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DeVita, Seffrin Present Cancer Czar Plan To Feinstein, Without Committee Sign-Off

The co-chairmen of the American Cancer Society-funded effort to rewrite the National Cancer Act recently presented a blueprint for a fundamental change in the management of billions of dollars the federal government spends on cancer, documents show.

The plan presented to Sen. Dianne Feinstein (D-CA) by Vincent DeVita and John Seffrin, chairmen of a committee advising the Senator on rewriting the 1971 law, would displace NCI as the lead agency in the cancer program.

Under the plan, authority over the program would pass to a 20-member commission that would include heads of government agencies

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In Brief:

Varmus, Branscomb Win Public Service Award From NSF; NCI Clarifies Plans For Large R01s

NATIONAL SCIENCE BOARD presented the Vannevar Bush Award for lifetime achievement in science and public service to **Harold Varmus** and **Lewis Branscomb**. Varmus, former director of NIH and a Nobel laureate for cancer research, is president of Sloan-Kettering Cancer Center. Varmus shared the 1989 Nobel Prize in Physiology or Medicine with his colleague at the University of California J. Michael Bishop for their work in retroviruses that led to an understanding of the genetic basis of cancer. During his tenure at NIH, Varmus is credited with changing public perception about biomedical research, generating investments for the Human Genome Project, reversing funding trends at the institute and expanding and improving NIH-supported clinical research facilities nationwide. Brascomb, professor emeritus in public policy and corporate management at the John F. Kennedy School of Government at Harvard University, is a physicist and a former chairman of the National Science Board. An authority in science and technology policy and management of innovation and technology, Branscomb's 1951 research verified the theory that the absorption of light by the negative hydrogen ion determines the surface temperature of the sun. He has served under five presidents from Kennedy to Reagan in various capacities. The Vannevar Bush award was established to commemorate the 30th anniversary of the National Science Foundation. . . . **CLARIFICATION:** In an article in the May 25 issue of **The Cancer Letter**, it was reported that NCI plans to conduct a single

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Cancer Commission, Czar, Would Lead Cancer Program

(Continued from page 1)

that deal with cancer, and representatives of advocacy groups and the private sector. The commission's director, who would be appointed by the President and confirmed by Congress, would, in effect become the federal Cancer Czar, a post similar to the Drug Czar.

Documents show that DeVita and Seffrin presented the proposal to Feinstein before obtaining approval of the National Cancer Legislation Advisory Committee, the group formulating a "white paper" for the proposed law. Seffrin is the ACS chief executive, and DeVita is the director of Yale Cancer Center and former NCI director.

NCLAC members learned about the Feinstein briefing on May 10, more than a week after it took place, when a document titled "Briefing Background For Honorable Sen. Dianne Feinstein, May 2, 2001," was emailed to everyone on the committee.

Though six NCLAC members objected to what they described as a premature briefing, their objections may be moot. In an email addressed to NCLAC executive director Rebecca Kirch and a select group of committee members, DeVita indicated that Feinstein "already approved" the plan.

In the email, dated May 20, DeVita described the formation of the commission as "the one thing most needed, an effective mechanism for overview." DeVita declined to speak with a reporter.

The DeVita-Seffrin plan would make the following changes in the cancer program:

- Currently, the NCI director serves as head of the National Cancer Program. The structure proposed by DeVita and Seffrin would place the Cancer Czar above the NCI director, thereby downgrading research to the status of just one of the constituencies of a broader program.
- The proposed structure would be likely to threaten NCI's existing "bypass" budget authority, which allows the Institute director to go over the heads of the NIH director and HHS secretary to inform the President about research opportunities in cancer.
- Under the DeVita-Seffrin plan, the National Cancer Advisory Board, which advises the NCI director on the implementation of the cancer program, would become an institute council. Unlike members of other NIH institute councils, NCAB members are appointed by the President.
- The President's Cancer Panel, a group that advises the President on obstacles to progress in the war on cancer, would be abolished, and the National Cancer Policy Board, a group funded by NCI, but operated by the Institute of Medicine, would become a resource to the new commission and the Cancer Czar.
- The new 20-member board, which would be called the National Cancer Council or National Cancer Commission, would "set government-wide goals" and "review and comment on cancer budgets of cancer programs," the document states.
- This new entity would be similar to the Office of National Drug Control Policy, and the Council on Environmental Quality, the document states. Heads of these agencies are the principal White House advisors in their areas. The drug control agency, and its director, the Drug Czar, coordinates federal, state, and local anti-drug programs, runs counter-drug technology assessment programs, and programs aimed at cutting the supply of drugs and their use. The director of the environmental council coordinates federal environmental programs, and intervenes when agencies clash over environmental assessment.
- If the proposed cancer council and the Cancer Czar are able to influence the allocation of funds in the President's budget proposal, the new administrative structure could become more vulnerable to political manipulation. Money could be shifted from NCI, where it is distributed through peer review, to agencies

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like Centers For Disease Control and Prevention, which uses block grants to states. While peer review is usually immune to pork barrel politics, block grants are not protected from mandates and other forms of interference.

● Unlike the White House environmental council and the Drug Czar's office, the new government entity would engage advocacy groups and industry representatives in policy-setting roles. This would be unprecedented in the federal government.

ACS would be well positioned to place its representatives on the policy-making commission. Also, the Society would be represented through its common interests with CDC, its Atlanta neighbor. Lobbying for CDC has emerged as the principal thrust of ACS efforts in Washington in recent years. CDC has awarded the Society a sole-source, multi-year cooperative agreement (**The Cancer Letter**, Sept. 22, 2000).

The central controversy in this debate is as old as the National Cancer Act: a clash between advocates of research and advocates of public health interventions. Advocates of interventions argue that quality cancer care does not reach all Americans equally.

"I find it incredibly important that we look at going to linkages, so we can pass the baton from science to its application in the community," said NCLAC member Armin Weinberg, professor at Baylor College of Medicine and co-founder of the Intercultural Cancer Council.

Advocates of research urge caution in the design of such linkages, arguing that a firewall should protect funds devoted to peer-reviewed research, and that the cancer program should be driven by science—and therefore by NCI.

"Majority is Usually Enough in a Democracy"

NCLAC was expected to complete its white paper early this year. However, the process dragged on, and the issue of oversight for its plans was not addressed in detail.

At a committee meeting last April, DeVita asked for volunteers to design an oversight structure. Several hands went up, and the group got together once on a conference call, where NCLAC member Paul Calabresi, professor of medicine at Brown University, was asked to write the work group report.

Documents obtained by **The Cancer Letter** indicate that no written report existed at the time of DeVita's and Seffrin's presentation to Feinstein.

NCLAC members learned that the briefing had taken place when they received the one-page background document in an email from Calabresi. The May 10 email described the document as "an outline prepared by Vince DeVita for his presentation to Sen. Dianne Feinstein, which I heard was extremely well received."

Refraining from comment on the recommendations, Calabresi diplomatically described the briefing document as "an excellent format for a report," and invited the members' "contributions to provide supporting data for this proposal."

After Calabresi distributed the document, at least six members voiced objections to what they described as a premature presentation. These letters were written by Anna Barker, president and CEO of Bio Nova Inc., a Portland biotech firm; Joan Brugge, professor of cell biology at Harvard Medical School; John Glick, director of the University of Pennsylvania Cancer Center; Ronald Herberman, president of the Association of American Cancer Institutes; Ellen Sigal, chairman of Friends of Cancer Research; and George Vande Woude, director of Van Andel Institute of Grand Rapids, MI.

In a May 20 email to Kirch, copied to Seffrin and Calabresi, DeVita noted opposition from Sigal and NCI.

"Ellen saw to it that anything like that was taken out of past studies to suit the needs of one person," DeVita wrote in an apparent reference to NCI Director Richard Klausner, who opposes diluting the research emphasis of the cancer program.

In the email, DeVita urged Calabresi to stand by the recommendations. "Paul, I hope you will wind up the committee report unaltered," DeVita wrote.

Two days later, on May 22, DeVita explained to a wider group of NCLAC members that the briefing in question was requested by Feinstein, and that the Senator had specifically asked about the subcommittee's recommendations.

"I explained what the committee had discussed, and the direction of the final report, but we were clear to make it an incomplete 'work in progress,'" DeVita wrote to committee members.

In another widely circulated email that day, DeVita wrote that the controversy would be resolved democratically—by a vote.

"I have never felt that consensus and unanimity were the same," DeVita wrote. "I have never believed that we would achieve unanimity of opinion on all these difficult issues.

"Majority is usually enough in a democracy," he wrote.

Sigal agrees that the controversy should be resolved through NCLAC. "I am deeply opposed to the proposed commission, which puts politics—not the NCI director—at the helm of the cancer program," Sigal said to **The Cancer Letter**. However, Sigal said the DeVita-Seffrin proposal was preliminary, and did not merit coverage.

"I believe this story generates more heat than light, because the proposal to establish a commission has neither been fully discussed nor vetted by NCLAC," Sigal said. "Reporting speculations rather than facts only fuels divisiveness in an already fractious cancer community, which spends too much time beating up each other, rather than beating the disease."

Why NCLAC?

It is unclear how the principles of democracy apply to NCLAC. Even the words "advisory committee" in the committee's name are misleading. NCLAC has no charter, and since it is funded by charity funds raised by ACS, the committee is exempt from open meetings requirements that apply to government-funded groups.

The committee operates entirely behind closed doors.

ACS officials describe the committee as an offshoot of the National Dialogue on Cancer, a Society effort to develop an overarching cancer agenda. However, ACS officials are always quick to point out that NCLAC and the Dialogue are separate entities.

The committee's formation was announced to Dialogue participants in August 1999, as were the names of the co-chairmen.

The intricate, related-yet-unconnected structures of the Dialogue and NCLAC were put in place by the consulting group Shandwick International. Shandwick was fired by ACS after **The Cancer Letter** reported that the firm also represented R.J. Reynolds Tobacco Holdings Inc. (**The Cancer Letter**, Jan 21, 2000).

NCLAC has assembled a group of 25 members, many of them individuals respected in cancer research, cancer care, and advocacy. The committee has held many hours of hearings, and examined a wide range of documents.

Now, the committee members will be asked to cast their votes, and, technically, 13 votes may be enough to give weight to legislation. However, NCALC member Calabresi said he would prefer to develop a plan that would generate wide acceptance.

"We should get the writing committee together to come up with a plan that would offer one or several options for coordination, and this ought to be brought to the entire group for discussion," said Calabresi. "This should be something that Rick Klausner, and the scientific community, and the advocacy community, and the medical community would agree with.

"My feeling is that there should be a great-majority consensus," Calabresi said. "If NCLAC came out with a 13-12 plan, it wouldn't be very effective."

If the DeVita-Seffrin plan survives, it will end up in the "white paper" that would be used in the drafting of a bill. If the proposal dies, it may still end up in the bill, especially if Feinstein has indeed "already approved" it.

A spokesman for Feinstein was unable to comment on the Senator's position on the plan by press time.

Plan Consistent With Earlier Statements

The recommendations presented by DeVita and Seffrin are consistent with their earlier public statements.

In an address to the President's Cancer Panel in December 1999, Seffrin made repeated references to the NCLAC product as the National Cancer *Control* Act. The new law would be based on two principles, he said.

First, coordination of cancer programs isn't what it needs to be, and, second, "we need, at the highest levels, to get all three sectors together around a common table," Seffrin said to the panel (**The Cancer Letter**, Jan. 21, 2000).

Two months later, in an interview with Yale Bulletin and Calendar, DeVita provided a more detailed description of the plan.

"The issue has come up of establishing a National Cancer Authority of some sort," DeVita said in an interview published Feb. 4, 2000. "For example, the Centers for Disease Control would handle a lot of the cancer control of the plan.

"You could see a scenario where CDC could receive a great deal of money, and let the states apply for grants to support cancer control programs. If this turned out to be $400 million a year, it wouldn't go into the NCI at all. It would go into the CDC.

"So, the NCI wouldn't be thrown out of balance with the other components of the NIH. If you created some sort of a national fund for support of clinical

trials, which is desperately needed, and you funded it outside of the NCI, then that money wouldn't go into the NIH budget, either.

"That would take some of the anxiety away that people usually have about putting a lot of money into one basket (**The Cancer Letter,** Sept. 22, 2000)."

This "anxiety" has been gaining intensity in recent months, as the Bush Administration has made it a priority to fund biomedical research at NIH, while cutting some health programs.

In the budget proposal for fiscal 2002, NIH is slated to receive a 13.5 percent increase, while CDC is cut by 3 percent. The most severe cut—23 percent—affects the principal beneficiary of ACS lobbying, the CDC Chronic Disease Prevention and Health Promotion Program.

Administration Support For NIH, Klausner

Funding research at NIH is a matter of strategy for the Administration, said HHS Secretary Tommy Thompson as he discussed the budget proposal at a recent press conference.

"This whole budget, with NIH leading it, is going to have some real breakthroughs in the near future," Thompson said (**The Cancer Letter**, April 13). "There are encouraging signs coming out of NIH and the scientific community of breakthroughs that I happen to be very excited about, and I hope you are, and I know the President is."

Peer-reviewed research is a good investment, Thompson continued. "To me, that is going to be one of the best things that we can do to control health costs in the future," he said. "If you have a breakthrough in one of these diseases, it's going to hold exponentially the health care costs."

Thomson has been consistent in expressing support for NCI Director Klausner.

"In my months at HHS, I've come to greatly appreciate Dr. Klausner and his fine stewardship of NCI," Thompson said at a May 25 meeting of the President's Cancer Panel. "He is a valued member and partner and friend of all the HHS team."

Thompson said he recently stopped formal participation in the National Dialogue on Cancer, which he joined as Wisconsin governor. After he took over HHS, Thompson was advised by attorneys that his continued formal participation would be inappropriate.

"I was a member of the Dialogue until my attorneys told me I had to resign," Thompson said. "But I still go to the meetings."

President's Cancer Panel:

NCI's Approach "Paying Off," Thompson Tells Cancer Panel

NCI's "multi-pronged approach" to cancer research is "paying off" with new treatments and approaches, HHS Secretary Tommy Thompson said to the President's Cancer Panel last week.

In his May 25 remarks at the panel's meeting in Washington, Thompson said President Bush's budget proposal includes an increase of $514 million for cancer-related research for NIH in 2002, a 12 percent increase.

"The President's budget reflects how serious he is about the whole Administration waging a fight to win this war against cancer," Thompson said. "The President is sending a clear message. He doesn't just want us treating a disease, he wants us beating a disease."

Following Thompson's prepared remarks, Panel Chairman Harold Freeman said the panel often hears in testimony from health care professionals and patients that the "discovery system is working well," but the delivery system doesn't reach many people, for a variety of reasons.

"There's no question our health care delivery system needs some shoring up, some replacements, some improvements, and a lot of modifications," Thompson replied. "You've got 43 million people uninsured, and a lot of underinsured. We've done a poor job sometimes on research between different races and sexes. It's necessary for us to try to do a better job."

Administration proposals such as expansion of funding for community health centers for the uninsured by $124 million, as well as a tax credit, would begin to help, he said.

Thompson said that while he was governor of Wisconsin, he got approval from HHS to expand health programs for the working poor, and now as Secretary he is trying to streamline the process of granting waivers to states for these types of programs.

"I'm proud to say that in Wisconsin, 93 percent of our citizens are covered by insurance," he said. "If I can replicate that across the nation, Dr. Freeman, I'm going to feel very good about that."

Panel member Fran Visco noted that the newly approved drug Gleevec, which Thompson hailed in his remarks, would not be covered by Medicare because it is an oral drug.

Thompson said that problem would be solved if

Congress approved a prescription drug benefit for Medicare. "We feel confident there is going to be a prescription drug benefit for Medicare," he said.

"We would like to strengthen and reorganize Medicare so it's there for the people who need it," Thompson said. "It's going to be a difficult job, made more difficult with the switch of the partisan control of the Senate yesterday, but I still think there is great hope, great opportunities, and we're going to push hard to get it done."

Following is the text of Thompson's remarks:

Let me start off by thanking all of you for doing this wonderful, responsible task that is so important to all Americans. I thank you so very much, Dr. Freeman, for your leadership. I'm also very happy that the acting head of NIH, Ruth Kirschstein is here, and is doing a wonderful job, and thank her so very much, along with her husband [NCI Deputy Director Alan Rabson].

I just would like to start off by thanking all of you for what you are doing in the fight against cancer. It's an insidious disease and something that we've got to overcome, but I think we are making a lot of progress. I certainly am one of those members of a family that has been devastated by cancer, losing a grandfather, a mother, a mother-in-law, and my wife has had breast cancer and is recovering from that. So I know first-hand as an individual the devastating impact that cancer can have on a family.

I'm very pleased to be joined by those of you who are cancer patients and cancer survivors. You certainly are the reasons why we're here today. Your courage and tenacity are inspiring. We certainly need your counsel, and we value your input. Thank you for allowing us to hear your stories and gain insight from your experience. There's no question that all of us must fight this battle together. None of us can do the job alone, but together, we can form a powerful alliance against the common enemy, the ravaging disease called cancer.

Let me just say at the outset that all of us at the Department of Health and Human Services need your help, but more than anything, we need your advice and counsel.

We're on the verge of implementing treatments that will change the way we deal with cancer patients. I will talk more about that in a moment. But please know that I consider myself, and all those people at HHS, your partners in the truest sense of the word.

Before I talk with you about what the Administration is doing in our fight against cancer, let me make two personal observations.

First, I come from a very small, rural, poor area in Wisconsin called Elroy, and I tell people it's a town of about 1,500 population. It's so small you can call somebody and get a wrong number and still talk for half an hour. That's how small my hometown is.

You gain a perspective on life you never lose. People in small cities or towns aren't statistics or numbers on a page. They're real individuals. When someone gets a disease like cancer, it affects the whole community because you know that person, as a friend and a neighbor.

As a governor and now as Secretary of the Department of Health and Human Services, I've carried that understanding with me. Public policies affect real people, not nameless lines in an actuarial table.

But let me also share my experience even closer to home. My wife Sue Ann is a long-time breast cancer survivor. I know what it's like to be told that a person you love has cancer. I know the courage it takes to fight the disease. And I also know the joy of seeing Sue Ann win her fight.

That victory would not have been possible without the help of dedicated people like you. Without the physicians, nurses, researchers that work to thwart cancer. Each of us has our own story, and all of us share the common basis, the need to win this fight against cancer.

We all know how high the stakes are, for us personally and for our country. Every year, 1.2 million Americans develop some form of cancer. One of every four deaths that occur annually is cancer-related. That's 550,000 individuals.

But there's good news, as well. There are some astonishing new treatment possibilities, such as treating cancer at the genetic level and eliminating diseased cells while protecting healthy ones.

I can't tell you how excited I was about six weeks ago when Dr. Rick Klausner came into my office on a Friday afternoon and told me about Gleevec and the possibilities that that drug has. So we announced that new treatment just a few weeks ago, when the HHS, through the Food and Drug Administration, approved the drug called Gleevec. It's a pill that puts a form of leukemia, called chronic myeloid leukemia, into remission and actually kills those cancer cells.

Gleevec targets a single cancer-causing protein and, like a light switch, turns off its signal to produce leukemia cells. We haven't had it long enough to know

if it's permanent, but the first research really is promising. The researchers at NIH who are fantastic, and I tell people this, we have the best doctors and researchers and scientists in the world working for us at NIH, and how fortunate we are to have them. Those researchers at NIH were able to develop Gleevec, because for many years, they worked to understand the biology of the cancer cell at the molecular level.

Let me take just a moment to thank Dr. Rick Klausner for his outstanding leadership in spearheading the Gleevec project. In my months at HHS, I've come to greatly appreciate Dr. Klausner and his fine stewardship of the National Cancer Institute at NIH. He is a valued member and partner and friend of all the HHS team.

NIH has joined those researchers with extensive human clinical trials and the development of a national network of cancer centers that link research. I have one of those cancer centers in my home state of Wisconsin and they do just a remarkably outstanding job. These cancer centers also work to keep doctors and other health care professionals abreast of the latest developments. NIH also operates an unrivaled cancer surveillance and epidemiology program for monitoring cancer at every level.

This multi-pronged approach is paying off, as now, other promising treatments are in the offering. One of them is a process called anti-angiogenesis, which denies malignant tumors the blood they need to continue to grow. The National Cancer Institute has supported 71 clinical trials of these drugs. Gleevec is the first, and it's exciting, but we have others in the pipeline, and will be ready to come out on the market. We're reviewing those tests and the data they've produced. We don't have a definite answer yet as to how effective those drugs might be, but we continue to explore this exciting potential treatment.

Of course, these developments don't tell the whole story. If they did, we wouldn't be here today. Let me talk with you about what else we're doing at HHS to combat cancer, what our agenda is for the future.

President Bush has submitted an aggressive, forward-looking budget, and of course, all of know how President Bush's father has been involved in the Cancer Dialogue [National Dialogue on Cancer] and I'm a member of that—was a member of the Dialogue until my attorneys told me I had to resign—but I still go the meetings.

The budget is an aggressive, forward-looking budget that's designed to boost anti-cancer efforts as never before. The President's budget reflects how serious he is about the whole Administration waging a fight to win this war against cancer. The President is sending a clear message. He doesn't just want us treating a disease, he wants us beating a disease, especially such an onerous disease as cancer.

Our budget provides $23.1 billion for the National Institutes of Health, a $2.75 billion increase over 2001 and the largest increase ever for NIH. And I think Congress is probably going to increase that amount. Our funding for NIH includes 34,000 research grants, the most ever provided.

People don't understand the 75 to 80 percent of our dollars that go into NIH go back to these cancer clinics and research centers all over America, so we have the best scientists weighing in, not only on cancer, but other diseases as well. Great research is being done.

A cornerstone of this year's NIH budget is an increase of $514 million for cancer-related research in 2002. That's a 12 percent increase. While I'm discussing the NIH budget, let me also note that NIH is revitalizing the way it develops and conducts clinical trials of cancer treatments. We want to make the trial process more flexible and more inclusive. We want to encourage greater feedback from patients and their families, as well as the researchers and practitioners who conduct these trials. The new system is designed to speed new ideas from the lab to the clinic, streamline the paperwork, and expedite the reporting process. The bottom line is the new clinical trials system will enable people with cancer to receive a higher quality of care, and, yes, receive it faster.

Our budget also includes funds to continue the revitalization of key facilities at the Centers for Disease Control and Prevention in Atlanta. It's important for us to do that. As many of you know, the CDC has a cancer screening program that's available to poor women nationwide, and under legislation that took effect last October, the federal share of costs for treating cancer in women on Medicaid can now go as high as 85 percent. That's going to enable many disadvantaged women, poor women, minority women, to receive treatment that they otherwise could not afford.

At a broader level, the President's budget seeks to improve access to basic health care to everyone, including those with limited incomes and limited access to care, so that diseases such as cancer can be diagnosed and treated as early as possible. Because of our commitment to better health care for all

Americans, and we're also mindful of the 43 million people in this country who lack health insurance. We're looking at ways to address that problem.

We're also looking at ways to reform the National Health Service Corps to better target placement of providers in areas experiencing the greatest shortage of health care professionals.

These are significant goals, but also obtainable ones. They are important because they will help deliver quality care to people in some of our neediest communities.

The President is also working to strengthen and modernizing Medicare, in part, by adding a prescription drug benefit. I should note that just last September, Medicare began paying for the routine health care costs of beneficiaries in clinical trials. This will provide a special benefit for older Americans.

But the budget we're proposing goes beyond numbers and programs. It's about innovation and effectiveness and even moral courage. We can no longer be content with doing things as they've always been done. Many of you have remarkable, moving stories about how you have fought or even now are fighting your own war with cancer.

As I said at the beginning, I appreciate deeply your sharing that with us and applaud your courage. We need to persevere until the threat of cancer is much more distant and much less severe. With your help, that's exactly what the President, my colleagues, and I at HHS intend to do. It's wonderful to be with you. The President's Cancer Panel is doing a tremendous job, and I thank each and every one of you.

In Brief:

NCI Clarifies Plan For Review Of Epidemiologic Research

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review cycle for R01 grants over $500,000 in direct costs. NCI officials clarified the plans this week. The Institute will issue a Program Announcement with a special review and set-aside (PAR-S) for grant applications that involve epidemiologic cohorts with budget requests in any grant year over $500,000 direct costs. The advantage for the NCI is control over costs and the ability to determine in advance how much it can afford to spend in this area. The benefit to grantees is review within the NCI structure. NCI staff are now working on the PA. Details will be forthcoming soon about review dates. It is expected that the first receipt date will be October-November 2001. . . . **KOEN VAN BESIEN** and was named director of the Transplant and Lymphoma Program at the University of Chicago by **Everett Vokes**, John E. Ultmann Professor of Medicine and Radiation Oncology and director of the Section of Hematology/Oncology at UC. Van Besien, whose research interests include allogeneic and autologous transplantation for hematologic malignancies as well as the conditioning regimens and studies of unrelated and alternative donor transplant procedures, was director of stem cell transplantation at the University of Illinois-Chicago Medical Center. He is a member of the American Society of Hematology, the American Society of Clinical Oncology, and Cancer and Leukemia Group B. . . . **H. LEE MOFFITT Cancer Center & Research Institute** received $1 million for an endowed chair in the name of **William Dalton**, deputy director and associate center director for clinical investigations at Moffitt. The gift was given by Frank and Carol Morsani for clinical cancer research. . . . **GREGORY MUNDY** was named SBC communications chairman and director of the Cancer Therapy and Research Center Institute for Drug Development of San Antonio. IDD is a private, non-profit, medical research organization that develops cancer treatments through the integration of research programs of excellence in the basic, translational and clinical sciences. Mundy is Joseph C. and Irene Heyser Professor of Bone and Mineral Metabolism, Head of the Division of Endocrinology and Metabolism and Assistant Dean for Clinical Research at the University of Texas Health Science Center at San Antonio, where he has been since 1980. He will continue to occupy those positions. At the IDD, Mundy will direct a staff of 139 with a budget of $13.1 million. He is a bone and cancer metastasis researcher, is board certified in internal medicine and endocrinology and metabolism and serves on a number of NIH study groups, said **Charles Coltman, Jr**., president and CEO of the CTRC. . . . **THE CANCER LETTER** and its editors were profiled in an article in The New York Times, Science Times section, on May 29. The story, "Newsletter Trains Muckraking Eye on Cancer World," by Alexis Jetter, is available online at: http://www.nytimes.com/2001/05/29/health/29GOLD.html?ex=992168542&ei=1&en=e15c335510387d9a or check **The Cancer Letter** Web site at http://www.cancerletter.com next week for a link to the story once linking permissions are obtained.

THE CANCER LETTER

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Business & Regulatory Report

Clinical Trials:

For ER+ Breast Cancer, Post-Tamoxifen, NSABP Testing Aromasin In Large Trial

National Surgical Adjuvant Breast and Bowel Project of Pittsburgh said it has begun a phase III trial to evaluate exemestane (Aromasin) in 3,000 postmenopausal women diagnosed with estrogen-receptor-positive breast cancer who have completed five years of tamoxifen therapy.

Known as Protocol B-33, the trial will determine whether exemestane will prolong disease-free survival and overall survival, NSABP said. Over

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Oncology Management:

US Oncology To Conduct Up To 5 Studies Of PG-TXL In Colorectal, Lung Cancers

Cell Therapeutics Inc. (Nasdaq: CTIC) of Seattle, and **US Oncology Inc.** (Nasdaq: USON) said they have entered into a research services agreement under which US Oncology will conduct up to five clinical studies in colorectal and lung cancers with the cti PG-TXL.

PG-TXL links paclitaxel, the active ingredient in Taxol to a biodegradable polyglutamate polymer, the company said. PG-TXL is in a single-agent phase I trial in the U.K. and in phase I/II trials as single-agent therapy and in combination with other drugs in the U.S.

"We are enthusiastic about playing a significant role in the clinical development of this drug because of the ease of administration, as well as the potential for reduction in neurologic toxicity and improved anti-tumor activity," said Alan Keller, co-medical director of clinical research at US Oncology.

* * *

Oncology Nursing Society of Pittburgh, said it would endorse the patient and nursing education components of the **iKnowMed** iKnowChart, a web-based, electronic charting solution designed for medical oncology professionals.

The charting solution, which streamlines workflow for nurses, features embedded, intelligent decision-support that interacts directly at the point of care in the ambulatory setting, said ONS.

"This offering demonstrates the power of bringing information and informatics technology together to enhance the delivery of cancer care," said Bridget Culhane, executive director of ONS.

(Continued to page 8)

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Aromasin In Phase III Trial For Use After Tamoxifen

(Continued from page 1)

100 sites in the U.S., Canada, and Puerto Rico are expected to take part in the trial.

Exemestane, developed and marketed by **Pharmacia Corp**. is approved for the treatment of advanced breast cancer in postmenopausal women whose tumors have stopped responding to tamoxifen, said NSABP. It is the first and only oral drug in a class of therapies called aromatase inactivators that selectively target and irreversibly inactivate the aromatase enzyme, which is required to produce estrogen. In contrast to aromatase inhibitors, which only temporarily inhibit the enzyme, Exemestane reduces the supply of estrogen to cancerous cells and prevents them from growing.

"The study could ease concerns regarding breast cancer recurrence and what treatment options are available after tamoxifen therapy is complete,"said Roy Smith, NSABP director of medical affairs and oversight, and protocol officer for B-33.

In the trial, women who have completed five years of tamoxifen therapy will be randomly assigned to take 25 mg of exemestane daily for two years or placebo, said NSABP. The most commonly reported side effects associated with exemestane include mild to moderate hot flashes, nausea, and fatigue.

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AstraZeneca (NYSE: AZN) of Wilmington, DL, said it has completed enrollment in the phase III trial of Iressa (ZD1839) for non-small cell lung cancer.

The compound is an oral treatment that targets the epidermal growth factor receptor inhibiting tyrosine kinase activity, the company said. Expression and overexpression of EGFR is found in many tumor types. Clinical data suggests that excessive levels of the receptor are linked to poor prognosis, including tumor invasion and development of metastatic cancer, the company said.

Over 2,000 patients at 477 centers worldwide are enrolled to study the effectiveness of adding the compound to two different standard chemotherapy treatments in the randomized, double-blind, placebo-controlled trials for advanced stage III/IV non-small cell lung cancer. All patients received standard therapy (gemcitabine and cisplatin or paclitaxel and carboplatin) and one of the following: ZD1839 250 mg, ZD1839 500 mg or placebo orally each day, the company said.

The company said it has completed patient recruitment in two global multi-center monotherapy trials testing the drug as a single agent for NSCLC which has progressed following standard chemotherapy.

Clinical studies of Iressa are being conducted for other solid tumors: global phase I combination therapy trials in hormone refractory prostate cancer and a phase II monotherapy trial for HRPC are in the U.S. Phase II monotherapy trials in breast cancer are slated to begin later this year, the company said. Trials testing the compound in combination with other standard chemotherapies in recurrent NSCLC will be starting in the near future and pediatric trials in solid tumors later this year.

NCI or oncology cooperative groups are accruing patients into clinical trials with the compound in renal cell, bladder, glioblastoma and brain cancers, the company said. Other NCI trials will be starting in the next few months, including studies in brain, prostate, colorectal, lung (including mesothelioma), endometrial, ovarian, head and neck and other solid tumors. A large cooperative group trial for newly diagnosed stage III NSCLC will also be opening shortly. Trial participants will be given conventional chemo-radiation therapy for four months followed by 3 cycles of docetaxel and then will be randomized to Iressa versus placebo, the company said.

* * *

BioTransplant Inc. (Nasdaq: BTRN) of

Charlestown, MA, said that **Eligix, Inc**. has received clearance from FDA to begin a phase III trial of its BCell-HDM cell separation system for low-or intermediate-grade non-Hodgkins lymphoma.

The trial would serve as the principal basis for a pre-market approval application, the company said.

The randomized trial, which will take place at 12 cancer centers in North America, would eliminate malignant B-cells from autologous stem cell transplants, the company said.

BioTransplant has signed a definitive agreement to acquire Eligix in a merger, which is subject to certain conditions including stockholder approvals, the company said.

The product was demonstrated in a feasibility clinical trial at Dana-Farber Cancer Institute, the company said. B-cells were effectively depleted from all but one patient stem cell collection, and no delayed recoveries or adverse events related to use of BCell-HDM were observed.

* * *

Celsion Corp. (Amex: CLN) of Columbia, MD, said it is requesting FDA approval to expand the number of phase II trial sites of its focused heat treatment system from six to ten for benign prostatic hyperplasia.

Recruitment would focus on high volume private urology practices, such as the Linked Urology Research Network, the company said. Celsion has already agreed to enroll three LURN sites with a combined total of 71 urologists who treat 15,000 patients per month. The four new sites will supplement the traditional teaching hospitals already included, the company said.

The company said it is in discussion with FDA about using a modular submission process in applying for its pre-market approval to expedite the PMA process approving individual sections of the total application package in advance of the final submission of patient data, the company said.

* * *

Enzon Inc. (Nasdaq: ENZN) of Piscataway, NJ, said it has begun a phase I trial for PEG-paclitaxel for advanced solid tumors and lymphomas.

The 40-patient trial is designed to determine the safety, tolerability, and pharmacology of the treatment, the company said.

PEG-paclitaxel is a PEG modified version of paclitaxel formulated for ease of administration, the company said. Preclinical animal studies have demonstrated that PEG-paclitaxel can be dosed at higher levels than Taxol (paclitaxel), which may allow increased efficacy, the company said.

Using the Enzonproprietary PEG technology, paclitaxel was modified through the chemical attachment of PEG using a linker designed to deteriorate over time, giving PEG-paclitaxel prodrug attributes, the company said. The treatment was to be delivered without the need for solubilizing agents or premedications.

* * *

ImmunoGen, Inc. (Nasdaq: IMGN) of Cambridge, MA, said it has begun enrollment for a third phase I/II study of its tumor-activated prodrug huC242-DM1/SB-408075 for colorectal, pancreatic and certain non-small cell lung cancers.

The study will evaluate the treatment in a more dose- intensive regimen at the Institute for Drug Development of the Cancer Therapy and Research Center in San Antonio, under the direction of Anthony Tolcher and Eric Rowinsky.

Another phase I/II study, designed to evaluate the safety of huC242-DM1/SB-408075 when administered on a weekly regimen, is ongoing at the University of Chicago Cancer Research Center under the direction of Richard Schilsky, the company said.

TAP technology delivers cytotoxic agents directly to tumor cells with minimal harm to healthy tissue, the company said. Each TAP product is comprised of a small molecule effector drug, which is 100- to, 1000-fold more potent than existing chemotherapeutics conjugated to a tumor-targeting monoclonal antibody. The TAPs are designed to act as prodrugs and remain nontoxic while circulating in the body, only activated once they are inside the target cell, the company said. In preclinical studies, TAPs have shown therapeutic efficacy and complete cures at doses with no clinical signs of toxicity [RVJ Chari et al., Proceedings of AACR, 39:4382(1998)].

HuC242-DM1/SB-408075 is a TAP created by conjugating the cytotoxic maytansinoid drug DM1 with the humanized monoclonal antibody huC242, the company said.

* * *

MGI Pharma Inc. (Nasdaq:MOGN) of Minnneapolis said it has initiated a phase II trial of irofulven, an anti-cancer compound for recurrent malignant glioma.

The international, multi-center study will evaluate anti-tumor activity, safety, and pharmacokinetic/ pharmacodynamic profile of irofulven as a single agent in up to 27 patients, the company said. Objective

tumor response rate is the primary endpoint of the trial; duration of response, time to disease progression, and overall survival are secondary endpoints.

"In preclinical studies, irofulven has demonstrated tumor regression or prolonged survival in mice implanted with several human glioma tumor cell lines," said Henry Friedman, James B. Powell Jr. Professor of Neuro-Oncology at Duke University Medical Center and an investigator the clinical trial. "Irofulven has shown marked activity against glioma xenografts, including an intracranial xenograft model, which demonstrates the drug has the ability to cross the blood-brain barrier in an active form."

"The use of irofulven in the treatment of recurrent glioma is of particular interest because its anti-tumor activity is independent of common drug-resistant mechanisms and it has no cross resistance with alkylating agents," said Eric Raymond, medical oncologist at Institut Gustave Roussy in Villejuif, France, and lead investigator for the trial.

Irofulven, known as MGI 114, hydroxymethylacylfulvene, is being tested in a series of clinical trials for solid tumors across a variety of cancers, the company said. The compound has demonstrated anti-tumor activity as a single agent in clinical testing against pancreatic, ovarian and prostate cancers. Earlier this year, the company said it initiated a phase III trial of the compound for advanced-stage, gemcitabine-refractory pancreatic cancer.

Side effects from irofulven are comparable to those seen with marketed chemotherapies and include bone marrow suppression, nausea, vomiting and fatigue, the company said.

In another development, the company said it has begun a phase II trial of irofulven for advanced or metastatic refractory sarcoma.

The international, multi-center trial will evaluate the anti-tumor activity and safety of the drug as a single agent in up to 40 patients, the company said. Objective tumor response rate is the primary endpoint in the trial; duration of response, time to disease progression, and overall survival are secondary endpoints. Qualitative and quantitative toxicities will also be assessed, the company said.

In a phase I trial, the drug has demonstrated clinical activity in sarcoma patients that had failed prior therapies, the company said. One partial response lasting six months, and four disease stabilizations lasting for at least four months, have been achieved among the 12 advanced sarcoma patients evaluable for response.

"Based on the clinical data, irofulven deserves further clinical evaluation in soft tissue sarcoma, a disease known to be refractory to standard treatments and for which no effective second line therapy exists," said Jean-Yves Blay, professor of medical onocology at Hopital Edourd Herriot in Lyon, France, and principal investigator for the trial.

* * *

Ontogen Corp. of San Diego, said it has begun a phase I study of intravenous paclitaxel (Taxol) in combination with oral OC144-093 for multidrug resistance at British Columbia Cancer Agency in Vancouver, following approval of its Canadian IND.

Multidrug resistance is recognized as the most common cause of failure of cancer chemotherapy, the company said.

In the six-cohort trial, each patient receives Taxol alone followed by escalating doses of both Taxol and oral OC144-093, the company said.

"Positive results in the multi-dose trial will advance the drug to a phase II efficacy trial in patients receiving Taxol for metastatic breast cancer," said Ross Dixon, executive director of drug development at Ontgen.

"Historically, the idea was that therapy in MDR would not be administered until resistance appears, due to inherent risks involved with existing MDR therapy," said Barry Toyonaga, president and CEO of Ontogen. "Beyond the OC144-093 use after MDR develops, we are looking for a high safety profile with the drug in combination with Taxol that should enable the administration of OC144-093 at the onset of chemotherapy in order to both treat and prevent the emergence of MDR."

* * *

SciClone Pharmaceuticals (Nasdaq: SCLN) of San Mateo, CA, said it has begun a phase II trial combining its immune system enhancer, Zadaxin, with transarterial chemoembolization for hepatocellular carcinoma.

Zadaxin, a synthetic preparation of thymosin alpha 1, a peptide that occurs naturally in humans, stimulates the maturation and differentiation of stem cells into disease-fighting helper T-cells and natural killer cells and increases the identification of cancerous cells for immune intervention, the company said.

TACE is a procedure by which a chemotherapeutic agent, in this case cisplatin, is infused directly to the tumor site rather than administered systemically, the company said. Robert Gish of California Pacific Medical Center in San

Francisco is the principle investigator of the trial.

A phase II trial in January combined Zadaxin with radio frequency ablation, a process that destroys tumors using radio waves delivered via a probe-bearing needle, the company said. TACE and RFA are the two current treatments of choice for HCC when surgery or liver transplantation are not options. Neither TACE nor RFA, however, achieves more than modest success when used alone, the company said.

In the open label, controlled TACE trial, patients will be randomized in equal numbers to one of two treatment arms, TACE alone or TACE plus Zadaxon, the company said. They will receive treatment for 6 months, followed by a 12-month observation period. Primary endpoints will be tumor response and patient survival. A secondary endpoint will be the number of patients who become eligible for liver transplantation due to a reduction of tumor burden, the company said.

In a pilot study conducted in Italy, patients treated with the combination of Zadaxin plus TACE showed a statistically significant longer survival time than patients treated with TACE alone, using historical case-matched controls, the company said.

Malignant melanoma, for which trials already have begun in Australia, is likely to become the next U.S. phase II target, the comapny said.

Deals & Collaborations:

UAB To Evaluate Firm's Prostate Cancer Treatment

Galenica Pharmaceuticals of Birmingham, said it will collaborate with the **University of Alabama** at Birmingham to evaluate its proprietary immune enhancer adjuvant GPI-0100 on mucosal immunity.

The GPI-0100 series, currently in a phase I trial for prostate cancer under an agreement with Memorial, is comprised of second-generation, semi-synthetic derivatives of certain natural saponins, the company said. These plant-derived pathogen-resistant agents stimulate antigen-specific cytotoxic T lymphocytes production that seek and destroy cells carrying abnormal markers, such as viral, intracellular parasites or tumor markers.

Suzanne Michalek, professor at the UAB Department of Microbiology, is scientific director of the studies. "As GPI-0100 has already been proven to enhance both humoral and cellular immunity it makes an attractive experimental compound for stimulating mucosal immunity," she said.

* * *

Inex Pharmaceuticals Corp. (TSE: IEX) of Vancouver, said it has formed a joint venture with **Elan Corp. plc** (NYSE: ELN) to develop and commercialize Onco TCS for a number of cancers.

Onco TCS is a proprietary drug comprised of the off-patent cancer drug vincristine encapsulated in the Elan TCS (liposomal) drug delivery technology, the company said. The technology provides prolonged blood circulation, tumor accumulation and extended drug release at the cancer site, which increase the effectiveness and reduce the side effects of the encapsulated drug, the company said.

Inex could receive up to Cdn$60 million (US$39 million) in funding related to the joint venture and an upfront Cdn$7.5 million purchase of Inex common shares. Inex and Elan will share profits from the commercialization of the product, the company said.

The drug is in a phase II/III trial for relapsed aggressive non-Hodgkin's lymphoma, the company said. The trial is could provide sufficient data to seek marketing approval, with a regulatory filing in late 2002 or early 2003. The drug is in phase II trials for small cell lung cancer, relapsed solid tumours and leukemia in children and adolescents and first-line treatment of non-Hodgkin's lymphoma.

* * *

Leukemia & Lymphoma Society said it is collaborating with **Novartis** to educate the public about Gleevec, approved by FDA for CML in the blast crisis, accelerated phase or the chronic phase after failure of interferon.

The society's Information Resource Center staff can provide callers with information on CML, Gleevec and free patient services programs available nationwide. The center can be reached at phone 800-955-4572 from 9 a.m. to 6 p.m. EST, or via e-mail infocenter@leukemia-lymphoma.org.

In selected cases in which sufficient funding is not available, Novartis will help patients obtain the drug. For information, call 1-877-GLEEVEC (877-453-3832).

Because Gleevec is an oral cancer therapy, it will not be covered under Medicare. Working to change policy on the coverage of drugs like Gleevec continues to be a priority, the society said. "New oral drugs are becoming an important part of cancer therapy," said George Dahlman, vice president of public policy of L&LS. "Congress needs to ensure that Medicare covers these new treatments so that patients are assured the best in cancer care and medical

research is encouraged to find more agents like Gleevec."

* * *

Merck KGaA of Darmstadt, Germany and **Biomira Inc**. (Nasdaq: BIOM) (TSE:BRA) of Edmonton, said they have entered into a global product development and co-promotion collaboration for the breast and lung cancer vaccines Theratope and BLP25.

Theratope is in a phase III trial for metastatic breast cancer, the companies said. The BLP25 vaccine is in a phase IIb study for non-small cell lung cancer. The collaborative agreement covers the entire field of oncology for the two products.

Under the agreement, the companies said they will jointly market products in the U.S. Merck will market the products through its U.S. affiliate, EMD Pharmaceuticals, of Durham, NC. Merck will have sole development and marketing rights worldwide with the exception of Israel and the Palestinian Autonomy Area for which agreements were already in place.

Biomira will retain marketing rights in Canada; the company will receive an up-front cash payment and equity investment. Biomira will also receive cash and equity investments for biologics license application submissions for first and second cancer indications, on regulatory approvals for first and second indications, and for sales milestones.

The total value of the agreement to Biomira is more than $150 million in license, milestone payments and equity investments. The parties will share development costs in North America, and Merck KGaA will be responsible for clinical studies and marketing outside of North America, the companies said.

The 120 clinical site phase III trial of Theratope, one of the largest trials ever undertaken with an immunotherapeutic agent in breast cancer, has resulted in an FDA designation as a Fast-Track development program, the companies said. Final analysis of the trial data is expected to begin in mid-2003.

Results of phase I and II trials of BLP25 vaccine for metastatic lung cancer showed it well tolerated and capable of triggering a T-cell mediated immune response against cancer cells, the companies said.

Both cancer vaccines are synthetic mimics, the companies said. Glycoprotein MUC1 is a cancer mucin, a cancer-associated marker that has been shown to inhibit T-cells and cause the immune system to ignore the presence of disease. The vaccines are designed to restore the body's immune function to recognize the foreign antigen and mount an attack against cancer cells.

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H. Lee Moffitt Cancer Center & Research Institute, of Tampa and **Watson Clinic** of Hillsborough and Polk Counties, FL , said they have signed an affiliation alliance contract for oncology services that will provide a seamless transition between the community and academic health settings.

The agreement would promote joint education, clinical research protocols and complex cancer treatment, the groups said.

"The affiliation will allow patients increased access to special protocols available only through an NCI designated comprehensive cancer center such as Moffitt and expanded treatment opportunities for patients within their own communities," said John Ruckdeschel, center director at Moffitt.

* * *

Pharmacyclics Inc. (Nasdaq: PCYC) of Sunnydale, CA, said it has regained its rights from **Nycomed Amersham plc** (NYSE: NYE; London: NAM) to develop and market Lutrin (motexafin lutetium) injection for cancer treatment in Europe, Asia, South America and Central America.

Lutrin, a photosensitizer in a class of drugs called texaphyrins, selectively targets and accumulates in cancer cells and disrupts cellular metabolism by a unique mechanism of action, the company said. By interfering with the flow of energy in cancer cells, the drug makes certain tumors more responsive to the effects of photodynamic therapy.

Parmacyclics entered into an agreement with Nycomed in 1997 that gave Nycomed a license to develop and commercialize Lutrin for cancer outside the U.S., Canada and Japan, where Pharmacyclics had retained its rights.

Under the original agreement, Nycomed was obligated to make certain milestone payments and fund a portion of research and development, the company said. As a result of a Nycomed merger with Amersham International in 1997, Pharmacyclics has reacquired its rights and will receive a one-time fee from Nycomed Amersham this fiscal quarter to cover their future R&D obligations.

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Research Triangle Institute, of Research Triangle Park, NC, and Manchester, UK, said it has begun **RTI Health Solutions**, a business unit that assesses the value of healthcare products for pharmaceutical, medical device, and other health industry clients.

A multi-national organization, the business focuses on health economics and outcomes research programs, with emphasis in the following areas: health economics and quality of life; statistics, surveys, and data management; epidemiology and clinical research; and market research and business strategy, the company said.

The staff includes economists, statisticians, psychometricians, epidemiologists, clinical trials specialists, survey researchers, and market research specialists with experience in business, government, consulting, and academic research.

By creating international project teams with researchers from relevant disciplines, the unit can support clients with a range of projects, such as evidence-based reviews and meta-analysis; healthcare product cost-effectiveness analyses; statistical analyses of clinical trial and observational data; patient and healthcare provider questionnaire development and validation; data collection through telephone, internet, and face-to-face interviews; market assessments and product profiling; and product positioning and branding, the company said.

* * *

University of Pennsylvania Cancer Center and the **Department of Radiology** of Philadelphia, said they have joined with **Integral PET Associates, LLC**, an operator of fixed-site positron emission tomography scanning centers, to create the PENN PET Program to make cancer diagnostic tools available to community hospitals throughout Eastern Pennsylvania and New Jersey.

Integral PET will manage the sites, while Penn radiologists interpret the PET scans and oversee the medical aspects of program, the center said. Abass Alavi, chief of nuclear medicine, will lead the PENN PET Center physician team.

Seven PET centers will open at community hospitals in the UPCN within the next six months, each with fixed PET scanners, the center said. Future sites may have fixed or mobile scanners, depending on patient demand.

"A primary goal in forming the cancer network has been to transfer advances in cancer diagnosis and treatment to the community setting as quickly as possible," said John Glick, director of the UPCC and professor of medicine hematology/oncology at the University of Pennsylvania School of Medicine.

Because of its unique ability to measure metabolic activity, PET can lead to accurate, noninvasive detection and staging of many cancers, including: lung, melanoma, lymphoma, esophageal, colorectal, breast, thyroid, ovarian, cervical, endometrial, pancreatic, testicular, brain, head and neck, the center said.

Emerging Technologies:

Company To Expand Program Studying Polymer Platinates

Access Pharmaceuticals Inc. (Amex: AKC) of Dallas, said it would expand its polymer platinate activities to include a development program for the DACH form of platinum.

Oxaliplatin, another form of DACH platinum, is marketed in Europe and is indicated for first-line treatment of metastatic colorectal cancer in combination with 5-flurouracil and folinic acid, the company said. It has a similar mechanism of action as other platinum derivatives, however it is the only platinum drug effective in the treatment of colorectal cancer.

In preclinical models, DACH polymer platinate demonstrated superior anti-tumor activity in the B16 melanoma model, when compared to carboplatin, the leading platinum product, the company said.

Access Pharmaceutical would expand its platinate program by investigating alternate platinum structures in combination with their polymer technology, the company said.

* * *

Genesis Bioventures (AMEX:GBI) of New York, NY, said its portfolio company, **Biomedical Diagnostics Inc.** will introduce its mammastatin serum assay for breast cancer risk assessment into the U.S. healthcare market via specialized reference laboratories.

The assay is a blood test technology that measures the levels of mammastatin in the blood, the company said. Mammastatin is a naturally occurring protein that controls cell growth in breast tissue. In early clinical studies, it was found to be present in relatively high levels in the blood of more than 85 percent o healthy women and low or absent in more than 75 percent of breast cancer patients.

Product Approvals & Applications:

FDA Approves Campath For B-Cell Leukemia

Berlex Laboratories Inc., of Montville, NJ, the U.S. affiliate of **Schering AG**, (NYSE: SHR) said

FDA has approved the marketing of Campath therapy (alemtuzumab), a humanized monoclonal antibody for B-cell chronic lymphocytic leukemia when treatment with alkylating agents and fludarabine therapy have failed.

The therapy was developed by **M&I Partners**, a joint venture of **Millennium Pharmaceuticals** Inc. (Nasdaq: MLNM) and **Ilex Oncology Inc.** (Nasdaq: ILXO), the company said.

Campath targets the CD52+ antigen on the malignant lymphocytes, binds to the antigen and induces antibody-dependent lysis following binding, the company said. Malignant lymphocytes are thereby removed from the blood, bone marrow, and other affected organs. Treatment with the therapy may improve blood counts and decrease the size of the liver and spleen, the company said.

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Hoffmann-La Roche Inc. of Nutley, NJ, said FDA has approved Xeloda (capecitabine), the first oral chemotherapy for metastatic colorectal cancer.

The pill works through enzymatic activation to the cancer-fighting substance 5-FU, the company said. The body produces the enzyme thymidine phosphorylase, which converts Xeloda into 5-FU.

A survival benefit has not been demonstrated with Xeloda monotherapy as with the combination chemotherapy, the company said. Use of Xeloda instead of 5-FU/LV combinations has not been adequately studied to assure safety or preservation of the survival advantage.

Patents:

Genentech Didn't Infringe Patents, Delaware Jury Finds

Genentech Inc. (NYSE: DNA) of South San Francisco, said a federal jury in Delaware unanimously found that its oncology products, Herceptin (trastuzumab) and Rituxan (rituximab), do not infringe patents held by **GlaxoSmithKline.**

The jury found that all of the patent claims that GlaxoSmithKline asserted against Genentech were invalid, the company said.

"GlaxoSmithKline technology played no role in the development of Herceptin and Rituxan, and its patent claims are invalid because Genentech scientists and others working in the field earlier developed the very technology that GlaxoSmithKline was claiming as its own," said Arthur Levinson, chairman and CEO of Genentech.

GlaxoSmithKline filed its lawsuit in May 1999 asserting that Genentech infringed four of its U.S. patents, the company said. Two of the patents related to the use of specific kinds of antibodies for diseases, including cancer. The other two patents asserted against Genentech related to preparations of specific kinds of antibodies to make them more stable and the methods by which such preparations are made, the company said.

Oncology Management:

OTN, NexCura Enter Alliance For Licensing Web Tools

(Continued from page 1)

ONS developed its Seal of Endorsement program to allow health care professionals and consumers to select quality educational materials related to cancer care and assures the information presented—in educational seminars, publications, or other resources—is reliable and credible, the society said.

The endorsement is the first joint accomplishment since the merger of iKnowMed and CancerSource, the companies said. CancerSource is chaired by Vincent DeVita Jr., director of the Yale Cancer Center.

* * *

Oncology Therapeutics Network, a subsidiary of **Bristol-Myers Squibb Co.** (NYSE: BMY) of San Francisco and **NexCura, Inc**. of Seattle, a clinical data and communication services company that provides proprietary, Web-based decision-support technologies, said they have entered into a multi-year strategic alliance, which includes a three-year master licensing contract for embedding, marketing, and distributing the NexCura suite of cancer treatment decision applications on the OTN oncology portal and to oncology practices.

The NexCura evidence-based cancer profiler treatment decision tools will support the OTN educational resources to oncologists with personalized evidence based information that save time and improve patient satisfaction, the company said.

"Community oncology practices are under tremendous time pressures from increased caseloads, making it challenging to stay abreast of the latest treatment modalities and diagnostic procedures and continue to provide cancer patients with on-going information and support," said Tom Ludlam, president of OTN. "By partnering with NexCura, we are able to provide convenient access to relevant information based on definitive clinical research."

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