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NCI To Expand Quality Of Care Research, Lead HHS Panel On Cancer Care Policy

Administration officials have designated NCI as the lead agency that would research and define quality cancer care and work with other agencies to ensure that high quality cancer care is delivered through health programs administered by the Department of Health and Human Services.

"The issue is straightforward," NCI Director Richard Klausner said to the National Cancer Advisory Board at a Sept. 23 meeting.

"It is time for us to speak more forcefully, clearly, and continually that what the NCI is about—the generation of information, evidence, and the asking of questions—has the ultimate goal of improving the quality of care in cancer and reducing the burden of disease."

Klausner said the initiative puts NCI in "a leadership role across the

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In Brief:

Lasker Awards Recognize Six Scientists; NCAB Honors Vande Woude For Work At NCI

ALBERT LASKER Medical Research Awards will be presented on Oct. 1 to six scientists. Winners of the Albert Lasker Award for Basic Medical Research are **Clay Armstrong,** University of Pennsylvania School of Medicine; **Bertil Hille,** University of Washington; and **Roderick MacKinnon,** Rockefeller University, for pioneering research elucidating the functional and structural architecture of ion channel proteins. **David Cushman** and **Miguel Ondetti**, both of Bristol-Myers Squibb Pharmaceutical Research Institute, will receive the Lasker Award for Clinical Medical Research for the development of an innovative approach to drug design based on protein structure and using it to create ACE inhibitors. **Seymour Kety,** Harvard Medical School, will receive the Lasker Award for Special Achievement in Medical Science, honoring a lifetime of contributions to neuroscience. . . . **GEORGE VANDE WOUDE**, director of the NCI Division of Basic Sciences for the past 16 months and a prominent scientific administrator working within or as a contractor to NCI for the past 27 years, received a plaque from the National Cancer Advisory Board last week commending him for his service to the Institute. Vande Woude plans to leave NCI on Oct. 8, to take his new position as director of the Van Andel Research Institute, in Grand Rapids, MI. Last year, Vande Woude had announced his intention to move to the new institute (**The Cancer Letter**, May 22, 1998). Vande Woude, an expert in molecular oncology, served since 1995 as advisor for basic

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Shalala Approves NCI Proposal On Quality Of Care Research

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department to direct the important questions about quality of care."

NCI's willingness to become fully involved in setting the standards for quality care represents a significant departure from the past practice of simply handing off data to the policy-makers. The Institute began moving in that direction several years ago when it worked with the Veteran's Administration and the Department of Defense to develop agreements on participation in cancer clinical trials of individuals covered by the military insurance programs.

Under a proposal approved by HHS Secretary Donna Shalala earlier this month, the Institute will expand research programs in quality assessment and cancer surveillance, and develop a "national cancer data system" that would provide quality benchmarks for providers to use.

At least two new grant programs would be funded in fiscal year 2000 to support the research. NCI plans to work with a number of private-sector organizations, including academic institutions, state cancer registries, professional associations, and advocacy groups on these programs, Klausner said.

To begin the process of using research findings to influence policies, NCI has proposed the formation of a task force representing all HHS agencies involved in health care services or research, including the Health Care Financing Administration, which oversees Medicare and Medicaid; the Centers for Disease Control and Prevention; the Agency for Health Care Policy and Research; the Health Resources and Services Administration; and the Office of the Assistant Secretary for Planning and Evaluation.

Klausner said NCI was spurred to take action on quality of care issues by a report of the National Cancer Policy Board of the Institute of Medicine. The policy board was formed at NCI's request four years ago to independently study issues such as the quality of cancer care, Klausner said.

The policy board's report, issued last spring, found that no uniform standards exist for measuring the quality of cancer care, and that evidence collected piecemeal suggests the quality of care is uneven at best (**The Cancer Letter**, April 9). The report, "Ensuring Quality Cancer Care," emphasized the role of the federal government in working with the private sector to establish measurements of quality and to hold health-care providers accountable, particularly in the Medicare program, which provides cancer care to the estimated six out of 10 newly diagnosed cancer patients who are over age 65. The NCAB endorsed the policy board report in a resolution last June (**The Cancer Letter**, June 25).

The President's Cancer Panel also issued a report on the quality of cancer care that reached similar conclusions, calling for further research into the quality of care in cancer, as well as access to quality health care.

"I favor NCI being a lead organization among all of those involved in cancer care delivery, because it has the experience in dealing with research protocols that puts it in a good position for understanding the kind of data that are needed, and how to interpret that data," said Joseph Simone, vice chairman of the policy board and senior clinical director of the Huntsman Cancer Institute at University of Utah.

Klausner was scheduled to present the NCI plan to policy board members at a meeting on Oct. 5.

Gaps In Knowledge About Quality Of Care

"Ensuring the quality of health care is clearly an increasingly important and talked about issue for Americans, politically, socially, and economically," Klausner said to NCAB. "The [IOM] report tells us that there are tremendous gaps in our knowledge

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Founded Dec. 21, 1973, by Jerry D. Boyd

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about the quality of cancer care, and that there are major problems that need to be addressed.

"Much that we would like to know about quality care, we do not know, and won't without addressing both the infrastructure and methodologies, and funding issues to do this sort of research," Klausner said.

Klausner said NCI plans to address six problems in quality of care:

1. There is no generally accepted core set of measures of quality of care that can be applied across the cancer continuum.

2. There is no national system to measure and monitor quality of care.

3. New discoveries in the laboratory often do not move quickly enough into clinical trials and then out of clinical trials to the benefit of cancer patients.

4. The communication of evidence-based information to the general population, caregivers, and cancer patients must be considered an essential component of high-quality cancer care and needed for informed decision-making.

5. Increased attention needs to be paid to inequities in the quality of cancer care experienced by different segments of the U.S. population.

6. Interagency integration of research on the quality of cancer care and its application to the delivery of care is limited.

The NCI Research Plan

The NCI research plan, as described in a memorandum dated Sept. 3 to Shalala, will have the following objectives:

1. Develop a core set of outcome measures for each major form of cancer. In FY 2000, which began Oct. 1, NCI plans to:

—Conduct several literature reviews to evaluate existing outcomes literature and identify strengths and weaknesses of a range of measures currently used. This project will be conducted by the Outcomes Research Branch of the NCI Applied Research Program, with the participation of AHCPR.

—Review quality-of-life measures used in clinical trials. The project will be conducted by the NCI Cancer Therapy Evaluation Program.

2. Launch a coordinated program of research to improve the methodological and empirical base for quality of care assessment in cancer. Through a new Request for Applications seeking cooperative agreements with teams of researchers, NCI will:

—Support studies of newly diagnosed patients to determine whether observed patterns of care are associated with good outcomes.

—Test the feasibility of using a core set of outcome measures for each disease site to streamline data collection and analysis and promote the comparability of studies.

—Investigate methodological innovations to improve the efficiency or reduce the cost of data collection, compensate for data problems, and account for complex factors that influence relationships between interventions and outcomes.

—Promote the development and evaluation of a national cancer data system that will monitor whether the provision of care is consistent with evidence-based guidelines, determine whether certain populations have inadequate access to cancer care and identify strategies for reducing barriers, and reassess whether quality benchmarks lead to improved outcomes that are of value to patients.

Under this initiative, NCI and the Centers for Disease Control have agreed to develop a Memorandum of Understanding to establish new cancer registries in a number of states, expanding the NCI Surveillance, Epidemiology and End Results program. "This will clarify how we are going to expand SEER, which we are committed to do, and to address populations that are not currently well served, as well as to expand the nature and depth of information and develop national standards," Klausner said.

3. Assure continued improvements in the quality of cancer care through a restructured clinical trials program. This is underway through several pilot projects conducted by CTEP with the clinical trials cooperative groups, Klausner said.

4. Improve the quality of cancer care by improving the quality of communications. In FY 2000, NCI plans to:

—Conduct the planning necessary to implement in FY 2001 a national cancer communications survey.

—Develop an RFA to create Cancer Communications Centers of Excellence.

—Develop plans for new communication products to help people make informed decisions.

Linking Research To Policies

Defining quality cancer care is a challenge that has engaged virtually all the key players in oncology. Developing bureaucratic mechanisms for translating these findings to the bedside could be an even greater challenge.

"More difficult [than the research plan], but

certainly just as important, is to begin to create the expectations and the framework, within the department, to link this role of talking about and doing research in quality cancer care and outcomes to the policy that profoundly affects the actual experience of patients, particularly through Medicare," Klausner said.

"One important component will be to have a standing task force to deal with—in two-way conversations," he said. "We need to hear from Medicare, as well as from other payers, what are the outcomes issues, communications issues, evidence issues, that they need for decision-making and how can we, the evidence-based community, be at the table involved with informing decision-making by those entities."

Klausner said NCI is the logical choice for spearheading the trans-HHS initiative.

"What's going to make this work is another intangible that I have seen build over the last several years, and that is, the best working relationship between NCI and the other agencies in HHS," Klausner said. "The working relationships at multiple levels are superb. That's a central development that's going to allow this to take off and to be successful."

President's Cancer Panel Chairman Harold Freeman said he hoped researchers and policy-makers would examine the issue of access to care. "We tend to talk about quality of care as if people are getting care, but an estimated 43 million Americans don't get care because they are uninsured," Freeman said. "Let's look at the problem for all American people."

NCAB member Larry Norton, of Memorial Sloan-Kettering Cancer Center, said he supported this new role for NCI. "NCI should be the engine in making this work," he said. However, he said the job of putting research on outcomes into practice "will take a lot of coordination," particularly when faced with socioeconomic problems.

"We need to play a larger role, but our expertise is the science," Klausner said. "We are not going to solve the problem of the uninsured, but we need to be at the interface. Whatever arguments are needed to drive policy need to be based on information."

Freeman agreed: "You are not empowered to do the whole job, but you are empowered to research the whole job."

The NCI research plan is described in testimony of Robert Hiatt, deputy director of the Division of Cancer Control and Population Sciences, before the Senate Cancer Coalition on Sept. 16. The testimony is available at http://www.nci.nih.gov/legis/cancercare.html.

On Capitol Hill:

Proposed Increases Brighten Funding Outlook For NIH, NCI

Fiscal year 2000 was shaping up as a belt-tightening year for NIH and NCI.

The House and Senate allocations for spending bills that fund the departments of Labor, HHS, and Education were so low that appropriations subcommittees did not want to waste their time marking up spending bills.

However, the NIH funding outlook suddenly brightened in late September, as the House Labor, HHS and Education Subcommittee gave NIH a 9.2 percent increase over last year, and the Senate subcommittee came in with a 12.8 percent boost. The increments were identical to those in last year's bills, when the Senate numbers won out in the final bill.

Under the House bill, NIH would get $16.9 billion, of which NCI would get $3 billion, a 9 percent increase over the current year. Under the Senate bill, NIH would get $17.6 billion, and NCI would get $3.3 billion, a 13.2 percent increase.

The appropriation process this year was rendered dysfunctional by the Republican leadership's adherence to spending caps established under the 1997 Balanced Budget Act. At least in the House, the Labor, HHS bill was in even more dire straits because the appropriations committee essentially borrowed from its allocation in order to salvage other spending bills.

Meanwhile, Rep. John Porter (R-IL) and Sen. Arlen Specter (R-PA) continued to plead for realistic allocations—and declined to mark up the bills.

As the fiscal year drew to a close and the prospect of a government shutdown became more plausible, the appropriators sharpened their pencils and went on a desperate quest for "offsets" and creative schemes to borrow funds against fiscal year 2001.

In the House, creative accounting produced about $15.5 billion, boosting the spending bill to about $88.5 billion, a level Porter found acceptable. In the Senate, creative accounting produced about $4.5 billion, which increased the Labor, HHS spending bill to $91.7 billion.

In one accounting maneuver used in the House,

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about $1.1 billion in heating and cooling assistance subsidies for people living on low incomes was classified as "emergency funds," and thus no longer counted against the budgetary caps. The program has been in existence—and part of the standard budget—for years.

In the Senate, the needed funds were "found" by appropriations chairman Ted Stevens (R-AK), who borrowed the money from the DOD forward-funded programs. The funds Stevens borrowed were slated for the year 2001. Thus, the funds were not subject to the caps, Stevens and his supporters argue.

Sen. Pete Domenici (R-NM), chairman of the Budget Committee, said borrowing against next year is a prudent move. In fiscal 2001, the budgetary surplus is expected to reach $38 billion, well above next year's projected surplus of $14.5 billion, Domenici said at a press conference Sept. 28, two days before the official start of the fiscal year 2000.

"2001 is a much simpler year from the standpoint of accounting," Domenici said at the press conference.

Still, skeptics on both sides of the aisle point out that borrowing against fiscal 2001 creates a separate mini-deficit that will have to be repaid next year. In principle, this new kind of deficit can be carried over from year to year.

Stevens, Specter and Domenici claimed that the funds would not tap into next year's surplus from Social Security. However, this claim is subject to debate. A recent report by the Congressional Budget Office said the spending bills would take at least $18 billion out of the Social Security surplus.

"The conglomeration of accounting gimmickry going into these bills is more extreme that anything I have seen in recent years," said one appropriations staff member.

The Republican leadership's efforts to find the money, may end up sinking the entire appropriations bill. The White House has already indicated that the legislation would be vetoed over the House initiative to consolidate $490 million worth of the President's education programs and transfer them to block grants to states.

Be that as it may, the NIH constituencies have reasons for optimism, because at least in part, the gimmickry was used to locate funds for biomedical research. Thus, in the Senate, $2 billion of the $4.5 billion borrowed from DOD's 2001 carryover went to finance an increase for NIH.

"The increase in NIH funding is the most important part of this bill," Stevens said at the press conference. "This is very important to me, this NIH funding, because we are coming closer and closer to the time of the baby-boomers. If that enormous generation has the same expenses when they reach their later years as the current generation, literally that will break the bank. We are emphasizing research now so that we can have the breakthroughs that are necessary to give us the kind of health care that that generation deserves at a price the public can afford."

Specter said increasing the NIH budget was a top priority for his subcommittee.

"I say with some frequency that NIH is the crown jewel of the federal government," he said. "Sometimes I think it's the only jewel. There is a real hope and prospect of really making marvelous advances in medical research."

On Sept. 28, Congress passed a temporary spending measure that would give the government another three weeks of funding.

Cancer Advocacy:

Survivors, Supporters Light Candles, Curse The Darkness

An estimated 5,000 people gathered at the Lincoln Memorial Sept. 25 to honor cancer survivors, commemorate those who died of cancer, and to call on the federal government to increase funding for cancer research and assure high-quality cancer care.

The event, Rays of Hope, hosted by the National Coalition for Cancer Survivorship and sponsored by the Sidney Kimmel Foundation for Cancer Research, also marked the anniversary of last year's march on Washington by cancer advocacy organizations.

Queen Noor of Jordan served as honorary chairman of the event, which featured a day of educational activities, speeches, and entertainment, culminating with a candle lighting ceremony.

"It matters little whether you live in a royal palace or a small apartment in Anacostia, our very vulnerability draws us together," Noor said. "We must work to overcome the taboos which even in this country and in many other countries still prevent people from acknowledging their condition and seeking out the proper medical care.

"By speaking out, together we can be an inspiring and transforming force in this long war against cancer, a force for hope," she said.

In a videotaped statement played at the vigil, Vice President Al Gore repeated his proposal of

earlier this year to double federal funding for cancer research. “In the history of his dread disease, there has never been a more hopeful time,” Gore said. “It seems now every week brings another stunning discovery. We are on the verge of translating the stunning advances we've seen in genetics into an explosive growth in the possibility of fighting and defeating this cruelest of diseases....

“For generations we have waged war against this awful disease. With hard work and dedication, we can be the generation that finally wins that war.”

NCI Director Richard Klausner said researchers are making progress in treatment and prevention.

“Tonight we're here to light candles and we're here to curse the darkness, to curse the darkness of cancer, for it is by light that we will conquer cancer,” Klausner said. “We have yanked cancer out of its dark closet, of isolated whispers and loneliness of the disease that not that many years ago, polite society wouldn't even talk about. But the path to cures can only be lit by research.

“As we enter the new millennium, we can truly say that change is imminent,” Klausner said. “The revolution in molecular biology and genetics, along with the emergence of powerful new technologies are allowing us for the first time in human history to see the surface of the cells that go awry in cancer, to explain how tumor cells behave, to understand how this abnormal cell can prosper and invade the body's own defenses. This basic knowledge about the nature of cancer for the first time is giving us the tools to prevent and treat cancer more effectively.

“It takes real resources,” Klausner said. “This is an extraordinarily wealthy and talented country. It's up to us. We can either move forward into the still unlit territories of cancer with a flickering and weak candle, or we can choose lasers and 100,000 megawat bulbs, searchlights. It's our choice.

“We will look back on this time as the decade that we began to turn the tide on cancer.”

Sidney Kimmel, chairman of Jones Apparel Group, urged President Clinton to propose a $10 billion increase for cancer research, and challenged Presidential candidates to support increased funding for research.

Former U.S. Surgeon General Antonia Novello encouraged physicians to communicate better with cancer patients. “Never forget that what is routine for us is not routine for patients,” she said. Novello called for universal health insurance.

NCI Programs:

NCI Forms Colorectal Cancer Progress Review Group

NCI has formed the Colorectal Cancer Progress Review Group to assess the research in the disease and to recommend a plan to move research forward.

Co-chairmen of the group are Raymond DuBois Jr., the Mina Cobb Wallace Professor of Cancer Prevention and director of Gastroenterology, and Bernard Levin, of M.D. Anderson Cancer Center.

The Colorectal Cancer Progress Review Group is the third in a series, following similar groups on breast and prostate cancer, which submitted their reports to NCI last year.

The new PRG is expected to present its report to NCI next summer.

The first meeting of the panel took place Sept. 26-27 in Chantilly, VA.

Members of the Colorectal Cancer PRG are:

Monica Bertagnolli, associate professor of surgery, New York Presbyterian Hospital; Philip Frost, vice president, Wyeth Ayerst Research; Stanley Hamilton, M.D. Anderson Cancer Center; Ernest Hawk, medical officer, NCI; Fred Kadlubar, National Center for Toxicological Research; Barnett Kramer, deputy director, NCI Division of Cancer Prevention; Sanford Markowitz, Ingalls Professor of Cancer Genetics, Case Western Reserve University; Maria Elena Martinez, Arizona Cancer Center; Pamela McAllister, Colon Cancer Alliance; Edith Mitchell, Jefferson Hospital; Ronald Myers, Thomas Jefferson University; Cherie Nichols, NCI Office of Science Policy; Michael O'Connell, Mayo Clinic Cancer Center; Joel Tepper, professor and chairman, radiation oncology, University of North Carolina; David Vining, Wake Forest University Medical Center; Michael Wargovich, director, division of basic research, South Carolina Cancer Center; Raymond White, Huntsman Cancer Institute.

NCI Issues Statement On Role In Development Of Endostatin

NCI issued the following statment on its role in the development of endostatin:

“On Sept. 13, 1999, a report in the Wall Street Journal stated incorrectly that NCI scientists have failed to replicate Judah Folkman’s original findings showing that the antiangiogenesis compound endostatin can dramatically shrink tumors in mice.

"In February 1999, the NCI reported that two of its scientists had conducted experiments with mouse endostatin in Folkman's laboratory. These experiments verified the previously published results in mice. Efforts up to that point had not reproduced this result, and the murine endostatin produced in the Folkman laboratory lost activity on attempts to ship the material to NCI.

"With the availability of human endostatin produced by EntreMed, Inc., Rockville, Md., using a separate and distinct process that has shown good activity, NCI decided to proceed with two small clinical trials to begin evaluating the safety and preliminary biological activity of endostatin in people. NCI has not attempted to conduct additional experiments with human or murine endostatin in its own laboratories in Maryland, meaning there have been no "failed" laboratory studies with the material to be used in humans. NCI does not routinely require reassessment of the activity of agents ready for clinical evaluation in company-sponsored trials.

"The NCI's decision to move endostatin into clinical trials is based solely on science. Other published studies have shown endostatin's antitumor activity and have reported that in mice the human version of endostatin caused a marked inhibition of tumor growth, an indication that the human protein might also be effective in people. Moreover, toxicity studies have shown that endostatin is well tolerated in monkeys, even at extremely high doses, and causes no side effects.

"Given the reports of antitumor activity of human endostatin in mice and its documented lack of toxicity, NCI believes that the only way to begin to rigorously evaluate this unique compound in people with cancer is to move it into clinical trials."

Funding Opportunities:

Program Announcement

PAR-99-167: Specialized Program Of Research Excellence In Human Cancer

Letter of Intent Receipt Dates: At least sixty days prior to the specified receipt dates below.

Application Receipt Dates: Breast Cancer SPOREs: Feb. 1, 2000; Lung Cancer SPOREs: June 1, 2000; Prostate and Genitourinary Cancer SPOREs: Oct. 1, 2000

The NCI Organ Systems Branch of the Office of the Deputy Director for Extramural Science invites grant applications (P50) for Specialized Programs of Research Excellence (SPORE) in organ-specific cancers. Applicant institutions must be able to conduct the highest quality balanced translational research on the prevention, etiology, screening, diagnosis, and treatment of a specific organ-site cancer. Applicants are judged on their current and potential ability to translate basic research findings into innovative research settings involving patients and populations.

A SPORE is encouraged to conduct research on rehabilitation and quality-of-life. A SPORE must develop and maintain human cancer tissue resources for the particular organ-site that will benefit translational research; develop extended collaborations in critical areas of research need with laboratory scientists and clinical scientists within the institution and in other institutions; and participate with other SPOREs on a regular basis to share positive and negative information, assess scientific progress in the field, identify new research opportunities, and promote inter-SPORE collaborations to resolve areas of scientific controversy.

Each SPORE and the "networks" of SPOREs are expected to conduct research that will have the most immediate impact possible on reducing incidence and mortality of human cancer. A SPORE should support a mix of basic and clinical researchers whose formal interactive and collaborative research efforts will result in new approaches for early detection, diagnosis, therapy, and prevention and control. The SPORE mechanism is not intended to support basic research to the exclusion of clinical research or vice versa.

NCI policy for SPORE grants establishes the following limits: new or competing renewal P50 SPORE applications may request a maximum annual direct cost of $1.75 million and maximum annual total cost of $2.75 million per individual SPORE. In complying with the direct cost cap of $1.75 million, the facilities and administrative costs related to subcontracts to other institutions or organizations will not apply toward the direct cost cap. Applications can exceed these caps as a result of regular cost-of-living increases (currently 3% per year) or special supplements approved by NCI. A SPORE grant application may request up to five years of funding.

Inquiries: Jorge Gomez, M.D., Ph.D., Organ Systems Branch, Office of Centers, Training, and Resources, Office of Deputy Director for Extramural Science, NCI, Executive Plaza North, Suite 512, 6130 Executive Boulevard MSC 7386, Rockville, MD 20852-7386 (for express/courier service), Bethesda, MD 20892-7399, phone: 301-496-8528, email: jg1w@nih.gov

NCI Contract Awards

Title: Molecular Epidemiology AssaySupport

Contractor: BioReliance Corp., Rockville, MD; $12,302,709.

Title: Suppport Services for Viral Epidemiology

Contractor: Research Triangle Institute, Research Triangle Park, NC; $12,168,828.

In Brief:

George Vande Woude Praised For 27 Years Of Service To NCI

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sciences to NCI Director **Richard Klausner**, working on the reorganization of the intramural research program. Previously, Vande Woude was director of the Basic Research Program operated by NCI contractor Advanced Biosciences Laboratory at the Frederick Cancer Research and Development Center in Frederick, MD. . . . **"GEORGE HAS BEEN** as wonderful and remarkable and giving and productive a colleague as anyone would wish to have," Klausner said to the NCAB at its Sept. 23 meeting. "It's hard to imagine having done all the things we've done without his friendship and guidance." As DBS director, Vande Woude "has brought incredible concern for the quality of science and concern for people at every level," Klausner said. "For all that he's done, we are incredibly grateful." . . . **KLAUSNER RECALLED** visiting Vande Woude's home, a cattle farm in Virginia, in 1995 to talk about the intramural program reorganization. "We took a long walk and he suggested we go through the fields," Klausner said. "Now, these fields are filled with cows, which I found terrifying. He kept asking me, what did I really think I was getting into? Every time I would look at him, you could imagine what I would step in." . . . **NCAB CHAIRMAN J. Michael Bishop**, of University of California, San Francisco, could not attend the meeting, but relayed the following statement about Vande Woude: "George is one of the greatest people on the face of the earth. His departure represents a huge loss for NCI. But he will be rendering in his new job heading a new research institute a great service to biomedical science, so we cannot begrudge him this move. We can, of course, be sad.". . . **"I CONSIDER** myself very fortunate for having been here during a time when humankind has made probably the greatest discoveries of all time about the nature of living things and our level of understanding how we can utilize that for improving human health," Vande Woude said to the board. "I feel fortunate also for having, 15 years ago, the opportunity to establish a program at Frederick, and four years ago for Rick inviting me to participate in the revitalization of NCI. I viewed that as a major challenge, and I found the whole process very exciting." . . . **RAY WHITE**, director of the Huntsman Cancer Institute at University of Utah for the past five years, stepped down Sept. 21, following the dedication of the new institute, to return full-time to the laboratory. White will serve as senior research director and will take a lead role in the HCI research agreement with Incyte, a genomics firm in Palo Alto, CA. The former senior research director, **Stephen Prescott**, was named director of HCI. . . . **CITY OF HOPE CANCER CENTER** will open an 11,146 square-foot cancer treatment center in Brentwood, CA. The City of Hope West Los Angeles Cancer Center will offer residents standard cancer treatments and new or experimental therapies developed by NCI-designated City of Hope Comprehensive Cancer Center in Duarte. . . . **COLLEEN MCBRIDE,** associate professor of Community and Family Medicine, has been appointed director of the Duke Comprehensive Cancer Center Cancer Prevention, Detection and Control Research Program. McBride has served as interim director since 1997. . . . **UNIVERSITY OF PITTSBURGH CANCER INSTITUTE** will honor individuals for their contributions to patient advocacy and inspiration, civic leadership, patient care and scientific research. **General Norman Swarzkopf** and meteorologist **Joe DeNardo** will receive Spirit of Hope awards; **Elsie Hillman** will receive the Arthur F. McNulty Civic Leadership Award; **Donald Trump** will receive the UPCI Scientific Leadership Award; **Diane Buch Barker** will receive the Leo H. Criep, M.D., Excellence in Patient Care Award; **Julie Haught** will receive the UPCI Excellence in Patient Care Award. . . . **AlFRED KNUDSON,** Fox Chase Cancer Center Distinguished Scientist and advisor to the Center president, has received the 1999 Distinguished Career Award of the American Society of Pediatric Hematology/Oncology. . . . **JOSEPH MAROON** was appointed vice chairman and visiting professor of neurological surgery, department of Neurological Surgery, at University of Pittsburgh School of Medicine. Maroon was chairman of neurosurgery at Allegheny General Hospital and Heindl professor of neuroscience at Medical College of Pennsylvania. Four of his associates joined UPMC: **Adnan Abla** and **Matt Elkadi,** specialists in spine and disc disorders and researchers in new anti-scar materials used in spinal surgery; **Daniel Wecht,** specialist in vascular diseases of the brain; **Ghassan Bejjani,** specialist in skull base surgery and neoplasms of the brain and pituitary gland. Maroon and his group will operate at UPMC Presbyterian and other UPMC Health System hospitals.

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Business & Regulatory Report

Formerly "Cancer Economics"

Product Approvals & Applications:

FDA Approves Pharmacia & Upjohn's Ellence, For Early Breast Cancer Treatment

Pharmacia & Upjohn (NYSE: PNU) of Peapack, NJ, said FDA approved Ellence (epirubicin hydrochloride injection) as a component of adjuvant therapy following resection of early breast cancer that has spread to the lymph nodes under the arm.

The approval of Ellence is based on a clinical study showing a combination of drugs containing Ellence can reduce the risk of cancer recurrence and the risk of death significantly more than CMF in women with axillary-node-positive early breast cancer, the company said.

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Deals & Collaborations:

MedImmune To Purchase U.S. Bioscience Pending Stockholder, Regulatory Approval

MedImmune Inc. (Nasdaq: MEDI) of Gaithersburg, MD, and **U.S. Bioscience Inc.** (Amex: UBS) of West Conshohocken, PA, said they have entered into an agreement for MedImmune to acquire U.S. Bioscience.

Under the agreement, MedImmune will acquire all of U.S. Bioscience's outstanding shares in a tax-free, stock-for-stock merger that is intended for under pooling-of-interests treatment. The equity value is $492 million or a transaction value of approximately $440 million (net of cash) based on an average MedImmune stock price of $110 per share and 29.8 million fully diluted U.S. Bioscience shares.

The boards of directors of both MedImmune and U.S. Bioscience approved the merger. The agreement is subject to U.S. Bioscience stockholder approval and antitrust clearance.

* * *

ALZA Corp. (NYSE: AZA) of Mountain View, CA, said its stockholders have approved the merger with **Abbott Laboratories** (NYSE: ABT) of Abbott, IL.

Closing of the transaction remains subject to FTC clearance. The companies are in discussions with FTC about the divestiture of the U.S. rights to ALZA's Viadur DUROS leuprolide (leuprolide acetate implant) which would follow the closing of Abbott's acquisition of ALZA. Abbott and ALZA have initiated discussions with several pharmaceutical companies regarding Viadur.

Last May, ALZA submitted an NDA to the FDA for Viadur, a once-

(Continued to page 3)

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FDA Approves Ellence For Early Breast Cancer

(Continued from page 1)

The study, conducted by the NCI of Canada Clinical Trials Group and published in the Journal of Clinical Oncology in August, 1998, estimated 62 percent of women with early-stage breast cancer treated with a drug combination containing Ellence (cyclophosphamide, epirubicin, fluorouracil, known as CEF) will survive relapse-free for five years, compared to 53 percent of women treated with CMF. The estimated overall survival at five years was 77 percent in the CEF arm and 70 percent in the CMF arm.

Side effects from Ellence are predictable and manageable and are similar to those observed with other chemotherapies used in this setting. The most common side effects include hair loss, nausea, vomiting, mouth sores, and a low white blood cell count, due to myelosuppression, which can be severe, the company said.

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BSD Medical (OTC Bulletin Board: BSDM) of Salt Lake City, UT, said the Dutch Minister of Health has approved reimbursement for deep regional hyperthermia and radiation treatment of advanced cervical cancer.

The president of the Dutch Parliament said deep hyperthermia is the treatment of first choice for advanced cervical cancer. The decision by the Dutch Minister of Health and Social Affairs follows the successful conclusion of the National Dutch Deep Regional Hyperthermia Clinical Trial, led by the Daniel den Hoed Cancer Center of the University Medical School of Rotterdam, with the joint participation of the Radiotherapy Departments of the University Medical Schools of both Amsterdam and Utrecht. The trial involved the extensive use of the BSD-2000 deep regional hyperthermia system in Rotterdam.

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Cell Pathways Inc. (Nasdaq: CLPA) of Horsham, PA, said it had submitted an NDA to FDA for Aptosyn (exisulind), for the treatment of adenomatous polyposis coli. Adenomatous polyposis coli is a rare disease associated with a high risk of colon cancer.

In the patient group targeted by the company's phase III trial, Aptosyn demonstrated a clinically and statistically significant reduction in new polyp formation when compared to placebo.

In a phase I/II trial funded by the NCI, Aptosyn demonstrated a clinically and statistically significant dose response at six months; and, over periods ranging from six months to thirty months, continued to demonstrate clinically and statistically significant differences in the mean change in number of polyps between dose groups.

Regressing polyps showed substantial increases in the rate of apoptosis, while the rate of apoptosis in nearby normal tissue was unchanged, confirming a selective induction of apoptosis in neoplastic tissue without affecting normal cells. The company plans to submit additional data requested by the FDA later this year.

FDA designated Aptosyn a Fast Track product and an Orphan Drug.

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Chiron (Nasdaq: CHIR) of Emeryville, CA, announced the filing of updated survival data that reinforces the long-term benefit of Proleukin for some patients with advanced-stage kidney cancer or melanoma.

On July 30, Chiron filed a supplement to its existing BLA for Proleukin (aldesleukin) with FDA to comply with an ongoing post-marketing commitment.

The data show that administering Proleukin, a recombinant form of interleukin-2 (IL-2), can extend cancer-free survival more than 10 years in some patients with metastatic kidney cancer or metastatic

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melanoma. Proleukin is approved for metastatic kidney cancer and metastatic melanoma.

Of the 17 metastatic melanoma patients who had a complete response to Proleukin therapy, 59 percent were cancer-free at the time of the update, up to 10 years after treatment. No patient who remained in remission beyond 30 months showed disease progression. The results are an analysis of data from eight clinical trials studying 270 patients treated with Proleukin for metastatic melanoma.

Proleukin can result in a number of adverse events including capillary leak syndrome and flu-like symptoms.

Patients in the studies received short-term, intensive therapy and although nearly all patients experienced serious toxicities, in the majority of cases these adverse events were fully reversible after cessation of therapy. The adverse events caused by Proleukin included: low blood pressure, decreased kidney and lung function, respiratory distress, cardiac abnormalities, changes in mental status and edema.

* * *

Coulter Pharmaceutical Inc. (Nasdaq: CLTR) of South San Francisco and **SmithKline Beecham** (NYSE:SBH) of Philadelphia said FDA has requested modifications to the BLA for Bexxar (tositumomab, iodine I 131 tositumomab) for the treatment of relapsed or refractory low-grade or transformed low-grade B-cell non-Hodgkin's lymphoma.

FDA's requested reformatting of certain sections and additional analyses of existing data in the BLA. No additional trials were requested nor did the FDA require new information from ongoing trials or on manufacturing.

"We believe that we can respond quickly to these requests and will work closely with our partners and the FDA towards an expeditious acceptance of our application," said Coulter president and CEO Michael Bigham.

* * *

Diatide Inc. (Nasdaq: DITI) of Londonderry, NH, said NeoTect (kit for the preparation of technetium Tc 99m depreotide injection) is available. NeoTect is a novel imaging agent designed to help physicians distinguish benign and malignant lung masses.

NeoTect identifies somatostatin receptor-bearing pulmonary masses in patients with pulmonary lesions on computed tomography (CT) and/or chest x-ray who have had malignancy or who are highly suspect for malignancy.

The methods for determining malignancy are invasive. Biopsy has a complication rate of approximately 14%. Although NeoTect is not considered an alternative to CT or biopsy, NeoTect can deliver key information to a physician via a noninvasive procedure, the company said.

NeoTect will be copromoted with Diatide's marketing partner for this product, Nycomed Amersham Imaging.

In NeoTect clinical trials involving 647 patients, 4.5% experienced side effects. The most commonly reported side effects were headache (1%) followed by dizziness (0.8%), and nausea (0.6%). Most of the side effects were mild and not considered to be treatment-related.

In another development, Diatide said scientists from Diatide and the University of Alabama have found a new compound, rhenium-188 P2045, developed by Diatide, which can arrest the growth, and even induce regression of an aggressive pancreatic tumor in laboratory mice, without apparent harm to normal tissues.

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SICOR Inc. (Nasdaq: SCRI) of Irvine, CA, said its wholly owned subsidiary, Gensia Sicor Pharmaceuticals Inc., has received approval of an ANDA from FDA for Vincristine Sulfate Injection USP, a drug indicated for acute leukemia.

Atairgin In Collaboration With Northwestern University

(Continued from page 1)

yearly DUROS implant for the palliative treatment of advanced prostate cancer.

* * *

Atairgin Technologies Inc. of Irvine, CA, announced a research collaboration with Northwestern University in Evanston, IL, to develop and commercialize Atairgin's LPA test to detect ovarian cancer.

David Fishman, director of the Ovarian Cancer Detection Program at Northwestern, will direct the program. The program will use Atairgin's platform technology in lysophospholipids. Levels of lysophospholipids may be exceedingly high in abnormal tissues.

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Berlex Laboratories Inc. of Montville, NJ, said it has obtained exclusive U.S. distribution and

marketing rights for Campath (campath-1H), from LeukoSite Inc. and ILEX Oncology Inc.

Campath is a humanized monoclonal antibody in late-stage development for the treatment of patients with refractory chronic lymphocytic leukemia. Berlex also has the option to jointly develop Campath for other oncology indications and for use in multiple sclerosis and solid organ transplantation.

FDA recently gave Campath the Fast Track designation for CLL. The designation means that FDA is expected to review the Campath BLA within six months. The agency also made Campath eligible for rolling submission, which means FDA will accept and process sections of the BLA as they are completed. To date, both the Chemistry, Manufacturing and Controls, and the Pharmacology and Toxicology sections of the BLA have been submitted, the company said.

* * *

Bristol-Myers Squibb Co. (NYSE: BMY) of Princeton, NJ, and **Exelixis Pharmaceuticals Inc.** of South San Francisco said they have entered into a three-year research collaboration to identify novel, validated targets for new medicines using model system genetics.

Exelixis will utilize its technology to determine the molecular targets of compounds provided by BMS. Under the collaboration, BMS and Exelixis will share certain core technologies in genomics and lead optimization.

BMS will provide Exelixis with research funding and additional payments subject to the achievement of research and commercialization milestones. Exelixis will contribute to the work of BMS Department of Applied Genomics. Both companies have programs in model system genetics, the study of organisms such as yeast, worms (C. elegans) and fruit flies (Drosophila). Many genes and gene functions present in these model systems are conserved in humans, but are much easier to study in these simpler genetic systems, the companies said.

BMS will acquire Exelixis technology including a sublicense to the patented P-element technology, tools to manipulate genes in Drosophila and C. elegans, and access to the company's Drosophila EST database, FlyTag. Exelixis will acquire BMS lead optimization technology, the companies said.

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Cell Pathways Inc. (Nasdaq: CLPA) of Horsham, PA, said it will enter into collaboration with **Rhone-Poulenc Rorer (**RPR; NYSE: RP) to conduct clinical trials investigating the therapeutic potential of Aptosyn (exisulind) in combination with Taxotere (docetaxel).

The companies will share the cost of this effort. The initial trial will investigate the combination of Aptosyn, Taxotere, and carboplatin chemotherapy in previously untreated non-small cell lung cancer. Additional trials will investigate Aptosyn and Taxotere combinations in breast, prostate, and pancreatic cancers as well as previously treated non-small cell lung cancer, the companies said. Each company will retain all marketing rights to its respective products.

Aptosyn is the first product candidate from a novel class of compounds under development by Cell Pathways, called Selective Apoptotic Anti-Neoplastic Drugs, the company said. SAANDs inhibit cyclic GMP phosphodiesterase and selectively induce apoptosis in abnormally growing precancerous and cancerous cells.

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Cytoclonal Pharmaceutics Inc. (Nasdaq: CYPH, CYPHW, CYPHZ) of Dallas said it has received a second yearly payment from BMS, as part of its license and research agreements for the production of paclitaxel by fermentation and genetic engineering.

Recent advances in the isolation of paclitaxel-specific genes by Rodney Croteau, under contract with Cytoclonal, increases the feasibility of producing paclitaxel by genetic engineering and fermentation. A combination of these technologies has been used to achieve optimized production of a range of pharmaceutical products including antibiotics and insulin. The goal of the program is to generate an optimized production system for paclitaxel, given its increased utility in oncology and potential new indications, the company said.

* * *

Epimmune Inc. (Nasdaq:EPMN) of San Diego, said it will receive a $2 million milestone payment from **G.D. Searle Co.** as a result of Searle's acceptance of a lead product candidate for breast, lung and colon cancers.

Clinical trials conducted by Searle are expected to begin in the first half of 2000. The program uses Epimmune's epitopes, antigens capable of inducing the immune response, and Searle's progenipoietin, a protein currently under a phase I evaluation for safety and tolerability.

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Genzyme Molecular Oncology (Nasdaq: GZMO) of Framingham, MA, and the ATIII LLC, a joint venture between Genzyme Transgenics Corp. (Nasdaq: GZTC) and Genzyme General (Nasdaq: GENZ), said they have signed a letter of intent to develop and commercialize the angiogenesis inhibitor protein aaATIII as a potential treatment for cancer.

GMO and the ATIII LLC have agreed to equally share in the development costs of an aaATIII cancer therapy and equally share in any profits from a successful oncology product created through the collaboration.

The ATIII LLC will have the rights to develop aaATIII for potential non-oncologic indications. aaATIII, a modified form of antithrombin III, is an antiangiogenesis protein discovered in Judah Folkman's laboratory and exclusively licensed by Genzyme Molecular Oncology from Children's Hospital last February.

The company said that over the next few months, Genzyme will conduct studies to replicate the work of Folkman's laboratory, conduct other preclinical studies, and scale-up production of the protein.

* * *

Immunicon Corp. of Huntingdon Valley, PA, said it has signed a sponsored research agreement and an exclusive licensing agreement with the University of Texas Southwestern Medical Center at Dallas.

The agreements focus on research in cell-based diagnostics for cancer detection, monitoring and staging, the company said. The principal investigator will be Jonathan Uhr, professor of Microbiology and Internal Medicine.

The SRA is for three years and provides monetary support and other consideration for research into development of Immunicon's rare-cell detection and analysis platform technologies for the diagnosis, staging, treatment and monitoring for recurrence of invasive cancers of epithelial origin. The ELA grants an exclusive worldwide license to Immunicon for commercialization of technology developed under the SRA. Immunicon will make a restricted stock grant and pay a royalty to the University on the net sales of products incorporating intellectual property developed under the SRA.

* * *

Incyte Pharmaceuticals Inc. (Nasdaq:INCY) of Palo Alto, and **Huntsman Cancer Institute** said they have entered into a two-year collaboration to study the role of genes in the diagnosis, prevention, and treatment of cancer.

Under this agreement, HCI will be the first academic institution to access Incyte's LifeSeq Gold database of human genetic information. HCI will use Incyte's state-of-the-art microarrays and microarray data management software. The research tools help scientists analyze how genes function and identify which genes make the best drug targets.

Incyte will work with HCI scientists to access high quality tissue and tumor samples as well as to research findings from HCI's colon cancer program. The partnership will provide opportunities to analyze the genetics of cancer in families with a high risk of developing inherited forms of cancer.

Resources available to Incyte and HCI researchers will include high-risk cancer care clinics, the Utah population database, and the Utah cancer registry, the company said.

* * *

Medarex Inc. (Nasdaq: MEDX) of Annandale, NJ, said it has obtained an exclusive sublicense from **Gilead Sciences Inc.** (Nasdaq: GILD) to the CTLA-4 Blockade intellectual property rights owned by University of California, Berkeley.

Using its HuMAb-Mouse technology, Medarex has created fully human, high-affinity antibodies that inhibit CTLA-4, an immune system modulator. Medarex also has an option under the sublicensing agreement to pursue other non- antibody-based methods of blocking CTLA-4, the company said.

In studies conducted at Berkeley, James Allison, professor of immunology and director of the Cancer Research Institute, demonstrated that the blockade of CTLA-4 using antibodies can lead to the rejection of cancerous tumors in mice.

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LeukoSite Inc. (Nasdaq: LKST), of Cambridge, MA, **ILEX Oncology Inc.** (Nasdaq: ILXO) of San Antonio, TX, and **Schering AG**, (Dax: SCHG) of Berlin, said they have entered into a distribution and development agreement which grants Schering AG exclusive marketing and distribution rights to Campath in the U.S., Europe and rest of the world. LeukoSite and ILEX retain rights, however, in Japan and East Asia.

Campath is a humanized monoclonal antibody. LeukoSite and ILEX plan to submit the final segment of the BLA for Campath with FDA later this year.

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Schering-Plough Corp. (NYSE: SGP) of

Madison, NJ, and **British Biotech plc.** said they have entered into a licensing agreement to develop and commercialize British Biotech's matrix metalloproteinase inhibitors, including marimastat and BB-3644, for the treatment of cancer.

Under the agreement, Schering-Plough obtains exclusive worldwide rights to develop, manufacture and market MMPIs for cancer. The agreement excludes Japan and other Far Eastern territories previously licensed to Tanabe Seiyaku Co., Ltd.

British Biotech is expected to complete ongoing clinical studies for marimastat and the initial planned clinical development of BB-3644. Schering-Plough will be responsible for regulatory submissions for MMPIs and will receive assistance from British Biotech in making regulatory submissions, the companies said.

British Biotech will receive an upfront license fee of $4 million and milestone payments. In addition, Schering-Plough will make a $4 million equity investment in British Biotech. Schering-Plough's total payments to British Biotech, excluding royalties, could reach $60 million if all milestones are met.

Schering-Plough has agreed to make substantial investments in the continued development of marimastat and other MMPIs owned by British Biotech, including BB-3644, the companies said. In addition, British Biotech will receive royalties on sales of any of its MMPI products commercialized for cancer.

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UroCor Inc. (Nasdaq: UCOR) of St. Louis, and **Mallinckrodt Inc.** (NYSE: MKG), said Mallinckrodt will sell and distribute UroCor's new radiation treatment for prostate cancer through Mallinckrodt's 35 nuclear medicine pharmacies and more than 80 independent pharmacies. Mallinckrodt also will add the product to its group-purchasing contracts with hospital groups.

The product, ProstaSeed I-125 radioactive sources, has received clearance to market from FDA and is awaiting final approval from the Nuclear Regulatory Commission.

Clinical Trials:

Onyx Plans Phase III Trial Of ONYX-015 For Head & Neck

Onyx Pharmaceuticals Inc. (Nasdaq: ONXX) of Richmond, CA, said FDA has agreed to a phase III clinical development plan for ONYX-015, a therapeutic virus product. The company said it plans to initiate a phase III trial that would combine the virus with chemotherapy in the treatment of recurrent head and neck cancer.

The trial is expected to begin later this year or early in 2000, the company said. The proposed trial will be a randomized two-arm study comparing intra-tumoral injection of ONYX-015 plus standard chemotherapy (5-flurouracil and Cisplatin) versus chemotherapy alone. The study will take place at more than 40 centers in the U.S. and Europe and will include 180 evaluable patients with recurrent head and neck cancer in each of the study arms, the company said.

The primary endpoints will be progression-free survival and durable tumor responses. Secondary endpoints will include patient quality of life measurements and overall survival.

The company said it plans to conduct another study in recurrent head and neck cancer patients who have failed chemotherapy. Patients who are randomized to the control arm of the above phase III study will have an opportunity to be treated with the combination of ONYX-015 and chemotherapy once their disease has progressed. The primary endpoint will be durable tumor response.

Onyx said 50 to 100 patients will be accrued on the second study. Results from the open-label, single-arm study will be included in the eventual licensing application as supportive efficacy and safety data.

In a phase II study of ONYX-015 plus 5-FU/ Cisplatin therapy in head and neck cancer, 19 of 30 evaluable patients experienced regressions of greater than 50 percent in their injected tumors, with eight patients experiencing complete tumor regressions.

The data represent an overall response rate of 63 percent, compared to approximately 35 percent with chemotherapy alone. A complete response rate of 27 percent in the phase II study was also significantly higher than the complete response rate of less than 10 percent with chemotherapy alone.

The company said 17 percent of tumors injected in the phase II study have progressed over the six months following initial treatment. By comparison, progression occurred in 60 to 70 percent of tumors in prior multi-center studies using chemotherapy alone, based on standard Kaplan-Meier analysis. Treatment was generally well-tolerated, the company said.

Chemotherapy-related gastrointestinal symptoms and injection site pain were the most frequently reported adverse events, the company said.

ONYX-015 is a genetically modified adenovirus that has been shown in preclinical and clinical studies to replicate in and kill tumor cells deficient in p53 tumor suppressor gene activity.

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Agouron Pharmaceuticals Inc. of La Jolla, CA, said it has initiated a second phase III trial of the matrix metalloprotease inhibitor prinomastat (formerly AG3340) in combination with chemotherapy in patients with advanced non-small cell lung cancer.

In the new study, which is being conducted in North America, Europe, and Australia, patients with advanced non-small cell lung cancer will be randomized to receive either prinomastat in combination with gemcitabine and cisplatin or placebo in combination with gemcitabine and cisplatin. The primary objective is to compare time of overall survival between patients receiving prinomastat or placebo in combination with gemcitabine and cisplatin, the company said.

The company said it is also evaluating prinomastat as a first-line therapy, in combination with paclitaxel/carboplatin, for the treatment of advanced non-small cell lung cancer, and with mitoxantrone/prednisone, for the treatment of hormone-refractory prostate cancer, the company said.

* * *

Celsion Corp. (OTC BB: CELN) of Columbia, MD, said it has received FDA approval to begin phase I studies at two new sites to evaluate the company's focused heat breast cancer treatment system.

The principal investigator is Hernan Vargas, chief of surgical oncology at Harbor UCLA Medical Center. The three co-investigators are Jerome Block, a medical oncologist at Harbor UCLA, Robert Gardner, chief of the Center for Breast Surgery at Columbia Hospital, and Charles Vogel, medical director of Columbia Cancer Research Network.

The breast cancer treatment incorporates a focused heat system developed by Celsion. The system uses technologies licensed from several engineering and medical research institutions, the company said. The technologies include the Adaptive Phased Array focusing technology, which the Massachusetts Institute of Technology designed for the U.S. Department of Defense Star Wars Initiative which Celsion has adapted to focus microwave heat on tumors while leaving healthy skin and surrounding tissue unharmed.

* * *

Cryogenic Solutions Inc. (OTC BB: CYGS) of Houston said M. D. Anderson Cancer Center will conduct clinical research using the company's single stranded DNA intracellular expression vector to deliver sense and anti-sense molecules into the nucleus of cells for potential treatment of melanoma and psoriasis.

The studies will be conducted by Madeleine Duvic, chief of the Section of Dermatology, co-director of the Melanoma Skin Center, and Translational Research Program in Cutaneous T-cell Lymphoma and Skin Cancer.

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Immunicon Corp. of Huntington Valley, PA, said that following Institutional Review Board approval it has begun a clinical study of an in vitro high-sensitivity, tumor-cell analysis technology in breast cancer.

The principal investigator in the study is Daniel Hayes, clinical director, Breast Cancer Program, Lombardi Cancer Center, and associate professor of Medicine, Georgetown University Medical Center.

Data from the study will not be used to determine or change a patient's treatment plan, the company said. Standard methods of monitoring patients with breast cancer will be employed. These include bone, CT, and MRI scans. The data will be used as a basis of comparison with Immunicon's cancer test method, the company said.

* * *

The Liposome Company Inc. (Nasdaq: LIPO) of Princeton, NJ, said it has begun clinical trials in collaboration with **Bristol-Myers Squibb Co.** (NYSE: BMY). The trials evaluate the safety and efficacy of Evacet (previously TLC D-9) in combination with Taxol (paclitaxel) for the treatment of patients with metastatic breast cancer.

Evacet is a liposomal formulation of doxorubicin. On Sept. 16, the FDA Oncologic Drugs Advisory Committee recommended against approval of Evacet, in combination with cyclophosphamide, for the first-line treatment of metastatic breast cancer (**The Cancer Letter**, Sept. 24).

* * *

Procept Inc. (Nasdaq SmallCap: PRCT) of Cambridge, MA, said it has begun four phase I trials of its O6-Benzylguanine chemosensitizing agent.

The trials will determine the maximum tolerated dose of BCNU in combination with BG, the company said. The trials are sponsored by NCI.

The Ireland Cancer Center at University

Hospitals of Cleveland and Case Western Reserve University will enroll breast cancer patients in a trial directed by Timothy Spiro.

Gary Wood, also of CWRU, will conduct a trial for the treatment of cutaneous T-cell lymphoma. A third trial is being conducted through the Pediatric Oncology Group under the direction of Denise Adams, of the Duke University Medical Center, for primary central nervous system tumors refractory to standard therapy.

The fourth trial is conducted at the University of Chicago Medical Center under the direction of Mark Ratain. The objective of this study is to confirm the minimal BG dose that significantly inactivates the tumor DNA repair protein O6 alkylguanine-DNA alkyltransferase in patients with a variety of surgically resectable solid tumors.

* * *

Repligen Corp. (Nasdaq: RGEN) of Needham, MA, said it has entered into a Clinical Trial Agreement NCI for a phase II trial of CTLA4-Ig, a compound capable of selectively blocking immune responses.

NCI and Repligen will evaluate CTLA4-Ig's ability to prevent the development of graft versus host disease in bone marrow transplant procedures in which the marrow is donated by an unmatched donor.

Under the agreement, NCI will submit an IND for the drug and sponsor the clinical trial. Repligen will provide the CTLA4-Ig and will support laboratory measurements to confirm the drug's effect and the specificity of the induced immune tolerance. NCI expects to begin the phase II trial in early 2000 at a single site and to expand to multiple sites later in the year.

Oncology Management:

Impath Buys Specimen Repository Of BioClinical

Impath Inc. (Nasdaq: IMPH) of New York, said it has purchased the medical research network and specimen repository of **BioClinical Partners Inc.**, a medical research network that obtains and provides access to tissue and clinically relevant peripheral blood specimens to support oncology research and product development.

BCP provides customized clinical specimen collection programs, biorepository services, and access to an archive of 500,000 patient specimens. BCP currently has approximately $4.2 million in annual revenues, the company said.

Letter To The Editor:

To the Editor:

I would like to take this opportunity to clarify and respond to the article on Salick Health Care published in the August 1999 **Business & Regulatory Report**.

In that article, you reported on the organizational changes that have taken place at SHC. While we appreciate your attention and coverage of our company, we would like to comment on a few misstatements in the report.

The new 70,000 square foot Saint Vincents Comprehensive Cancer Center in New York, scheduled to open in October, is by no means, "plagued with delays and cost overruns" as you reported. On the contrary, any decisions to increase cost and construction were made deliberately to improve upon the original plans. We are very pleased that this center will be one of the best and most technologically advanced facilities of its kind anywhere. Ensuring this level of excellence has meant altering some plans along the way.

You also reported the sale of our dialysis unit as a casualty of the Saint Vincents project. This is simply not true. That sale was completed for one primary reason and indeed a much simpler one. SHC wants to better focus on our core business, the management of cancer centers. This intensified focus is also the reason that we have chosen to exit a select number of centers over the past three years. By eliminating underperforming units, we are in a better position to focus on growth in key areas, like New York.

Salick Health Care is fully committed to providing high-quality, patient-oriented care to cancer patients throughout our network of comprehensive cancer centers. We have not wavered in that commitment. Ensuring that we meet the needs of our patients, physicians and partner hospitals requires that we remain flexible in order to rapidly adjust our strategy to new developments.

At SHC our business goal is simple and overriding. We are dedicated to delivering the very best care in our centers across the country and nurturing our relationships with our partner hospitals and physicians. Any organizational or infrastructure changes you see have been made in order to achieve these important goals. We appreciate you bearing all of these facts in mind in any future reporting regarding the state of SHC.

Peter Jessup
CEO, Salick Health Care Inc.

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