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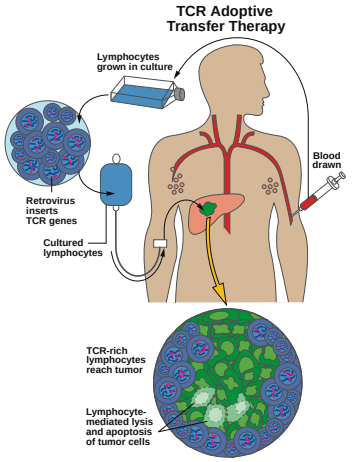
Gene Therapy Offers Treatment for Metastatic Melanoma

NCI researchers, led by Dr. Steven A. Rosenberg, chief of surgery in NCI's Center for Clinical Research (CCR), achieved sustained regression of advanced melanoma by genetically engineering a patient's own white blood cells to recognize and attack cancer cells, as reported online August 31 in *Science*.

The treatment resulted in tumor regression for 2 of 17 patients: a 52-year-old man with advanced melanoma that had spread subcutaneously and to his liver, and a 30-year-old man whose melanoma had metastasized to his lymph nodes. Both men have remained disease-free more than a year after their treatment.



This represents a promising advance in the use of gene therapy to treat cancer. "Technical issues remain to be resolved, but the relative ease

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Director's Update

Guest Update by Dr. Asad Umar

Dr. Asad Umar, Acting Chief, Gastrointestinal and Other Cancers Research Group, Division of Cancer Prevention

NCI Committed to Colorectal Cancer Prevention

Over the last several years, there has been important progress in clinical research testing the cyclooxygenase-2 (COX-2) inhibitor celecoxib (Celebrex) to prevent the recurrence of colon polyps in individuals who have had such polyps removed. This includes the recently published efficacy results of two phase III trials—the Adenoma Prevention with Celecoxib (APC) and PreSAP trials—both of which demonstrated a significant reduction in the recurrence of colon polyps among participants taking celecoxib compared with placebo.

These trials, however, were not entirely positive for the safety profile of celecoxib. According to an NCI-funded independent safety analysis of data from both trials, there is an increased risk of serious adverse

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(Gene Therapy continued from page 1)
of this gene therapy approach will allow for testing in a broad array of tumors other than melanoma," said Dr. Lee Helman, acting scientific director for clinical science in CCR. "Application to other cancers is a very exciting possibility."

The two patients who experienced regression of their melanomas maintained high levels of genetically altered lymphocytes over the course of the study. Two months after receiving gene therapy, all patients in the last two of three treatment groups still had 9 to 56 percent of their genetically modified lymphocytes. No patients experienced toxic side effects attributed to the gene therapy treatment.

The researchers converted each person's own white blood cells, or autologous lymphocytes, into cancer-fighting cells in the laboratory. They accomplished this by drawing a small sample of blood containing normal lymphocytes from each patient and infecting the cells with a retrovirus. The retrovirus delivers genes that encode T-cell receptors (TCRs) into cells.

When the genes are turned on, TCRs are manufactured and line the outer surface of the lymphocytes. The TCRs then recognize and bind to certain molecules on the surface of tumor cells and activate the lymphocytes to destroy the tumor cells.

In a process called adoptive cell transfer, the newly engineered autologous lymphocytes were infused back into 17 patients with advanced metastatic melanoma. The first of three patient groups consisted of three patients who showed no delay in the progression of their disease. As the study evolved, the researchers improved the treatment process of lymphocytes in the lab so that the cells could be administered in their most active growth phase, resulting in successful therapy for two patients in the second and third groups.

Approaches to increase the expression and function of the engineered TCRs, including the development of TCRs that can bind more tightly to tumor cells, as well as further improving delivery methods using retroviruses, are under investigation. The researchers have also isolated TCRs that recognize cancers other than melanoma.

"At present, we are treating advanced melanoma patients using adoptive transfer of genetically altered lymphocytes, and we have now expressed other lymphocyte receptors that recognize breast, lung, and other cancers," said Dr. Rosenberg. ◆

By Heather Maisey

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cardiovascular events associated with the daily use of celecoxib, particularly at higher doses. Celecoxib, the analysis found, can significantly increase blood pressure, which could possibly account for the increased cardiac risk. This must be investigated further, however. (Detailed information on the results of these studies and NCI-supported studies involving celecoxib are available on the NCI Web site.)

Despite these findings of increased cardiovascular adverse event risk, celecoxib is still the only FDA-approved drug used in conjunction with surgery to reduce the number of colorectal polyps in individuals with a hereditary condition called familial adenomatous polyposis (FAP). Based on the abundance of data demonstrating its efficacy in reducing the risk of precancerous colon polyps, NCI remains committed to investigating celecoxib for the prevention of colorectal cancer in a broader population at higher risk of developing cancer.

At NCI, we believe it is a clinical imperative to make cancer prevention a reality, particularly for a cancer that is as pervasive and deadly as colorectal cancer, of which 150,000 new diagnoses are made each year.

This will require altering how the research community approaches cancer prevention. In the treatment realm, once a drug is found to be effective, rarely is it abandoned purely because of toxicity concerns. Rather, additional research is performed to understand its toxicities while striving to minimize risks and maximize effectiveness.

To make greater advances in cancer prevention research, we are moving toward "molecular prevention": identifying molecular markers that can help us discern who is most likely to benefit from the drug as a cancer prevention agent.

In NCI's Division of Cancer Prevention, Dr. Iqbal Ali led a study published in 2004, for example, that used proteomic technologies to identify which individuals with FAP were most likely to benefit from celecoxib. Dr. Ali is continuing this research in other high-risk cohorts and preliminary results are encouraging.

More work in the laboratory and with animals should help us identify why celecoxib increases blood pressure and whether that underlies the increased cardiac risk associated with its use. In addition, more research is needed to understand the effect of different dosing regimens on cardiovascular toxicity and chemopreventive efficacy.

The challenge is to pursue the necessary science in a most efficient manner to translate the promise of cancer prevention into practice with minimum toxicity and maximum efficacy. ◆

Cancer Research Highlights

New Models of Breast Cancer Risk Focus on Breast Density

Two new models for assessing a patient's risk of developing breast cancer focus on breast density as an important predictor. The two studies are reported in the September 6 *Journal of the National Cancer Institute*.

In the first study, Dr. William E. Barlow of Cancer Research and Biostatistics, and Group Health Cooperative in Seattle, and colleagues identified 11,638 women diagnosed with breast cancer within the Breast Cancer Surveillance Consortium, a large prospective study of mammography in clinical practice in the United States. The study developed prediction models for pre- and postmenopausal women and used breast density reported as part of routine screening mammography by radiologists in clinical practice. The factors predicting risk in premenopausal women were limited to age, breast density, family history of breast cancer, and prior breast procedure. These factors also predicted risk for postmenopausal women, as did the additional risk factors of ethnicity, body mass index, natural menopause, use of hormone therapy, and a prior false-positive mammogram.

"The models establish breast density as a highly clinically significant predictor of breast cancer risk that is almost as powerful a risk factor as age…Nonetheless, ability to accurately predict breast cancer at the individual level remains limited," the authors wrote. However, these models may be helpful in identifying women at high risk for breast cancer who may benefit from preventive interventions or more intensive surveillance.

The second study, headed by Drs. Jinbo Chen and Mitchell H. Gail of NCI's Division of Cancer Epidemiology and Genetics, assessed the absolute risk of developing breast cancer using an updated version of the Gail model. The Gail model was developed in the 1980s to assess the risk of breast cancer for women who undergo annual mammography screening.

The new model included breast density, weight, age at first live birth, number of benign breast biopsy examinations, and number of first-degree relatives with breast cancer. The researchers investigated whether information on breast density, which was available for 7,251 women in the Breast Cancer Detection Demonstration Project (BCDDP), could improve absolute breast cancer risk projections compared with an earlier version of the Gail model, which was also based on BCDDP data.

The new model predicted higher risks than the previous model in women with high breast density, and previous analyses indicated that the new model had modestly higher discriminatory accuracy. However, Dr. Gail cautioned, "Independent validation studies are needed before we would recommend using this model for counseling."

Celecoxib Significantly Reduces the Risk of Precancerous Colorectal Polyps

The final results of two phase III clinical trials indicate that regular use of the COX-2 inhibitor celecoxib (Celebrex) significantly reduces the risk of precancerous polyps reoccurring in the colon or rectum.

In the NCI and Pfizer cosponsored APC trial and the Pfizer-sponsored PreSAP trial, risk reductions as great as 45 percent were seen in patients taking celecoxib compared with placebo. Participants receiving celecoxib in both trials had fewer new adenomas and, perhaps more importantly, fewer new advanced adenomas than those on placebo. The results were published in the August 31 *New England Journal of Medicine (NEJM).*

As reported previously, celecoxib use in both trials was also associated with a statistically significant increased risk of cardiovascular events. According to an NCI-funded independent safety analysis of the trials' results, published in the September 5 *Circulation,* when event data from both trials were combined, there was a nearly twofold increased risk of cardiac events in patients taking celecoxib.

The analysis also revealed dose-related increases in cardiovascular events and blood pressure, leading the authors to speculate that the increased cardiac events might be related to elevated blood pressure and that lower doses of the drug might have a wider safety margin with respect to cardiovascular disease while still reducing cancer risk.

In an *NEJM* editorial, Drs. Bruce Psaty from the University of Washington and John Potter from the Fred Hutchinson Cancer Research Center argued that, based on the available evi-

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(Highlights continued from page 3)
dence, celecoxib "has no role as a chemopreventive agent either in patients with nonfamilial colonic adenomas or in the general population."

But in the view of APC co-author Dr. Ernie Hawk, director of NCI's Office of Centers, Training & Resources, a more complex set of conclusions is warranted. "Celecoxib is already used by patients with familial adenomatous polyposis, who have a much higher risk of cancer than patients on the APC and PreSAP trials do. The high degree of efficacy demonstrated in the APC and PreSAP trials should provide major incentive for researchers to define the agent's mechanisms of action more fully with regard to benefits as well as risks."

Overweight, Obesity in Midlife Increases Risk of Mortality

NCI researchers, in collaboration with AARP, found that being overweight during midlife is linked to an increased risk of death, according to study results in the August 24 *New England Journal of Medicine*.

The study, led by Dr. Kenneth Adams of NCI's Division of Cancer Epidemiology and Genetics (DCEG), monitored the health status of 527,265 Americans aged 50–71 from 1995 to 2005 using mailed questionnaires and death records. The study's participants included 186,000 nonsmoking men and women. This allowed researchers to account for confounding factors of smoking, preexisting disease, age, race/ethnicity, education, physical activity, and alcohol consumption. The study accounted for preexisting chronic disease by asking participants to report their weight at age 50. Examining weight at an earlier age provides a measure of typical adult weight that is largely unaffected by the onset of chronic disease.

"We reasoned that BMI at age 50 gives a more accurate representation of the amount of excess weight a person was exposed to over many years," said Dr. Michael F. Leitzmann of DCEG, the study's senior author.

BMI analysis of nonsmokers at age 50 found that the risk of mortality among participants who were overweight increased by 20 to 40 percent, while mortality risk among obese participants increased two- to threefold.

Excess body weight is known to increase the risk of several cancers as well as heart disease, stroke, high blood pressure, pulmonary disease, and diabetes.

Suicidality Increased in Adult Survivors of Childhood Cancer

Even modern cancer treatments can result in significant, lasting physical and emotional side effects. Previous studies have shown that individuals diagnosed with cancer have an increased risk of suicide, but few studies have focused on the risk in cancer survivors years later. A new study in the August 20 *Journal of Clinical Oncology* indicates that adult survivors of childhood cancer have an increased risk of suicidal thoughts and suicide attempts.

Researchers from Dana-Farber Cancer Institute conducted the study, which included 226 survivors of childhood cancer participating in routine psychological screening at a multidisciplinary cancer survivor clinic. Patients provided demographic information; treatment methods were determined from medical records. All patients were asked standard questions designed to measure physical functioning, mental health, and suicidality. Out of the 226 participants, 29 (12.83 percent) reported suicidality. Longer time since diagnosis and treatment with cranial radiation were both associated with suicidality, as were the self-reported variables of depression, hopelessness, pain, and concern about appearance. Only 11 out of the 29 patients with suicidal symptoms were clinically depressed, indicating that factors such as physical functioning and pain should also be monitored during follow-up care.

The authors acknowledge that their study may be limited by the fact that all participants were taken from a single survivorship clinic, and may not be representative of cancer survivors from other institutions or socioeconomic backgrounds. Patients actively seeking follow-up care may also have more physical and emotional problems than the general population of survivors. Nonetheless, stated the authors, "This study demonstrated that suicidal symptoms are meaningfully related to cancer treatments and post-treatment health, even many years after completion of therapy." ◆

CCR Grand Rounds

September 12: Dr. Steven M. Larson, Chief, Nuclear Medicine Service; Memorial Sloan-Kettering Cancer Center. "Molecular Imaging in Drug Discovery."

September 19: Dr. Samuel Strober, Professor of Medicine, Stanford University School of Medicine. "Harnessing the Power of Graft Anti-tumor Activity after Bone Marrow Transplantation."

CCR Grand Rounds are held 8:30 to 9:30 a.m. at the NIH campus in Bethesda, Md., in the Clinical Center's Lipsett Amphitheater. ◆

Spotlight

After Avastin, Testing Theories about Blood Vessels and Cancer

Blood vessels are the lifelines of tumors, and they are increasingly the focus of cancer treatments. More than 400 clinical trials are testing ways to prevent blood vessels from supplying tumors with the nutrients and oxygen they need to grow.

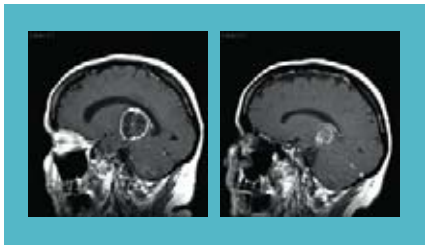
The best known strategy is to inhibit the growth of new blood vessels—angiogenesis—in and around tumors. The drug bevacizumab (Avastin) was designed to do this by blocking a protein called vascular endothelial growth factor (VEGF), which is a regulator of angiogenesis.

Since 2003, studies have shown that adding bevacizumab to standard chemotherapy can increase the survival of patients with advanced lung cancer or metastatic colorectal cancer. The combination has also benefited women with metastatic breast cancer.

Some of the newer "multitargeted" drugs inactivate the receptor protein for VEGF on cells as well as other proteins involved in tumor growth. Two of these, sunitinib (Sutent) and sorafenib (Nexavar), have benefited patients with advanced kidney cancer.

With mounting evidence that antiangiogenic drugs help certain patients, researchers are trying to understand how the drugs achieve their effects. For now at least, there are more theories than answers.

The conventional view of bevacizumab is that the drug inhibits the development of tumor blood vessels, a hypothesis that originated with the pioneering research on angiogenesis by Dr. Judah Folkman in the 1970s.



Courtesy of Drs. Tracy Batchelor and Scott Plotkin, Massachusetts General Hospital

MRI shows tumor regression in a woman with recurrent glioblastoma before (left) and after (right) treatment with bevacizumab and CPT-11.

But the fact that bevacizumab has demonstrated a benefit when added to chemotherapy raises the question: If bevacizumab diminishes the tumor blood supply and reduces blood flow to tumors, how does chemotherapy reach its targets?

"It's a very interesting paradox," says Dr. Rakesh Jain, a professor of tumor biology at Harvard Medical School. Five years ago he proposed an additional hypothesis to explain how certain antiangiogenic drugs work.

These drugs, he suggests, prune some blood vessels and structurally improve the remaining ones (tumor vessels are often inefficient and leaky). The result is "normalized" vessels that improve the delivery of oxygen and chemotherapy to tumors.

"This is a fascinating theory elegantly worked out in the lab, and now we need to see if it works in people," says Dr. Percy Ivy of NCI's Cancer Treatment and Evaluation Program (CTEP), who oversees clinical trials involving antiangiogenic agents.

A small trial testing bevacizumab for rectal cancer provided support for the hypothesis last year. The drug normalized the tumor blood vessels of 11 patients after 12 days, Dr. Jain and his colleagues reported.

Other trials are exploring the hypothesis, including a phase II study testing an experimental drug for recurrent glioblastoma brain tumors.

The primary goal of the study is to assess the benefits of the therapy, but the researchers will also use magnetic resonance imaging to study the effects of the drug on the function of blood vessels over time.

"We hope to use imaging tools to see if normalization is occurring in patients," says lead investigator Dr. Tracy Batchelor of Massachusetts General Hospital. The drug, AZD2171, selectively inhibits signals from the VEGF receptor.

Theories about antiangiogenic treatments are not mutually exclusive, Dr. Batchelor adds: "You may be improving blood flow to a tumor at one time and restricting blood flow at another."

Indeed, a drug may work through different mechanisms at different times, says Dr. Helen Chen of CTEP, who studies bevacizumab. Therapy is often given for months, and the mechanisms of action may vary depending on the stage of treatment, she says.

If normalization does occur, physicians might want to know so they could deliver antitumor drugs at optimal times. To learn about timing, Dr. Batchelor's team will collect images throughout treatment.

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Funding Opportunities

Following are newly released NCI research funding opportunities:

Innovations in Biomedical Computational Science and Technology Initiative

Announcement Number: PAR-06-534
Application Receipt Date: Sept. 24, 2006

This is a renewal of PAR-06-089 and will use the R41/R42 award mechanism. For more information, see http://cri.nci.nih.gov/4abst.cfm?initiativeparfa_id=3525. Inquiries: Dr. Peter Lyster—lysterp@mail.nih.gov

Innovations in Biomedical Computational Science and Technology Initiative

Announcement Number: PAR-06-535
Application Receipt Date: Sept. 24, 2006

This is a renewal of PAR-06-088 and will use the R43/R44 award mechanism. For more information, see http://cri.nci.nih.gov/4abst.cfm?initiativeparfa_id=3526. Inquiries: Dr. Peter Lyster—lysterp@mail.nih.gov

Technology Development of Image-Guided Interventions: Phase I

Announcement Number: RFA-EB-06-003
Letter of Intent Receipt Date: Sept. 25, 2006
Application Receipt Date: Oct. 23, 2006

This funding opportunity will use the R21 award mechanism. For more information, see http://cri.nci.nih.gov/4abst.cfm?initiativeparfa_id=3529. Inquiries: Dr. Keyvan Farahani—farahank@mail.nih.gov. ◆

Featured Clinical Trial

Bevacizumab for Hormone-Refractory Prostate Cancer

Name of the Trial
Phase III Randomized Study of Docetaxel and Prednisone with Versus without Bevacizumab in Patients with Hormone-Refractory Metastatic Adenocarcinoma of the Prostate (CALGB-90401). See the protocol summary at http://cancer.gov/clinicaltrials/CALGB-90401.

Principal Investigator
Dr. W. K. Kelly, Cancer and Leukemia Group B

Dr. W. K. Kelly

Why This Trial Is Important
At initial diagnosis, most cases of prostate cancer are "hormone dependent," meaning they require androgens (male sex hormones) to grow. Hormone-dependent prostate cancer is often treated with therapies aimed at depriving the cancer of the needed hormones. Although initially effective, these hormonal therapies eventually fail because prostate cancers ultimately develop the ability to grow in the absence of androgens. Such cancers are called androgen-independent or hormone-refractory prostate cancers.

In this trial, men with hormone-refractory prostate cancer that has spread (metastasized) will receive standard chemotherapy with the drugs docetaxel and prednisone. Half of the participants will be randomly assigned to additionally receive treatment with a monoclonal antibody called bevacizumab.

Bevacizumab blocks the activity of a protein called vascular endothelial growth factor (VEGF). Many cancers use VEGF to help form the new blood vessels they need for continued growth. Furthermore, high levels of VEGF in the blood and urine of patients with hormone-refractory prostate cancer have been found to indicate a reduced likelihood of survival.

"A previous phase II clinical trial that combined docetaxel and bevacizumab resulted in improved outcomes over historical controls," said Dr. Kelly. "This phase III trial will answer the question of whether adding bevacizumab to docetaxel and prednisone actually does improve survival over the current standard of care."

Who Can Join This Trial
Researchers will enroll 1,020 men with metastatic prostate cancer that is progressing despite previous hormone therapy. See the list of eligibility criteria at http://www.cancer.gov/clinicaltrials/CALGB-90401.

Study Sites and Contact Information
Study sites in the United States are recruiting patients for this trial. See the list of study contacts at http://www.cancer.gov/clinicaltrials/CALGB-90401 or call NCI's Cancer Information Service at 1-800-4-CANCER (1-800-422-6237) for more information. The toll-free call is confidential. ◆

An archive of "Featured Clinical Trial" columns is available at http://cancer.gov/clinicaltrials/ft-all-featured-trials.

Notes

NCI, FDA, Standards Institute to Collaborate on Nanotech Activities

NCI, the Food and Drug Administration, and the National Institute of Standards and Technology recently announced an interagency Memorandum of Understanding (MOU) to collaborate on oncology-related issues in nanotechnology development for clinical benefit and the standardization of approaches for evaluating nanotechnology devices and materials for cancer diagnosis and treatment.

The goal of the MOU is to develop safe and effective cancer therapies using nanotechnology. The collaboration will focus primarily on the Nanotechnology Characterization Laboratory—which performs preclinical efficacy and toxicity testing of nanoparticles—by establishing a framework for effective risk identification, assessment, and evaluation of emerging nanotechnology products. The laboratory serves as a national resource and knowledge base for all cancer researchers to facilitate the regulatory review of nanotechnologies intended for cancer therapies and diagnostics. Additional information is available at http://ncl.cancer.gov/index.asp.

New Members Appointed to DCLG

NCI Acting Director Dr. John Niederhuber has indicated his intent to appoint four new members to the NCI Director's Consumer Liaison Group (DCLG), NCI's only all-consumer advisory committee. The four new members, Dr. Grace L. Butler, Yvette Colón, Kelly L. Cotter, and Alan Kaye, would serve terms from 2006 through 2010. Two current members, Celeste Whitewolf and Margaret Anthony, have been reappointed for terms from 2006 through 2008. Dr. Niederhuber has also appointed current member Dr. Beverly Laird as DCLG vice chair and extended her term to 2008. Doug Ulman remains the chair. The DCLG charter has been renewed and the membership of the committee has been increased from 15 to 16 members. More information on DCLG is available at http://dclg.cancer.gov.

NCI Hosts Science Writers' Seminar on Cancer in Minority Populations

On September 6, from 1:00–3:00 p.m., NCI will host a Science Writers' Seminar on cancer rates in minority populations. The seminar will take place in the Natcher Conference Center, Room F1/F2, on the NIH campus in Bethesda, Md.

Topics will include the latest cancer statistics from the "Annual Report to the Nation," published that day in *Cancer.* In addition, four prominent scientists will explain how rates are changing in minority populations and what these trends mean for detecting and treating cancer effectively. Dr. Brenda Edwards of NCI will discuss perspectives on the "Annual Report to the Nation," Dr. Elmer Huerta of George Washington University will present information on cancer detection and prevention in Latino communities, Dr. Barry Miller of NCI will describe Latino cancer rates, and Dr. Grace Ma of Temple University will discuss acculturation in Asian American populations.

For additional information, contact the NCI Media Relations Branch at 301-496-6641 or ncipressofficers@mail.nih.gov. ◆

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Other researchers are testing a strategy known as "metronomic" chemotherapy. This involves administering low doses of chemotherapy frequently and without continuous interruption. The goal is to achieve antiangiogenic effects by not allowing time for tumor blood vessels to repair themselves after being injured by chemotherapy, while limiting toxicity to normal tissues.

Yet another theory proposes that anti-VEGF therapies may directly affect tumor cells, an idea that emerged with the recent discovery of VEGF receptors on some tumor cells.

"It's possible that these therapies may be diminishing the survival of tumor cells and making them more sensitive to chemotherapy," says Dr. Lee Ellis of the University of Texas M.D. Anderson Cancer Center.

Dr. Ellis is also studying the role of nitric oxide in mediating changes to blood vessels after anti-VEGF therapy.

"The smart approach is to assume that there are multiple mechanisms of action," he says. "Biology is not linear, and it's not simple. If any of us thinks there's only one mechanism, then we're going to miss opportunities to understand how these drugs work."

This research is driven partly by the need to identify patients who might benefit from these drugs—a growing priority, given the expense and potentially toxic side effects of the drugs. But the results may advance the field in unexpected ways.

"All of these studies contribute to our understanding of tumor biology, and the insights we gain will lead to the development of new agents," says Dr. Ivy. ◆

—By Edward R. Winstead

CCOP Profile

Upstate Carolina Community Clinical Oncology Program

Principal Investigator: Dr. James D. Bearden, III • Gibbs Regional Cancer Center, 101 E. Wood Street, Spartanburg, SC 29303 • Phone: 864-560-7050 • Web site: http://www.gibbscancercenter.com

Background and History

The Upstate Carolina Community Clinical Oncology Program (UC-CCOP) has achieved a national reputation for excellence in community cancer care through its 22-year participation in NCI programs. In 2003, UC-CCOP was highlighted by NCI as one of 27 CCOPs continuously funded since 1983. Dr. James D. Bearden, III, has acted as principal investigator since its inception.

UC-CCOP has eight research base affiliations, along with the NCI Cancer Trials Support Unit. AnMed Health in Anderson, S.C., as well as the Rutherford Cancer Resource Center in North Carolina are among the UC-CCOP affiliates.

Community Characteristics

UC-CCOP is housed in the Gibbs Regional Cancer Center on the campus of Spartanburg Regional Healthcare System (SRHS), one of South Carolina's largest community-based health care providers. Offering the latest in cancer, heart, women's, and orthopedic care, SRHS is also home to South Carolina's only accredited stroke and chest pain centers. SRHS has been named a "Top 100" hospital for computer technology and has received awards for patient satisfaction and nursing care. In 2005, Gibbs Regional Cancer Center at SRHS became one of only seven cancer centers worldwide to form an alliance with M.D. Anderson Cancer Center in Houston.

Outreach Activities

UC-CCOP has employed a variety of techniques to enroll patients in studies. Physician education and outreach is a primary focus. Community outreach and education on a grassroots level has been extremely successful, with UC-CCOP nurses and other staff reaching out through educational events and community groups. Consumer advertising has also been used for large trials.

Gibbs Regional Cancer Center

Awards and Other Notable Aspects of the Program

In June 2004, UC-CCOP was honored by the American Society of Clinical Oncology (ASCO) for its commitment to cancer research. The Clinical Trials Participation Award recipients were selected by each of the NCI Cooperative Groups and the ASCO Clinical Practice Committee. Awards went to those entities that enrolled the highest number of patients to phase III trials over a 3-year period.

Accrual of minority patients to studies has been an important focus of UC-CCOP. It has averaged 20 to 25 percent accrual in treatment trials and 15 to 20 percent minority recruitment to cancer control trials.

Total accrual to the SELECT trial was 1,338 men, the second highest total in the nation, including 197 African American men (15 percent), which placed UC-CCOP fourth nationally in minority accrual. UC-CCOP has 1,286 men in follow-up for the SELECT trial. Total accrual to the PREADVISE study (adjunct to SELECT, looking at Alzheimer's disease) is 402 men, ranking UC-CCOP second nationally.

Additionally, UC-CCOP earned a first-place national ranking by enrolling a total of 39 African American women to the STAR Trial.

Between June 1, 2001 and May 31, 2006, a total of 7,840 patients were accrued to and/or followed on NCI protocols. UC-CCOP has more than 2,300 clinical trial participants in active follow-up. ◆

The *NCI Cancer Bulletin* is produced by the National Cancer Institute (NCI). NCI, which was established in 1937, leads the national effort to eliminate the suffering and death due to cancer. Through basic, clinical, and population-based biomedical research and training, NCI conducts and supports research that will lead to a future in which we can identify the environmental and genetic causes of cancer, prevent cancer before it starts, identify cancers that do develop at the earliest stage, eliminate cancers through innovative treatment interventions, and biologically control those cancers that we cannot eliminate so they become manageable, chronic diseases.

For more information on cancer, call 1-800-4-CANCER or visit http://www.cancer.gov. Contact the *NCI Cancer Bulletin* staff at ncicancerbulletin@mail.nih.gov.