgery and Hyperthermic Intraperitoneal Chemotherapy (HIPEC) in the Management of Peritoneal Surface Malignancies of Colonic Origin," appears on the Web site for the Annals of Surgical Oncology, and can be accessed at http://dx.doi.org/10.1245/s10434-006-9185-7.

* * *

Quality Measures For Surgery

A set of quality measures used to evaluate the quality of care received by patients undergoing surgery for colorectal cancer has been created by researchers at University of California Los Angeles.

Improving the quality of surgical care for colorectal cancer patients is vital as the number of resections continues to increase in an aging population, said Clifford Ko, an associate professor of surgery at UCLA's Jonsson Cancer Center and lead author of the study.

Ko and his colleagues came up with 92 quality of care indicators in six broad areas that encompass everything from surgeon credentials to patient-care provider discussions to medication use. The study is published in the Nov. 15 of the Journal of the National Cancer Institute.

The new quality indicators cover all aspects of surgical care, including a patient's health evaluation before the surgery to the most appropriate surgical techniques to resect varying types of colorectal cancer to creating a list of medications the patient already is taking to avoid dangerous interactions. The new quality indicators, which expand on a set of practice guidelines created by the National Cancer Institute in 2000, also detail the best post-operative patient management practices.

"You can do the best operation in the world, but it doesn't mean much if the patient doesn't do well after surgery," Ko said.

To come up with the quality indicators, Ko and his team carried out structured interviews with leaders in the

field of colorectal cancer surgery, as well as a systematic review of the literature. A panel of 14 colorectal surgeons, general surgeons and surgical oncologists then evaluated the list and rated the indicators for validity, Ko said.

Of the 142 indicators on the original list, 92 were determined to be valid by the panel of experts and now make up the new list of quality indicators.

Ko and his team hope the quality indicators will be used as a checklist by surgeons and others in the community caring for colorectal cancer surgery patients. Most healthcare professionals probably already are doing some of the things on the checklist, Ko said, but the quality measures could serve as a safeguard to ensure that everything that should be done actually gets done.

The indicators will be distributed to healthcare professionals in the community in CD form. Ko said the indicators can be used by individual institutions to measure the quality of their care as well as devise ways to improve it.

* * *

Celebrex For Polyp Prevention

An international team of scientists reports that a single 400-milligram daily dose of Celebrex (celecoxib, Pfizer), significantly reduced recurrence of adenomas, or pre-malignant colon tumors, within three years of previous adenoma removal.

The New England Journal of Medicine published findings from the Prevention of Spontaneous Adenomatous Polyps (PreSAP) study, involving more than 1,550 participants at 107 sites in 32 countries on six continents.

The study was led by Nadir Arber, chairman of the Integrated Cancer Prevention Center and professor of medicine and gastroenterology at the Tel Aviv Sourasky Medical Center, and Bernard Levin, vice president of Cancer Prevention and Population Sciences at University of Texas M. D. Anderson Cancer Center.

"Celecoxib 400 mg once daily significantly reduced colorectal adenoma occurrence, with a greater effect on advanced adenomas," said Arber.

As excess amounts of the protein cyclooxygenase (COX-2) are associated with adenomas and colon cancer, PreSAP researchers studied celecoxib, a selective COX-2 inhibitor, to prevent the pre-cancerous lesions.

"There is no doubt that celecoxib is an effective agent in reducing the size and occurrence of adenomas in patients with higher risks for colorectal cancer," said Levin.

In the placebo-controlled, double-blind PreSAP trial, study leaders randomly assigned participants to receive either a single 400-mg dose of celecoxib (approximately 930 subjects) or a placebo (nearly 630 subjects). Subjects received colonoscopies after one and three years to detect potential pre-malignant tumors and their sizes, as well the overall adenoma burdens for participants. All polyps were removed and examined by study pathologists.

At the conclusion of the trial, the cumulative adenoma rate for the celecoxib study group was 33.6 percent, while the cumulative rate of adenoma development in the placebo group was 49.3 percent (a 36 percent reduction). Celecoxib administration was associated with a 50 percent reduction in larger, potentially more dangerous adenomas.

"Unlike the recent Adenoma Prevention with Celecoxib (APC) trial, we did not find a statistically significant increase in cardiovascular risk associated with the use of 400 mg of celecoxib once daily," said Levin. "That said, because of the significant cardiac side effects seen in the APC study, further cardiovascular research on the use of all anti-inflammatory drugs, such as Celebrex, Aleve and Motrin, as chemoprevention tools is warranted.

"Low dose aspirin also has been shown to reduce adenoma formation in individuals with a prior history of polyps and has the potential to decrease cardiovascular disease risk," said Levin. "However, its use is associated with an increased risk of upper-gastrointestinal bleeding and stroke."

The three-year APC study, with more than 2,000 participants, sought to reduce adenoma size and occurrence through the use of celecoxib. In the study, APC researchers administered celecoxib twice daily at either 200 mg or 400 mg doses. The study showed that the drug nearly doubled cardiovascular risk to participants.

"While our findings are exciting in that they suggest great potential for reducing adenoma formation in patients with high risk for colorectal cancer, we've scratched the surface with the PreSAP trial," said Levin. "Until these impressive prevention results are realized with lessened cardiovascular risk, we cannot advise celecoxib routinely as a tool for colon cancer prevention. Once daily dosing may provide an important insight into ways to diminish the untoward cardiovascular effects of celecoxib."

Levin has served as a consultant for Pfizer, which provided grant support for the PreSAP trial. These arrangements are managed by M. D. Anderson in accordance with its conflict of interest policies.

Childhood Cancer:

Some Long-Term Survivors At Higher Risk Of Stroke

A new study shows that long-term survivors of childhood leukemia and brain tumors are at increased risk of stroke years after their cancer treatment has ended, especially those treated with a particular type of radiation therapy.

The research, conducted as part of the Childhood Cancer Survivor Study (CCSS), was published online Nov. 6 in the Journal of Clinical Oncology.

"This is the first study to show that childhood leukemia and brain tumor survivors are at an increased risk of stroke," said Daniel C. Bowers, associate professor in pediatrics at University of Texas Southwestern Medical School in Dallas and the study's lead author. "These strokes can occur 10 to 20 years after diagnosis, when most people believe they are no longer at risk for new side effects of treatment, underscoring the need for long-term medical follow-up for childhood cancer survivors."

Leukemia and brain tumors together account for 53% of all cancers diagnosed in children younger than 15. Current five-year survival rates are nearly 80% for leukemia and 74% for brain tumors, making the long-term side effects of treatment for these cancers an important area of study. Treatment for both diseases involves therapy that targets the central nervous system; treatment for brain tumor patients usually involves moderate or high-dose radiation therapy to the brain (known as cranial radiotherapy). For leukemia patients, treatment includes drugs injected directly into the spinal fluid that bathes the brain and sometimes includes cranial radiotherapy.

CCSS researchers surveyed 4,828 leukemia survivors and 1,871 brain tumor survivors, as well as a control group of 3,846 of their siblings who had not had cancer, about their history of stroke. Among leukemia survivors, the occurrence of stroke was 0.8% (one in every 125 survivors), compared with 0.2% (one in every 500 survivors) for the control group. The mean interval from leukemia diagnosis to stroke was 10 years. For brain tumor survivors, the occurrence of stroke was 3.4% (one in 30 survivors), and as high as 6.5% (one in 15 survivors) for patients who had been treated with both cranial radiotherapy and chemotherapy. Among brain tumor survivors, the mean interval from cancer diagnosis to stroke following treatment was 14 years.

The authors noted that other late effects of childhood cancer treatment include secondary cancers, neurocognitive deficits, hormone deficiencies, cardiac problems, obesity, and short stature.

"It is important for survivors and their doctors to know that the impact of some of these long-term effects can be reduced through careful follow-up screening and care, and education to help survivors stay healthy long after their treatment has ended," Bowers said. "This study shows that we're not there yet. These efforts must be increased and improved."

Multiple Myeloma:

Lenalidomide, An Altered Thalidomide, Shows Promise

A designer drug significantly less toxic than thalidomide has shown impressive activity in prolonging survival of patients with advanced multiple myeloma, report researchers from Dana-Farber Cancer Institute.

A multi-center phase II study of lenalidomide, an altered version of thalidomide, found a response rate of 25 percent among patients with myeloma that had recurred despite multiple prior therapies. Especially important was that long-lasting responses averaging 28 months were seen. When another drug, dexamethasone, was added in patients who were not benefiting from lenalidomide alone, the response rate was improved in a third.

"This is very encouraging," said Paul Richardson, the Dana-Farber physician who is lead author and principle investigator of the study. "We have already begun testing lenalidomide in combination with both dexamethasone and bortezomib."

The findings, which will be published in the journal Blood, currently are available on the journal's Web site, www.bloodjournal.org.

The study involved 102 patients, randomly picked to receive the drug in once-daily or twice-daily doses. The patients' myeloma had relapsed despite having stem cell transplant (61 percent of participants), bortezomib (18 percent), and/or thalidomide (76 percent). The study showed that, when lenalidomide was given as a single dose each day for 21 days, only a few patients reported significant fatigue, neuropathy (nerve damage), and constipation. The daily dosing proved better tolerated than the twice daily regimen.

The most troublesome side effects were decreases in blood cell counts caused by the drug's suppression of bone-marrow function, although these proved manageable with dose reduction and growth factor support. Overall, three cases of deep venous thrombosis were seen, and only when dexamethasone was added.

The regimen defined in this study and the observation that the addition of dexamethasone was beneficial provided the basis for the large phase III trials that led to the drug's recent approval by the Food and Drug Administration. The Dana-Farber team participated in these studies and also led the phase I, II, and pre-clinical development of this agent.

Ovarian Cancer:

Book Offers Info For Women Considering Ovary Removal

Fox Chase Cancer Center, with support from the Sandy Rollman Ovarian Cancer Foundation, has published a book designed to present information women need as they consider risk-reducing surgery for ovarian cancer.

The book, titled "Ovarian Cancer Risk-Reducing Surgery: A Decision-Making Resource," is for women considering removal of their ovaries for cancer prevention (prophylactic oophorectomy).

"This resource covers topics that help women understand their risk of ovarian cancer and what they need to know if they are going to have risk-reducing surgery," said Mary Daly, director of the Margaret Dyson Family Risk Assessment Program and senior vice president for population science at Fox Chase. "Each section offers women a list of questions to discuss with a health-care team."

The book is available free of charge by sending an e-mail to surgerybook@fccc.edu.

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

Phase I and Pharmacokinetic Study of Oral 3-Aminopyridine-2-Carboxaldehyde Thiosemicarbazone in the Treatment of Advanced Solid Tumors. City of Hope National Medical Center, protocol 7225, Yen, Yun, 626-256-4673.

Phase I Trial of CC-5013 (Lenalidomide) and CCI-779 in Patients with Relapsed or Refractory Multiple Myeloma. Ohio State University Hospital, protocol 3507, Hofmeister, Craig, phone 614-293-3507.

Phase I Study of Halichondrin B Analog E7389 in Combination with Cisplatin in Advanced Solid Tumors. City of Hope, protocol 7427, Koczywas, Marianna, phone 626-359-8111, ext. 63155.

Phase I Study of Halichondrin B Analog E7389 in Combination with Gemcitabine Patients with Refractory or Advanced Solid Tumors. University Health Network-Princess Margaret Hospital, protocol 7444, Goel, Rakesh, phone 613-737-7700, ext 70171.

Phase II

Phase II Study of CCI-779 in Combination with Bevacizumab in Stage III or IV Melanoma. University of Virginia, protocol 7190, Slingluff, Craig Lee, phone 434-924-1730.

Phase II Study of MLN518 in Patients with Metastatic Clear Cell Renal Cell Carcinoma. Case Western Reserve University, protocol 7401, Garcia, Jorge, phone 216-444-7774.

Phase II Study of the Halichondrin B Analog E7389 in Patients with Advanced Non-Small Cell Lung Cancer Previously Treated with a Taxane. City of Hope National Medical Center, protocol 7437, Gitlitz, Barbara Jennifer, 323-865-3959.

Phase II Trial of Cetuximab and Bevacizumab in Patients with Recurrent or Metastatic Head and Neck Cancer. University of Pittsburgh, protocol 7440, Argiris, Athanassios, phone 412-658-6575.

Phase II Trial of VEGF Trap in Patients with Previously Treated Metastatic Colorectal Cancer. University Health Network-Princess Margaret Hospital, protocol 7498, Moore, Malcolm Joseph, phone 416-964-2263.

Phase II Study of VEGF Trap in Patients with Recurrent or Metastatic Transitional Carcinoma of the Urothelium. City of Hope National Medical Center, protocol 7533, Twardowski, Przemyslaw, phone 626-359-8111, ext. 2307.

Phase II Study of AZD0530 in Patients with Previously Treated Metastatic Colorectal Cancer. M.D. Anderson Cancer Center, protocol 7565, Eng, Cathy, phone 713-792-2828.

Phase II Study of Flavopiridol in Timed Sequential Combination with Cytosine Arabinoside(ara-C) and Mitoxantrone for Adults with Newly Diagnosed, Previously Untreated Poor-Risk Acute Myelogenous Leukemias. Johns Hopkins University, protocol 7845, Karp, Judith, phone 410-502-7726.

Phase II Study of Sunitinib Malate in Patients with Previously Treated Pancreatic Adenocarcinoma with Measurable Metastatic Disease Following Progression on Front-Line Gemcitabine-Based Therapy. Cancer and Leukemia Group B, protocol CALGB-80603, O'Reilly, Eileen, 212-639-6672.