THE CANCER LETTER

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AACR Selects Eight Finalists To Compete For $15 Million Grants Funded By Telethon

By Paul Goldberg

The organizers of the Stand Up To Cancer telethon said they have narrowed the competition for "Dream Team" grants to eight groups of researchers, four of which could be selected to receive funding.

The grants would pay as much as $15 million each over three years to as many as four groups. The announcement makes it clear that the organizers of the Sept. 5 telethon are spending only the $104 million they say they raised in connection with the event.

The group's public statements and exchanges of e-mail with The Cancer Letter don't provide a complete picture of the event's finances, but SU2C organizers said that the details would be made public after accounting is

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NCI Programs:

NCI To End CIS Partnership Program In 2010; Contracts Supported Community Outreach

By Kirsten Boyd Goldberg

NCI officials said they plan to eliminate a communications and community outreach program that has been part of the institute's Cancer Information Service since 1984.

The CIS Partnership Program, which had a budget of about $9.16 million in fiscal 2008 and supports 15 contracts, will not be renewed when the contracts end in January 2010.

The NCI Executive Committee made the decision to end the program, institute officials said in a Dec. 2 conference call with CIS grantees and representatives of cancer advocacy organizations.

"What that means is not that NCI is no longer interested in reaching out to communities and reaching out to organizations," said Lenora Johnson, director of NCI's Office of Communications and Education. "What the decision means is that we need an opportunity to pause and to reexamine the current environment in which we are operating. There are many challenges we face, and we want to take the opportunity between now and the end of the contract to reassess exactly what is happening in the field, gain a new understanding of the different roles that the many organizations play, how NCI is unique in those roles, and what can we put in place to have the greatest opportunity for impact in the communities we serve."

Also, the CIS, which operates the institute's 1-800-4-CANCER

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SU2C Raised $21 Million From Public, 20% Of Total

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completed in January. Financial results of special events, including gross and net proceeds, have to be reported on tax forms of non-profit organizations.

SU2C was organized by the Entertainment Industry Foundation. The American Association for Cancer Research is conducting peer review for awarding funds to scientists.

If SU2C events continue to raise money, they may open a new funding source for cancer research. If not, SU2C would become a one-time windfall for the funded researchers.

"The process clearly inspired applicants to think creatively about how they could reach across natural boundaries, of both institutions and nations, to collaborate more effectively and accelerate progress," the scientists directing the review said in a jointly issued "progress report."

The eight finalists weren't identified.

SU2C organizers declined to disclose whether the $104 million figure represents the gross or net proceeds from the event. However, they did report how the money would be apportioned:

—The Dream Teams would receive $72.8 million, which amounts to 70 percent of the total.

—The Innovative Grants, another grant mechanism, which would fund work by young researchers, would get $20.8 million, or 20 percent.

—Another $10.4 million—10 percent—would be set aside as a reserve, which would be held by EIF.

This would be a large windfall for the foundation. Though the Los Angeles-based charity is a powerful player that serves as a gateway to the entertainment industry, it is relatively modest in size. According to tax filings for 2006, the foundation raised $33.5 million. By way of comparison, the Lance Armstrong Foundation reported gross receipts of $43.2 million during the same year. AACR's gross receipts were $52 million.

Information released through an EIF spokesman makes it possible to attempt a back-of-the envelope calculation of cost allocation by the organizers of the event. If four Dream Teams will receive $60 million ($15 million each), this leaves the allocation of $12.8 million uncertain.

It's not publicly known whether this residual represents costs that have already been incurred or costs of continuing to run the Dream Team program.

Any impact of multi-year commitments isn't publicly known. Also, outsiders don't know how much of this money would go to AACR and how much would stay at EIF. And it's unclear whether a similar amount—about 18 percent—is being charged against other SU2C programs.

After the event, SU2C organizers said that administrative overhead, out-of-pocket expenses and ongoing administrative expenses were completely underwritten by corporate donors and wouldn't be withheld from the funds raised for research. However, AACR would withhold administrative fees for running the grants program, SU2C organizers said (The Cancer Letter, Sept. 12).

Another Event Being Planned?

The event's organizers declined to state directly whether another telethon is being planned.

"We are in the midst of refining the concept for our major 2009 event, which will again be geared toward raising awareness and galvanizing the public to support research," Tom Chiodo, a spokesman for SU2C, said in an e-mailed response to questions from The Cancer Letter. "As the details firm up, we will share them with you."

As they unveiled SU2C, organizers said informally that they hoped to raise $250 million. The group's announcements claim that "this is where the end of cancer begins."

However, the event attracted a small audience and ran into technical problems and ended up raising $21.3 million from the public.

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Their initial expectations notwithstanding, SU2C organizers now say that public donations to the telethon were similar to donations to a 2001 benefit for victims of the Sept. 11 attacks and the 2005 benefit for victims of Hurricane Katrina. These events raised $30 million each.

It's too early to say whether networks would be willing to donate additional time for an SU2C event next year.

Television industry sources estimate that commercial-free time donated by the three television networks was worth $14 million, about two-thirds of gross receipts from the public. Rental charges for the Kodak Theatre, the costs of travel, receptions, and other charges were substantial, too.

However, Major League Baseball, the philanthropist Sidney Kimmel, pharmaceutical companies, a yogurt-maker and a few others did make large, multi-year contributions. It is unclear whether these sources can be tapped again.

"The real question is what the goals were when they planned the event, and I am certain that generating awareness would have been one of them," said Suzanne Coffman, a spokesman for GuideStar, a reporting service on non-profits.

The fundraiser attracted 10.4 million viewers on all three networks. Taken individually, none of the networks was able to beat Fox Broadcasting Company's "Are You Smarter than a 5th Grader?" or CW cable channel's "Friday Night SmackDown," a professional wrestling program.

Funding Model "Breaks New Ground"

AACR Executive Director Marge Foti said the partnership with SU2C has given her association "an unprecedented opportunity to develop a funding model that breaks new ground, and to do it in a way that maintains the highest standards for scientific review."

"It's extraordinary to realize that the ideas were submitted in early fall and that the Scientific Advisory Committee will make its final decisions on the first round of funding in spring, 2009," Foti said in an e-mail. "This remarkable group has moved very fast especially when you consider the enormous amount of work that has to be done to get collaborative teams from multiple institutions up and running. Nothing like this has ever been done before. At the same time that they are moving quickly, the Review Committee is also using caution in evaluating the proposals to meet the goals of the SU2C founders. SU2C feels very strongly that this money should be allocated to the projects and teams that can have the greatest impact on patient care in the shortest amount of time. It is also important to remember that they don't see this as a one shot deal."

SU2C spokesman Chiodo said no new organization is being formed. "Stand Up To Cancer is a program of EIF, and the people from the media and entertainment businesses who established it continue to be involved," Chiodo, of the PR firm Rubenstein Associates, said in an e-mail. "EIF is currently recruiting an additional staff member, who will serve as SU2C's executive director."

SU2C said it received 237 brief descriptions of projects from scientists, selecting eight finalists. Typically, these project descriptions took up about two pages. In the next round, the eight finalists will submit formal proposals and will meet with the review committee.

"There is a significant amount of money that can make a difference, and what I care about is that we make good decisions about how to allocate the funds," said Brian Druker, director of the Oregon Health & Science University Cancer Center, and vice-chairman of the review committee for Dream Team projects. "Even if this were only one round of funding, if one of these programs makes an impact, it's a success. One success is all you need to set a paradigm."

Druker said the projects involve a greater level of collaboration than typical NIH grants. "I very much like the projects," he said. "They are bringing groups together than haven't been brought together before."

According to a progress report distributed by the reviewers, the teams funded by SU2C would include a leader and up to eight principal investigators.

"These eight groups [of finalists] have now been asked to submit comprehensive proposals describing their research plans, which the committee will review within the next few months to make final recommendations about which of these exciting projects to fund," states an update dated Nov. 24.

The document was signed by Phillip Sharp, chairman of the SU2C Scientific Advisory Committee and Institute Professor David H. Koch Institute for Integrative Cancer Research at Massachusetts Institute of Technology. The document was also signed by two vice chairmen of the review group: Druker and Arnold Levine, professor Institute for Advanced Study at the Cancer Institute of New Jersey, and Raymond DuBois, AACR President and provost and executive vice president at M. D. Anderson Cancer Center.

The Dream Teams will likely be selected in the spring, AACR said.

NCI Programs:

CIS Partners Lament Proposed Ending Of Outreach Program

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telephone hotline, will eliminate two of three "contact centers" upon recompetition in 2010. Only one contact center would handle public inquiries by phone, email, and internet.

The total CIS budget including the Partnership Program was about $16.6 million in fiscal 2008.

The Partnership Program provides support for the call centers to work with researchers to develop studies of health communications and then test them. In recent years, the program focused on reducing cancer health disparities by improving community access to NCI resources and evidence-based interventions.

Over the past 10 years, NCI has steadily reduced the funding and number of contracts for CIS. In 1999, NCI cut the number of call centers from 19 to 14, in response to a report by the HHS Inspector General criticizing the program's busy signal rate of 29 percent. By 2003, NCI officials said the service had a zero busy signal rate due to improved phone technologies. In fiscal 2002, NCI spent nearly $21 million on the CIS contracts (The Cancer Letter, Aug. 1, 2003).

In 2003, the institute decided to further cut funding for CIS by about $6 million by reducing the 14 call centers to four call centers. The Partnership Program, which had been part of the call centers, became a separate contract program, and 15 awards were made.

In October, NCI issued a notice of its intention to let one contract for the call center, and another notice of its intention to not to renew the Partnership Program.

"We will be engaging in a planning process that analyzes the current domain of cancer in different communities" over the next year, Johnson said. "We will be considering where are the greatest opportunities for impacting specific communities in cancer control activities and trying to understand what can we do in the next five years, in the next 10 years."

Johnson said an analysis of the Partnership Program is underway, but NCI officials had to decide before receiving the results of the analysis whether to continue the program. "The process for procurement is such that the decision to procure has to take place well in advance of actual award," she said. Because of the Executive Committee's decision, "we can only say it will not be renewed."

Madeline La Porta, associate director in the NCI Office of Partnerships and Dissemination Initiatives, said staff would work with contractors to try to find ways to continue research projects through other institute funding mechanisms.

"The priority here at NCI from now until the program ends will be to support the Partnership staff as they work with you to transition projects, to look for areas where we need to be building capacity, or helping you leverage scarce resources that can help keep the work growing," La Porta said on the conference call.

"We are not going to be able to replicate the work the CIS currently does on a national level," La Porta said. "But I want you to know that our commitment to you and to the public remains strong, and that we will be creative, collaborative, and dedicated to get cancer information to the most vulnerable populations."

Partnership Program Stakeholders Comment

On the NCI teleconference, representatives of cancer patient advocacy groups and CIS grantees said the Partnership Program is a unique and valuable resource that directly serves local community organizations.

Some of their comments:

—"What our regional representative from CIS provides to us is a lot of face-to-face time, contacts, and that sort of thing that allows us to give better service," said Toni Hart of Oklahoma State University. "I don't understand how NCI can duplicate that service with a website or printed materials, because we're rural. Most of Oklahoma is rural. I need that help and I don't understand how that's going to be replaced."

—"The North Carolina chapter of the Society for Public Health Education opposes the decision by NCI to dismantle the Cancer Information Service Partnership Program," said Julie Smith, past chapter president. "Many health educators in North Carolina have worked for years with the wonderful Cancer Information Service and felt it has been really, really helpful for consumers and the community."

—"It's sad to think we talk about community outreach and then we are going to take away one of the few resources that are there for community outreach," said Jean Mouch, coordinator of the Camden County (N.J.) Cancer Coalition. "Our experience with the CIS group in Philadelphia has been seamless. They have attended our county coalition meetings, they have helped us do simple evaluation plans, they have given seminars. It's a resource that volunteer coalitions just are going to be lost without. If any kind of plan doesn't have personnel that can come to the local level, then please don't use the words 'community outreach.'"

—"The CIS outreach coordinators are really

doing something that no one is doing—they are really building relationships," said Deborah Erwin, director of health disparities at Roswell Park Cancer Institute. "There is no way any kind of mail, email, electronic mechanisms are going to be able to work with so many of the community organizations. You all have done a fabulous job of training and hiring the very best people that built all of these contracts. If something were to start up and no transition made, it seems to me a great loss of resources, both individual as well as training and money that's already invested."

—"I understand the need to step back and look forward and make sure that all the best resources are mobilized as we work together on these efforts," said Armin Weinberg, member of the Intercultural Cancer Council and faculty member at Baylor College of Medicine. "I do think some of the comments illustrate, however, the importance of not pulling the plug or changing the treatment before you have the next plan in place. It is very clear from the comments so far that people feel this may have been prematurely dropped."

—"I can't express strongly enough the excellent work and the commitment for many years we have gotten from the Partnership Program here in metropolitan Detroit, particularly in guiding our activities to reaching those who are most in need and working on the dreadful problem of cancer disparities," said Maureen Keenan Meldrum, of Susan G. Komen for the Cure in Detroit.

Marlene Oliver, a board member of the National Association of Cancer Patients, and a member of the Washington (State) Comprehensive Cancer Control Program, urged the advocacy organizations and health care professionals to contact members of Congress.

"I'm going to be calling one of my senators, on the appropriations committee," Oliver said. "Her staff is going to be working very closely with me to see what I want in the budget for the next fiscal year. It's amazing people don't realize how much power they have in working with the staffers. A congressman will change his vote with as few as six letters.

"We have a lot of power," Oliver said. "Now is the time to start bombarding your senators and congressmen with these requests. If you want something in the budget, let them know. Get other people in your region to support these, and one by one, it can be done. I've done it before and it can be done again. So for anything near and dear to everybody's heart on the telephone, start now."

Neither budget cutting nor concerns about the quality of the program led directly to the decision to the end the program, Johnson said. However, the institute's tight funding situation didn't help.

"When resources are tight and our primary focus is research, that kind of climate forces you to ask very different questions than you would normally ask," Johnson said. "In this round, we were asked a lot of different questions than were asked five years ago and surely 10 years ago.

"That's not to say it was entirely a budget issue," she said. "From the time CIS began to now, many organizations have evolved. There are many more players in the field. We have heard that no one has done it like [CIS]. No one does it as good. But we are aware of the volume of organizations that have a shared mission. Given these changes over time, is it not time to pause and say exactly what is going on in the community, who are the organizations, what are the roles of organizations? There are a whole host of questions that make it time to pause, assess, and determine what is the best approach for NCI to move forward."

NCI has set up an email box to receive public comment on the decision: nciciscomments@mail.nih.gov. The Dec. 2 teleconference can be listened to through Jan. 2 by calling 800-262-5125. NCI posted a question-and-answer format document about the decision at http://cis.nci.nih.gov/CISppdecision.html.

Cancer Statistics:
For First Time, Incidence And Death Rates Fall Overall

A new report from the nation's leading cancer organizations shows that, for the first time since the report was first issued in 1998, both incidence and death rates for all cancers combined are decreasing for both men and women, driven largely by declines in some of the most common types of cancer.

Although the decreases in overall cancer incidence and death rates are encouraging, large state and regional differences in lung cancer trends among women underscore the need to strengthen many state tobacco control programs, the report said.

The findings come from the "Annual Report to the Nation on the Status of Cancer, 1975-2005, Featuring Trends in Lung Cancer, Tobacco Use and Tobacco Control," in the Journal of the National Cancer Institute on Dec. 2.

Cancer death rates have been dropping since the publication of the first Annual Report to the Nation 10 years ago, but the latest edition marks the first time the report has documented a simultaneous decline in cancer incidence, the rate at which new cancers are diagnosed, for both men and women.

Based on the long-term incidence trend, rates for all cancers combined decreased 0.8 percent per year from 1999 through 2005 for both sexes combined; rates decreased 1.8 percent per year from 2001 through 2005 for men and 0.6 percent per year from 1998 through 2005 for women.

The decline in both incidence and death rates for all cancers combined is due in large part to declines in the three most common cancers among men (lung, colon/rectum, and prostate) and the two most common cancers among women (breast and colon/rectum), combined with a leveling off of lung cancer death rates among women.

"The drop in incidence seen in this year's Annual Report is something we've been waiting to see for a long time," said Otis Brawley, chief medical officer of the American Cancer Society. "However, we have to be somewhat cautious about how we interpret it, because changes in incidence can be caused not only by reductions in risk factors for cancer, but also by changes in screening practices. Regardless, the continuing drop in mortality is evidence once again of real progress made against cancer, reflecting real gains in prevention, early detection, and treatment."

The new report shows that, from 1996 through 2005, death rates for all cancers combined decreased for all racial and ethnic populations and for both men and women, except for American Indian/Alaska Native men and women, for whom rates were stable. The drop in death rates has been steeper for men, who have higher rates, than for women. Death rates declined for 10 of the top 15 causes of cancer death among both men and women. However, death rates for certain individual cancers are increasing, including esophageal cancer for men, pancreatic cancer for women, and liver cancer for both men and women. Overall cancer death rates were highest for African-Americans and lowest for Asian American/Pacific Islanders.

Among men, incidence rates dropped for cancers of the lung, colon/rectum, oral cavity, and stomach. Prostate cancer incidence rates decreased by 4.4 percent per year from 2001 through 2005 after increasing by 2.1 percent per year from 1995 to 2001. In contrast, incidence rates increased for cancers of the liver, kidney, and esophagus, as well as for melanoma (2003-2005), non-Hodgkin lymphoma, and myeloma. Incidence rates were stable for cancers of the bladder, pancreas, and brain/nervous system, and for leukemia.

For women, incidence rates dropped for cancers of the breast, colon/rectum, uterus, ovary, cervix, and oral cavity but increased for cancers of the lung, thyroid, pancreas, brain/nervous system, bladder, and kidney, as well as for leukemia, non-Hodgkin lymphoma, and melanoma.

"While we have made progress in reducing the burden of cancer in this country, we must accelerate our efforts, including making a special effort to reach underserved cancer patients in the communities where they live," said NCI Director John Niederhuber. "This report gives us a better understanding of where we may need to redouble our efforts and try to find new ways of preventing or reducing the occurrence of kidney, liver, and other cancers that continue to show increases in both mortality and/or incidence."

The Special Feature section of the report highlights wide variations in tobacco smoking patterns across the U.S., which, coupled with differences in smoking behaviors in younger versus older populations, helps explains the delay in an expected decrease in lung cancer deaths among women and a slowing of the decrease in lung cancer deaths among men.

The report finds substantial differences in lung cancer death rate trends by state and geographic region. For example, lung cancer death rates dropped an average of 2.8 percent per year among men in California from 1996 through 2005, more than twice the drop seen in many states in the Midwest and the South. The geographic variation is even more extreme among women, for whom lung cancer death rates increased from 1996 through 2005 in 13 states and decreased only in three. The report also notes that, in five states (Pennsylvania, Illinois, Minnesota, Nebraska, and Idaho), lung cancer incidence among women showed an increasing trend, whereas the mortality trend was level.

"It's very promising to see the progress we are making in our fight against cancer," said Centers for Disease Control and Prevention Director Julie Gerberding. "Unfortunately, tobacco use continues to plague our country, and it's the primary reason why lung cancer continues to rob too many people of a long, productive, and healthy life. We must recommit ourselves to implementing tobacco control programs that we know work if we are truly going to impact the staggering toll of tobacco on our society."

Variation in smoking prevalence among the states is influenced by several factors, including public awareness of the harms of tobacco use, social acceptance of tobacco use, local tobacco control activities, and tobacco industry promotional activities targeted in a geographic area. The 13 states where lung cancer death rates for women are on the rise have higher percentages

of adult female smokers, low excise taxes, and local economies that are traditionally dependent on tobacco farming and production.

California, which was the first state to implement a comprehensive, statewide tobacco control program, was the only state in the country to show declines in both lung cancer incidence and deaths in women.

According to a U.S. Surgeon General's report, cigarette smoking accounts for approximately 30 percent of all cancer deaths, with lung cancer accounting for 80 percent of the smoking-attributable cancer deaths. Other cancers caused by smoking include cancers of the oral cavity, pharynx, larynx, esophagus, stomach, bladder, pancreas, liver, kidney, and uterine cervix and myeloid leukemia.

"We can see that, in areas of the country where smoking and tobacco use are entrenched in daily life, men and women continue to pay a price with higher incidence and death rates from many types of cancer," said Betsy Kohler, executive director of the North American Association of Central Cancer Registries. "This type of geographic variation in smoking-related cancers is due to smoking behaviors, not regional environmental factors."

"The observed decrease in the incidence and death rates from all cancers combined in men and women overall and in nearly all racial and ethnic groups is highly encouraging," conclude the authors. "However, this must be seen as a starting point rather than a destination." A dual effort, combining better application of existing knowledge with ongoing research to improve prevention, early detection, and treatment will be needed to sustain and extend this progress into the future, the report said.

The report is available at http://jnci.oxfordjournals.org.

"This year's report demonstrates the real advances that have been made across all areas of cancer prevention, research, and treatment," said Richard Schilsky, president of the American Society of Clinical Oncology. "We are pleased to see that the nation's investment in cancer research coupled with public education about healthy lifestyles and cancer screening is now translating into meaningful, tangible results—reduced incidence as well as reduced mortality. But we can't be complacent. Some cancers are still on the rise, and nearly 1,500 Americans still die every day from cancer. Continued progress requires that we redouble our national commitment to cancer research funding and that all Americans have access to proven effective strategies for cancer detection and treatment."

Professional Societies:

ASCO Strategic Plan Addreses Projected Workforce Shortage

The American Society of Clinical Oncology has issued a strategic plan to address recent projections showing that demand for oncology services will outstrip supply of practicing oncologists in coming years.

ASCO recommends transforming oncology care delivery through collaborative care and innovative practice models, training the next generation of oncologists to practice in a time of shortage, and gathering and assessing data to track trends in the oncology workforce.

"Workforce shortages are affecting the entire medical community. Unless action is taken, we will face a crisis in the nation's ability to provide quality cancer care to patients," said Michael Goldstein, co-chairman of ASCO's Workforce Advisory Group. An article that details ASCO's plan to combat the oncology workforce shortage is being published in the November 2008 issue of the Journal of Oncology Practice.

"No single action will fill the likely gap between supply and demand for oncology services and care," Goldstein said. "But through its workforce strategic plan, ASCO is developing a multifaceted approach to address the likely shortages in meeting the future demand for oncology services."

The strategic plan follows up on an ASCO study released in 2007 that projected a significant shortage of medical and gynecologic oncologists in the U.S. by 2020, due to an aging and growing population, increasing numbers of cancer survivors, and slower growth in the supply of oncologists.

One major action that ASCO, along with the Association of American Medical Colleges' Center for Workforce Studies, is undertaking to divert the projected crisis is to develop an information database that will track real-time trends in the oncology workforce.

Through this database, ASCO will monitor the oncology workforce supply by gathering actual figures on the number of practicing oncologists in the U.S. and compare that to benchmarks established in its 2007 workforce study. The first report on this data will be issued toward the end of 2009.

The workforce strategic plan also highlights areas where improvements can be made to bolster the oncology workforce:

—While the majority of oncologists already work with non-physician practitioners such as nurse practitioners and physician assistants, only half of

these non-physician practitioners perform advanced activities, such as assisting with new patient consults or ordering routine chemotherapy. ASCO recommends innovative practice models to improve delivery of care, such as increased collaboration with non-physician staff and part-time practice options for oncologists near retirement or parents with young children.

—There is a limited number of oncology training positions available for those considering a career in oncology. Expanding the number of oncology training slots in residency and fellowship programs and increasing medical student and resident exposure to oncology are just two methods highlighted in ASCO's strategic plan.

—Once a patient's cancer is in remission and he or she is not longer in active treatment, the path for continuing follow up care is not clear. ASCO is examining the growing use of "survivorship clinics" to provide ongoing care for cancer survivors that optimizes integrated survivorship care. Some practices have established these clinics with non-physician practitioners to ensure that patients have access to ongoing oncology care.

"ASCO's main goal is to ensure that patients with cancer continue to have access to high quality cancer care," said Dean Bajorin, co-chairman of ASCO's Workforce Advisory Group. "There have been extraordinary developments in cancer research and care over the past several decades. That progress is at risk if we don't have the capacity to treat our patients."

For more information on ASCO's workforce initiatives, visit www.asco.org/workforce.

AACR Named Collaborator Of Love/Avon Army of Women

The American Association for Cancer Research said it will serve as official scientific collaborator for the Love/Avon Army of Women initiative.

The Army of Women seeks to link more than one million women volunteers with cancer researchers across the country to discover the causes of breast cancer and aid in its prevention. Healthy women of every age and ethnicity, including breast cancer survivors and women at high-risk for the disease, are eligible.

AACR will contribute to the review of the research projects. AACR member physicians and scientists working in the field of breast cancer research will occupy eight seats on the Scientific Advisory Committee and one seat on the Steering Committee. Through these positions, the AACR will assist in major decision making regarding the policies, direction, and vision of the project, and in the review of requests from scientists seeking permission to solicit volunteers from the Love/Avon Army of Women for their breast cancer research studies.

Access to the Love/Avon Army of Women is provided solely to investigators who have a peer-reviewed study. Scientists apply to the Love/Avon Army of Women for the opportunity to recruit volunteers for their research. Their studies undergo a thorough scientific, safety and ethical review by expert scientists including members of AACR.

An email describing approved research projects is sent to the Army of Women volunteers with information about the study. Those who are interested then participate in a more thorough process to determine their eligibility. Selected participants who meet the criteria are instructed on how to contact the researcher or a designated Army of Women research center.

Interested researchers can learn more at www.armyofwomen.org.

The researchers conducting studies through the Love/Avon Army of Women will share their data and report to the women involved. Forums for the presentation of research conducted through the Army of Women will be offered at the AACR's major scientific meetings and in its Cancer Prevention Research journal.

Funding Opportunities:

PAs, RFP Available

PAR-09-026: Collaborative Research in Integrative Cancer Biology and the Tumor Microenvironment. U01. Letters of Intent Receipt Date: Jan. 19, Sept. 19. Full text: http://www.grants.nih.gov/grants/guide/pa-files/PAR-09-026.html. Inquiries: Jennifer Couch, 301-435-5226; couchj@mail.nih.gov.

PAR-09-027: National Institutes of Health Rapid Access to Interventional Development Program. X01. Letters of Intent Receipt Date: Dec. 16; April 15. Full text: http://www.grants.nih.gov/grants/guide/pa-files/PAR-09-027.html. Inquiries: Tony Jackson, 301-594-4660; nih-raid@mail.nih.gov.

RFP N02-CM-87025-39: Preparation of Radiolabeled Materials. Full text: http://www.fbodaily.com/archive/2008/11-November/26-Nov-2008/FBO-01709713.htm. Inquiries: Theresa Shroff, 301-228-4223, ts144t@nih.gov.

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THE CANCER LETTER

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Business & Regulatory Report

Deals & Collaborations:

Eli Lilly Completes Acquision Of ImClone; ImClone CEO Johnson To Retain Position

Eli Lilly and Co. (NYSE:LLY) of Indianapolis said it has completed its acquisition of **ImClone Systems Inc.** ImClone Systems is now a wholly-owned subsidiary of Lilly.

"The ImClone transaction will broaden Lilly's portfolio of marketed cancer therapies and boost Lilly's oncology pipeline with up to three promising targeted therapies in phase III in 2009," said John Lechleiter, president and CEO of Lilly. "The acquisition also adds late-stage assets,

(Continued to page 2)

Clinical Trials:

Pixantrone Achieves 20 Percent CR Rate For Non-Hodgkin's Lymphoma In Phase III

Cell Therapeutics Inc. (Nasdaq and MTA: CTIC) of Seattle said it achieved the primary efficacy endpoint of its phase III EXTEND (PIX301) trial of pixantrone (BBR2778) in advanced, relapsed aggressive non-Hodgkin's lymphoma based on a preliminary intent to treat efficacy analysis.

Randomization to treatment with pixantrone achieved a high rate of confirmed and unconfirmed complete remissions compared to treatment with standard chemotherapy (14 of 70 patients, or 20 percent) for pixantrone arm compared to 4 of 70 or 5.7 percent for the standard chemotherapy arm, ($p = 0.02$).

No patient in the standard chemotherapy arm achieved a confirmed complete remission compared to 8/70 (11 percent) of pixantrone recipients, the company said. Pixantrone treatment also increased the overall response rate with (26/70, 37.1 percent) for pixantrone arm compared to 10/70, 14.3 percent) for the control arm ($p = 0.003$).

The most common serious toxicities (>5 percent) seen in previous trials of pixantrone include grade 3 and 4 neutropenia and febrile neutropenia. Complete safety information is not available. The study was monitored by an independent Data Safety Monitoring Committee and no serious concerns were raised. Seventy-four percent discontinued therapy for disease progression or death, the majority of which were in the standard chemotherapy control arm, the company said.

CTI said it would request a pre-NDA meeting with the FDA and would begin submission of a rolling New Drug Application in early 2009.

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Eli Lilly Completes Purchase Of ImClone Systems Inc.

(Continued from page 1)

early- and mid-stage prospects, and the opportunity to generate additional value from Erbitux."

John Johnson, CEO of ImClone, will retain his current position after the acquisition and will report directly to Lechleiter.

"I look forward to continuing to lead ImClone's dedicated employees in their efforts to discover and develop promising oncology therapies," said Johnson. "We are excited with the potential to further accelerate our proprietary pipeline of novel antibodies by leveraging Lilly's global capabilities to bring these compounds to cancer patients around the world."

Lilly and ImClone entered into a merger agreement on October 6, 2008 pursuant to which Alaska Acquisition Corp., a wholly-owned subsidiary of Lilly, began a tender offer to purchase all of the ImClone outstanding shares for $70.00 per share in cash. On Nov. 21, Lilly completed a cash tender offer for all outstanding shares of ImClone. As a result of the cash tender offer, Lilly, through Alaska Acquisition, acquired 85,401,945 shares (including 5,175,275 shares that were tendered pursuant to guaranteed delivery procedures), representing 95.5 percent, of the ImClone issued and outstanding shares. The merger was completed on Nov. 24, when Alaska Acquisition was merged with and into ImClone, the companies said.

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As a result of the merger, all outstanding shares of ImClone common stock not purchased by Lilly in the tender offer were converted into the right to receive $70.00 per share in cash. Wells Fargo Bank N.A., the paying agent for the merger, will mail instructions on how to surrender share certificates for the merger consideration to shareholders who did not tender their shares. ImClone shares will be delisted from the NASDAQ.

Accuray Inc. (Nasdaq: ARAY) of Sunnyvale, Calif., said **Fox Chase Cancer Center** has purchased its CyberKnife Robotic Radiosurgery System.

The system at Fox Chase will be the third to be installed in Pennsylvania, and will be housed in a radiation facility under construction in Buckingham, the company said.

The technology enables Fox Chase to expand its radiation offerings to patients unable to tolerate other treatments or have medically inoperable tumors.

The CyberKnife System, a robotic radiosurgery system, delivers precision high doses of radiation to tumors anywhere in the body non-invasively, the company said.

Using continual image guidance technology and computer controlled robotic mobility, the CyberKnife System automatically tracks, detects and corrects for tumor and movement in real-time throughout the treatment.

BioVectra Inc. of Toronto and **Therapure BioPharma Inc.** of Charlottetown said they agreed to co-develop a PEGylated biologic drug target for cancer treatments, with a goal of advancing the project to a regulatory filing stage, suitable for a marketing partner to add to its portfolio of biologic products.

Over the past five years, BioVectra has been developing proprietary technologies for PEGylation as a mechanism for drug delivery. The partnership with Therapure builds upon the BioVectra production of modified biologic molecules using a proprietary MPEG technology, the companies said.

Cyntellect of San Diego said it has entered a research collaboration agreement with the **University of Florida Interdisciplinary Center for Biotechnology Research** in stem cell research, which includes the purification and analysis of cancer stem cells.

The collaboration will use the Cyntellect proprietary LEAP system to purify the CSCs and their progeny without disturbing them from their growing

environment. Under the agreement, UF would gain access to LEAP and Cyntellect would receive payments and commercial rights to discoveries.

Gene Network Sciences Inc. of Cambridge, Mass, said it has created a subsidiary company, **Fina Technologies Inc.,** to leverage its proprietary Reverse Engineering, Forward Simulation software platform, or REFS, in the e-commerce and financial trading markets, while remaining focused on its drug development mission.

REFS was originally developed by GNS to process raw clinical and genomics data to identify drug targets, biomarkers and drug and disease mechanisms for cancer, diabetes and inflammation, and has been used by GNS in partnership with pharmaceutical companies and clinical research organizations such as Johnson & Johnson, Pfizer, Novartis AG, Biogen Idec, UCSF Cancer Center, and Jackson Labs., the company said.

"Hidden complex networks govern everything from human diseases to financial markets and the internet, making reliable predictions impossible," said Colin Hill, president and CEO of GNS and chairman of the board of Fina. "Terabytes of data, on-demand supercomputing, and next-generation artificial intelligence software have converged to enable the uncovering of such networks, and prediction of their behavior, such as predicting how a combination of two cancer drugs would affect the size of a tumor with a particular DNA sequence."

GNS, which developed its proprietary REFS technology over the past eight years, uses supercomputers to accelerate the processing of raw data into biomedical outcomes.

Fina Technologies is supported through an initial round of investment led by Reed Elsevier Ventures, the venture arm of Anglo-Dutch media conglomerate Reed Elsevier, owner of Lexis-Nexis, and by a board of directors in finance and e-commerce, the company said. In addition to Colin Hill, co-founder and president and CEO of GNS, the board of Fina includes Bill Trenchard, founder of Jump Networks. Also on the Board are Kevin Brown, partner at Reed Elsevier Ventures; and Robert Maroney, investment manager at Connecticut Investments LLC.

REFS technology begins with raw data and rapidly performs billions upon billions of calculations using supercomputers to determine how the individual components in the system interact with one another. The computer-assembled models are then simulated using billions of in silico queries to discover the highest-impact components and to predict outcomes for previously unseen scenarios.

Infinity Pharmaceuticals Inc. (Nasdaq:INFI) of Cambridge, Mass., said it has entered into a global strategic alliance with **Purdue Pharmaceutical Products L.P**. and **Mundipharma International Corp. Ltd**. for research, development, and commercialization of the Infinity early clinical and discovery programs, including IPI-926, the Infinity inhibitor of the Hedgehog signaling pathway.

"The alliance with Purdue Pharma and Mundipharma provides Infinity with the financial resources and independence to continue our productive discovery efforts, to expand our clinical development capabilities, and to build our own organization to commercialize our products in the U.S," said Steven Holtzman, chairman and CEO of Infinity.

The alliance would advance the development of the Infinity early stage small molecule drug candidates, which include IPI-926, an inhibitor of the Hedgehog pathway. IPI-926 is in a phase I study in advanced solid tumors and has demonstrated anti-tumor activity in preclinical models, the company said. Earlier stage discovery programs, include a program directed to fatty acid amide hydrolase, an emerging target for neuropathic pain. The Hsp90 inhibitor program, comprising IPI-504 (retaspimycin hydrochloride), which is in an international phase III registration trial in refractory gastrointestinal stromal tumors (the RING trial), and IPI-493, the Infinity oral candidate in a phase I study for advanced solid tumors, remains partnered with AstraZeneca and is excluded from the alliance. The Infinity program targeting the Bcl family of proteins, which was transitioned to Novartis in February of 2008, is also excluded from the alliance.

Under the alliance, Purdue made an equity investment of $45 million in Infinity through the purchase of four million shares of Infinity common stock. Mundipharma will participate in the Infinity Hedgehog program as well as new Infinity discovery and development programs for three years, with an ability to extend this right for two additional one-year terms, the company said.

The alliance will also encompass the Infinity discovery program directed to FAAH. Purdue and Mundipharma will have the right to assume development of the FAAH program at the conclusion of phase I studies by funding the research and development costs of the program through approval and paying a royalty to Infinity on global net sales.

Medicsight PLC of New York said it has entered into a global partnership with **Ziosoft Inc** to combine Ziosoft-Medicsight products that detect colorectal polyps for distribution through the Ziosoft network.

Ziosoft, which markets its 3D workstations, is working with Medicsight to integate the Medicsight ColonCAD with the Ziosoft Ziostation. The product will be available in the U.S. following its clearance with FDA early next year.

"The partnership will enable us to combine our revolutionary 3D imaging applications with the CAD and image analysis solutions of Medicsight to fulfill our goal, which is to meet the needs of any hospital," said Mark Koeniguer, chief operating officer of Ziosoft.

Northwestern Medical Faculty Foundation said it has signed a long-term agreement with **Northern Illinois Proton Treatment and Research Center** to provide radiation oncologists and proton cancer treatment services.

NIPTRC, which is under construction 30 miles west of Chicago in the DuPage National Technology Park, will be a proton cancer treatment and research center for the Chicago area and the upper Midwest, the foundation said.

"This agreement is the most significant milestone yet in our progress," said Ray Alden, chairman of the NIPTRC board of managers and executive vice president and provost for Northern Illinois University, which is spearheading the project.

"When proton beam therapy is an appropriate cancer treatment, patients in the Chicago area are forced to travel to one of the only five proton therapy centers operating in the U.S. because it is not yet available in Illinois," said Bharat Mittal, chairman of the Department of Radiation Oncology at the Northwestern University Feinberg School of Medicine and NIPTRC board member. "This center is not-for-profit and the Northwestern Medical Faculty Foundation and NIPTRC share a mission to serve all, regardless of ability to pay.

In keeping with the holistic approach to treatment, NIU and NIPTRC said they would establish a residential facility next to the NIPTRC facility. NIU will provide a hospitality program that will operate and maintain the facility.

A not-for-profit medical treatment center with a charity care program, NIPTRC is associated with Northern Illinois University, and is working cooperatively with Fermilab and Argonne National Laboratory.

Northwestern Medical Faculty Foundation is a physician group at the Feinberg School of Medicine, Northwestern University.

Sysmex America Inc. of Mundelein, Ill., said it has entered into a five-year service agreement with **Sutter Health** of Northern California, to standardize hematology instruments, reagents, training, services and support within the Sutter 25 hospitals and nine medical foundations.

"Our decision to partner with Sysmex America for our hematology standardization needs was a methodical one based on value criteria, site visits and financial impact studies, among other considerations," said Ronald Workman, vice president of pathology and laboratory medicine for Sutter Health.

Sutter Health is a not-for-profit network of physicians, hospitals and other health care service providers.

Vical Inc. (NASDAQ: VICL) of San Diego said it has received a $1.0 million milestone payment from **Merck & Co. Inc.** based on the Merck initiation of a phase I trial of an investigational plasmid DNA cancer vaccine.

The candidate vaccine is based on the Vical DNA gene delivery technology and encodes human telomerase reverse transcriptase. hTERT is the subject of separate license agreement.

"The breadth of applications for Vical's gene delivery technology continues to grow, and now encompasses vaccine candidates against infectious diseases and cancer, cancer immunotherapies, and gene-based angiogenesis for cardiovascular diseases," said Vijay Samant, president and CEO of Vical. "Our long-standing partner Merck is expanding to a second clinical-stage evaluation of our technology in the cancer area."

Product Aprovals & Applications:

FDA Accepts sBLA For Zevalin As Therapy For B-Cell NHL

Cell Therapeutics Inc. (Nasdaq and MTA: CTIC) of Seattle said FDA has accepted for filing and review, and has granted priority review status to the supplemental Biologics License Application for Zevalin ([90Y]-ibritumomab tiuxetan) as consolidation therapy in follicular B-cell non-Hodgkin's lymphoma after response to first-line therapy.

A Prescription Drug User Fee Act target date

of April 2, 2009 has been established by FDA for an approval decision on the sBLA, the company said.

CTI and Spectrum Pharmaceuticals Inc. said they entered into an agreement to form a 50/50 owned joint venture, RIT Oncology LLC, to commercialize and develop Zevalin in the U.S. The transaction will close this month, the companies said. CTI initially acquired the U.S. rights to the agent from Biogen Idec in December 2007. CTI gained access to the First-line Indolent Trial data through an agreement with Bayer Schering Pharma AG, Germany, who used the data to obtain approval for Zevalin as first-line consolidation treatment in Europe.

"In addition to shortening the timeframe for FDA review from 10 months to 6 months, it would also enable physicians to get the drug to those who may benefit from it sooner," said James Bianco, CEO of Cell Therapeutics. "If approved, it also pushes up our anticipated timeline for commercial launch for first-line indication by 4 months which should result in a substantial increase to our revenue forecast in 2009."

The multinational, randomized phase III FIT 414-patient study evaluated the benefit and safety of a single infusion of Zevalin in CD20-positive follicular non-Hodgkin's lymphoma after achieving a partial response or a complete response after standard first-line chemotherapy regimens. When used as a first-line consolidation therapy, Zevalin significantly improved the median progression-free survival time from 13 months (control arm) to 37 months (Zevalin arm) ($p<0.0001$), the company said.

The primary investigators concluded that the Zevalin consolidation of first remission in advanced stage follicular non-Hodgkin's lymphoma is highly effective, resulting in a total complete response (CR + CRu) rate of 87 percent and prolongation of median progression-free survival by two years, with a toxicity profile comparable to that seen with the Zevalin use in approved indications. Zevalin-treatment had reversible grade 3 or 4 hematologic side effects including neutropenia in 67 percent, thrombocytopenia in 61 percent, and anemia in 3 percent of patients. Nonhematologic toxicities were 24 percent grade 3, 5 percent grade 4, and grade 3/4 infection was 8 percent.

In a related development, **Spectrum Pharmaceuticals Inc.** (NASDAQ:SPPI) of Irvine, Calif., and **Cell Therapeutics Inc.** said they have entered into an agreement to form a 50/50 owned venture, **RIT Oncology LLC**, to commercialize and develop Zevalin ([90Y]-ibritumomab tiuxetan) in the U.S.

Zevalin, a radioimmunotherapeutic, is marketed in the U.S. by Cell Therapeutics Inc. for relapsed or refractory, low-grade or follicular B-cell non-Hodgkin's lymphoma, including rituximab-refractory follicular NHL, the company said. CTI said it submitted a supplemental Biologics License Application in September to expand the label for first-line consolidation therapy in untreated follicular NHL.

"The partnership will enable CTI to deploy a larger combined sales and marketing team to accelerate top-line product revenues in the near-term and reduce our costs to develop Zevalin for new growth opportunities, resulting in an increase in CTI's bottom-line overall," said James Bianco, CEO of Cell Therapeutics. "Spectrum has a wealth of experience in the field of oncology, including the sales and marketing leadership that oversaw the successful launch of Abraxane and Xeloda."

Under the agreement, upon closing of the transaction the companies will become sole members of a limited liability company whose sole purpose would be to commercialize Zevalin in the U.S. A board of managers comprised of an equal number of members from both companies would govern. Both parties will equally provide for the future capital requirements of the LLC and share equally in its profits and losses. CTwill receive an initial payment of $7.5 million at closing and $7.5 million in early January, in addition up to $15 million product sales milestone payments upon achievement of revenue targets. The closing of the transaction is subject to customary closing conditions, including the consent of Biogen Idec Inc. to convey the Zevalin-related assets to the LLC. CTI and Spectrum expect the transaction to close this month.

Debiopharm Group of Lausanne, Switzerland, said its New Drug Application for the six- month formulation of Trelstar (triptorelin pamoate) has been accepted by FDA.

Trelstar is a luteinizing hormone releasing hormone agonist for locally advanced or metastatic prostate cancer, the company said. Once approved, the drug will be commercialized in the U.S. by Watson Pharmaceuticals Inc.

"Last September we filed the product with the European Agencies, under the name Decapeptyl," said Rolland-Yves Mauvernay, president and founder of Debiopharm Group. "We have accomplished the simultaneous filings of Trelstar and Decapeptyl in both the U.S. and Europe. Our FDA inspected research development and production facility, Debio R.P., will produce both products for global distribution."

The NDA for the six-month formulation of

Trelstar is supported by data from a phase III study on the efficacy and safety of two consecutive injections of triptorelin 6-month formulation in 120 patients with advanced prostate cancer. The results showed 97.5 percent achieved castrate levels of serum testosterone 28 days after the first injection and that 93 percent maintained serum testosterone levels below castrate level (defined as < 1.735 nmol/L or 50 ng/dL) from week 8 to 48. The efficacy results are similar to those obtained with repeated administrations of the 1- and 3-month formulations of Trelstar, which are already marketed by Watson Pharmaceuticals Inc.

IDM Pharma Inc. (Nasdaq: IDMI) of Irvine, Calif., said the Committee for Medicinal Products for Human Use of the European Medicines Agency approved a Centralized Marketing Authorization for mifamurtide (L-MTP-PE), or MEPACT in Europe, for non-metastatic, resectable osteosarcoma.

The approval allows L-MTP-PE to be marketed in the 27 member states of the European Union, as well as in Iceland, Liechtenstein and Norway, the company said.

The decision was based on a phase III L-MTP-PE trial (INT-0133), an NCI-funded Children's Oncology Group study in osteosarcoma, enrolling 800 patients. The study evaluated outcomes with the addition of L-MTP-PE to three- or four-drug adjuvant chemotherapy (cisplatin, doxorubicin, and methotrexate with or without ifosfamide), the company said.

Overall survival after six years of follow-up with chemotherapy treatment and L-MTP-PE, was 78 percent, compared to 70 percent with chemotherapy treatment (p=0.03) alone, the company said. The addition of L-MTP-PE to chemotherapy resulted in a 30 percent decrease in the risk of death.

Treatment with L-MTP-PE was well tolerated in all phases of clinical development. Adverse events were mild to moderate in severity and included chills, fever, nausea, vomiting, myalgia, headache, tachycardia, hypo- and hypertension, fatigue and shortness of breath, all of which are consistent events with the activation of monocytes and macrophages by L-MTP-PE and the flu-like symptoms that follow cytokine release, the company said.

IPSOGEN SA of Marseille, France, and New Haven, CT, said its MapQuant Dx HER2 Test for breast cancer is ready for the European market.

"I was very pleased to collaborate with Ipsogen in rapidly and efficiently moving from our research findings to a market-ready diagnostic test," said Francois Bertucci, medical oncologist at Institut Paoli Calmettes Cancer Center, Marseille. "As a translational researcher, I believe that MapQuant Dx is a comprehensive plug & play solution, making research rapidly available to patients."

The MapQuant Dx HER2 test correlates with the expression of the HER2 protein at cell membrane level, the company said. Developed on a set of 152 tumors, the test was validated in 4 independent datasets totalling 269 tumors. The test correlates with the IHC method in 95 percent of the cases and it resolves IHC equivocal cases in 95 percent of cases.

Medicsight PLC (AMEX:MGT) of New York said it has submitted a 510(k) Premarket Notification for clearance to market to FDA for its ColonCAD image analysis software.

Medicsight said it has completed a multi-reader CT Colonography clinical trial reviewing patient datasets to support the FDA submission. The study, which demonstrates the benefits of ColonCAD technology on the diagnostic performance of radiologists, was led by Steve Halligan of University College Hospital, London.

The company said it already received regulatory approval to market the technology in Europe, Canada, Australia, China, and Brazil.

Colon CAD technology detects colonic lesions, that if detected early, can make colon cancer treatable, the company said.

"Medicsight has assembled a strong team of leading clinical, statistical and regulatory experts to produce a 510(k) submission which we believe clearly demonstrates the safety and effectiveness of the ColonCAD product, said David Sumner, CEO of Medicsight. "The recently reported outcomes of the U.S. National CT Colonography Trial, ACRIN 6664, demonstrating the efficacy of CT Colonography as a primary screening examination for colorectal cancer, and the inclusion of CT Colonography in the 2008 American Cancer Society guidelines for colorectal cancer screening, increasingly support the predicted growth of the U.S. CT Colonography market."

Medicsight PLC is a subsidiary of MGT Capital Investments Inc.

Ortho Biotech Products L.P. of Bridgewater, N.J., said it has submitted a New Drug Application to FDA for trabectedin when administered in combination with Doxil (doxorubicin HCI liposome injection) for

relapsed ovarian cancer.

Trabectedin combined with Doxil could provide a non-platinum treatment option in the U.S., the company said.

The application is based on a multicenter, randomized phase III 672-patient study, ET743-OVA-301, in ROC, comparing the combination of trabectedin and Doxil to Doxil alone. The combination treatment had a statistically significant improvement in the primary endpoint of progression-free survival compared to treatment with Doxil alone, the company said.

The ET743-OVA-301 study data were evaluated by a blinded, independent radiology review and a blinded, independent oncology review, the company said.

The trabectedin/Doxil combination demonstrated a statistically significant improvement in PFS compared to Doxil alone (median PFS 7.3 versus 5.8 months, respectively) and a statistically significant reduction of 21 percent in the risk of progression or death during the observation period in the independent review of radiologically measurable disease (HR=0.79, 95 percent CI (0.65;0.96), p=0.0190), the company said. The result is consistent with those of the independent oncology review that takes into account clinical as well as imaging data in the assessment of progression. In the review, there was a 28 percent risk reduction for disease progression or death with the trabectedin/Doxil combination (HR=0.72, 95 percent CI (0.60; 0.88), p=0.0008).

Secondary endpoints included response rate, overall survival, and safety. A statistically significant increase in response rate was seen with the trabectedin and Doxil combination (28 percent) compared to Doxil alone (19 percent), as measured by the independent radiology review. A final protocol-specified survival analysis is planned after the occurrence of 520 events. The safety profile in the study was consistent with previous experience with trabectedin and Doxil.

Trabectedin is an cytotoxic antitumor agent that was originally derived from the Caribbean tunicate, Ecteinascidia turbinate, or sea squirt, the company said. The compound is now produced synthetically. Trabectedin binds to the minor groove of DNA, interfering with cell division and genetic transcription processes and DNA repair machinery.

ProStrakan Group plc (LSE: PSK) of Bedminster, N.J., said its Sancuso (granisetron transdermal system) patch is available by prescription for chemotherapy-induced nausea and vomiting.

Sancuso was approved by FDA in September as the first and only patch to provide up to five consecutive days of control of nausea and vomiting for patients receiving a moderately and/or highly nausea-inducing chemotherapy regimen.

The patch delivers granisetron, an active component and an established preventor of nausea and vomiting, through a thin layer of adhesive that attaches the patch to the skin on the upper outer arm. The medicine is then released slowly and continuously into the bloodstream for up to five consecutive days.

The Sancuso 67-person sales force has been trained by oncology nurses through a partnership with ONSEdge, a subsidiary of the Oncology Nursing Society, the company said. Each member of the sales force participated in a detailed training program administered by oncology nurses focusing on both general oncology and CINV.

The company said it has developed a patient assistance in the U.S., and is also working with regulatory authorities to bring Sancuso to market in Europe.

Clinical Trials:

Phase III EXTEND Trial Meets Primary Endpoint In NHL

(Continued from page 1)

"These data are consistent with the extensive experience with pixantrone in our phase I and phase II studies and demonstrate the ability to offer patients with advanced, relapsed NHL the potential to obtain a clinically meaningful response like a complete remission, despite having failed multiple other courses of chemotherapy or immuno-chemotherapy," said James Bianco, CEO of Cell Therapeutics.

The EXTEND trial is a phase III single-agent trial of pixantrone in relapsed, aggressive non-Hodgkin's lymphoma where two or more prior therapies were received and where sensitivity to anthracycline treatment occurred. The trial was conducted at 130 sites in 17 countries. The 140 patients were randomized to receive either pixantrone or another single-agent drug selected by the physician. The trial examined the complete remission or unconfirmed complete remission rate, overall survival and progression-free survival. The study received Special Protocol Assessment approval from FDA in 2004 and pixantrone has received Fast-Track designation for the indication,the company said.

Pixantrone is a DNA intercalating antitumor agent that contains an aza-anthracenedione molecular structure,

differentiating it from anthracycline chemotherapy agents, the company said. The agent reduces the potential for heart damage compared to available anthracyclines or anthracenediones without a loss in anti-tumor or immunomodulatory activities.

Bionovo Inc. (NASDAQ: BNVI) of Emeryville, Calif., said its drug candidate for metastatic breast cancer, BZL101, will advance to phase II testing after the completion of a second phase I trial.

The phase IB 27-patient trial identified the maximum tolerated dose of the agent and determined the safety and feasibility of the oral treatment, the company said. To date, 48 women with advanced breast cancer have been treated with BZL101 in all clinical trials.

The phase II trial is enrolling 80 women diagnosed with advanced, measurable breast cancer who have received no more than two prior cytotoxic cancer therapies, the company said. Charles Shapiro, director of breast oncology at Ohio State University is principal investigator.

BZL101 is an oral drug for advanced breast cancer.

Boehringer Ingelheim of Ingelheim, Germany, said it has begun phase III trials for its oncology compound, Vargatef (BIBF 1120), a triple angiokinase inhibitor.

The two studies, known as LUME-Lung 1 and LUME-Lung 2, will evaluate the molecule as a second-line therapy in combination with standard chemotherapy agents in advanced non-small-cell lung cancer.

The company said its portfolio spans three areas: angiokinase inhibition, signal transduction inhibition and cell cycle kinase inhibition, confirming its commitment to the field of oncology.

In addition, Tovok (BIBW 2992), its most advanced compound, will enter its second pivotal trial, LUX-Lung 3 in first-line NSCLC, the company said. A new compound and first-in class-molecule, polo-like kinase 1 (Plk1) inhibitor, BI 6727, has demonstrated positive phase I results that it will progress to phase II.

"The fact remains that one in two non-small cell lung cancer patients who receive treatment fail their initial therapies and remain well enough to receive additional options," said Nasser Hanna, associate professor of medicine in the Division of Oncology at Indiana University and principal investigator of one of the LUME-Lung studies. "The LUME-Lung studies will look at whether the addition of Vargatef to standard second-line treatment regimes will improve the outcome for these patients, and with 2,600 patients, is one of the largest clinical trial programmes in the indication."

Vargatef simultaneously inhibits vascular endothelial growth factor receptors, platelet-derived growth factor receptors and fibroblast growth factor receptors and is administered as a capsule taken twice daily, the company said.

In a phase II Vargatef 72-patient study of relapsed, advanced NSCLC, results were reported for good performance status (ECOG* 0 or 1) (n=57): patients experienced longer overall survival (median OS was 9.5 months), longer progression free survival (median PFS was 2.9 months) and a higher rate of disease control (59 percent) compared to the overall study population. Stable disease rate was 48 percent. Adverse events reported were mild to moderate in nature, the company said.

Celator Pharmaceuticals of Princeton, N.J., said it has begun treatment in a randomized phase II study of CPX-351 (Cytarabine:Daunorubicin) Liposome Injection in newly diagnosed acute myeloid leukemia.

The first patient was enrolled by Eric Feldman at the Weill Medical College of Cornell University and New York Presbyterian Hospital.

CPX-351 is a liposomal formulation of cytarabine and daunorubicin delivered in a 5:1 molar ratio for use in combination chemotherapy. The agent represents a new approach to developing drug combinations in which drug ratios are pre-selected based on synergistic anti-tumor activity observed preclinically and where the ratios are maintained through the Celator proprietary CombiPlex technology platform, the company said.

The 120-patient study will be conducted in newly diagnosed AML, in greater than or equal to 60 but <76 years of age, with the ability to tolerate intensive chemotherapy, the company said. The randomized (2:1) would compare CPX-351 to the conventional method of administering cytarabine and daunorubicin, commonly referred to as 7+3. The reference 7+3 refers to the administration days of the drugs (cytarabine is administered as a 7 day continuous infusion and daunorubicin is administered on days 1, 2 and 3). CPX-351 is administered on days 1, 3 and 5. The primary endpoint is complete remission rate. Secondary endpoints are duration of complete remission, time to treatment failure, survival at 12 months, 30, 60, and 90 day mortality and safety and tolerability.

Interim phase I data with CPX-351 reported complete remissions in advanced leukemia, the company said.