# THE CANCER LETTER

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# **SWOG, NCI Canada Stop Two Large Trials Of Iressa For Non-Small Cell Lung Cancer**

By Paul Goldberg

The Southwest Oncology Group and the NCI Canada Clinical Trials Group have stopped two large clinical trials of Iressa for locally advanced and adjuvant non-small cell lung cancer.

The closing of the trials was urged by NCI and is the consequence of an AstraZeneca study that failed to demonstrate a survival advantage for Iressa (gefitinib) over placebo.

The SWOG and NCIC trials were stopped based on unplanned interim analyses conducted before the planned interim analysis targets were reached. In the absence of safety concerns, stopping a trial based on an (Continued to page 2)

#### FDA News:

# **Oncologist Richard Pazdur Named Director Of FDA's New Office of Oncology Drug Products**

By Kirsten Boyd Goldberg

Richard Pazdur was appointed director of FDA's newly formed Office of Oncology Drug Products, within the Office of New Drugs, Center for Drug Evaluation and Research, the agency said April 22.

The new office will consolidate the review of drugs and biologics for cancer, including the Division of Oncology Drug Products that Pazdur has led for the past six years. The office also will review drugs and biologics for hematologic diseases and medical imaging, and lead a "comprehensive oncology program" that will coordinate oncology across all FDA centers, the agency said.

Pazdur, a medical oncologist, came to FDA from M.D. Anderson Cancer Center in 1999 to serve as director of the Division of Oncology Drug Products in the Office of Drug Evaluation I. He was a professor of medicine and assistant vice president for academic affairs at M.D. Anderson.

The new office is expected to open officially in July, as part of a reorganization of the Office of New Drugs, but Pazdur will begin work as the office director on May 1, FDA officials said.

"Dr. Pazdur brings tremendous energy and innovative ideas to this very important position," said CDER Acting Director Steven Galson. "Dr. Pazdur's work will benefit cancer patients everywhere and reaffirm FDA's ongoing commitment to improving the efficiency and consistency of product development and review, so cancer patients will have access as quickly as possible to quality new treatments."

Two cancer organizations that endorsed Pazdur's candidacy for the (Continued to page 5)

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# **Trial Closures Narrow Avenues For Future Iressa Investigation**

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unplanned interim analysis is an unusual step for clinical investigators.

The trial closures contribute to the accumulation of negative results that narrow the avenues for future investigation of Iressa, observers in government and academia say.

The SWOG 0023 trial compared Iressa, a tyrosine kinase inhibitor, with placebo in stage III NSCLC patients who had completed therapy with cisplatin, etoposide, and radiation. Altogether, 678 patients were to be randomized. As of last month, 611 patients enrolled in the trial, and 276 were randomized. Interim analyses were planned at 127 and 305 deaths, and a final analysis at 508 deaths.

The NCIC BR 19 trial assessed overall survival with Iressa vs. placebo in adjuvant NSCLC after definitive surgery, with chemotherapy and radiation allowed at the discretion of investigators. The trial was powered to detect a 33-percent increase in overall survival. As of March, 457 of the planned 1,242 patients were accrued. Interim analyses were planned at 179 and 358 deaths, and a final analysis at 537 deaths.

The Canadian trial accrued about a third of the needed patients. Completion was projected for 2008.

The closing of the SWOG trial was announced April 14. The NCIC announcement was made April 22.



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

The cooperative groups and NCI declined to disclose the number of events that occurred, stating only that the "futility analyses" were performed before the first interim analysis target was reached. These details are expected to be released at the annual meeting of the American Society of Clinical Oncology next month.

SWOG closed its trial after the Data and Safety Monitoring Board and the scientific leadership determined that Iressa had no realistic chance of meeting the goal of demonstrating a 33-percent increase in overall survival.

The SWOG trial appears to represent the fourth failure by Iressa to demonstrate a survival advantage in large, randomized trials. As a result of an earlier trial, doctors are advised to put new patients on Iressa's sister drug Tarceva (erlotinib). That drug, manufactured by Genentech Inc., has demonstrated a survival advantage in advanced lung cancer.

"We didn't foresee a circumstance in which Iressa could be shown to prolong progression-free or overall survival, based on the data that we looked at," said Laurence Baker, chairman of SWOG and professor of internal medicine and pharmacology at the University of Michigan in Ann Arbor. "Once that became clear, then continuing the study seemed to be improper."

In an e-mail to the scientific leadership of the trial, the NCIC Clinical Trials Group cited the SWOG results rather than an earlier AstraZeneca study or its own data.

"Based on their review of the [SWOG 0023] data, the NCIC CTG DSMC concluded that the clear lack of efficacy of [Iressa] in the [SWOG 0023] patient population, to the extent that the potential of a deleterious effect could not be excluded, warranted closure of the NCIC CTG BR 19 trial," wrote Chris O'Callahan, project coordinator for NCIC CTG and assistant professor at the Department of Community Health & Epidemiology Queen's University.

The letter, dated April 22, was distributed to the investigators on the trial.

#### **NCI Urged Re-Examination**

Iressa received an accelerated approval from FDA in May 2003, based on a single-arm phase II trial.

Recommending approval, the FDA Oncologic Drugs Advisory Committee disregarded two earlier randomized trials, which showed no benefit to adding Iressa to chemotherapy.

Though Iressa was approved on slim data, ODAC and FDA were expecting definitive results from a comparison of Iressa as a single agent vs. placebo in

1,692 patients with locally advanced or metastatic disease who had received one or two prior chemotherapy regimens and were refractory to the most recent regimen.

Last December, that trial—called Trial 709 or ISEL—failed to show a survival advantage for Iressa, and, in March, FDA asked ODAC to discuss the results. The agency stopped short of asking the committee whether the drug should be pulled off the market (The Cancer Letter, April 1, 2005).

The ISEL results made NCI question the wisdom of continuing support for Iressa trials, sources said. Institute officials were asking fundamental questions: With Tarceva having demonstrated a survival advantage in advanced disease, would it make sense to continue studying Iressa? Would the Iressa studies have to be repeated with Tarceva?

After Institute officials presented these concerns to SWOG and NCIC CTG leadership, the two groups said that they wanted to continue the studies, arguing that the trials in question were being conducted in different patient populations than those enrolled in the ISEL trial.

Tarceva hasn't been studied either in the adjuvant setting or in combination with chemotherapy and radiation for locally advanced disease.

Having reached an impasse with the groups, NCI asked four outside experts to review the studies, and held a conference call to seek advice. The experts, who weren't involved in the studies, largely agreed with the NCI position, sources said.

"They agreed that these trials didn't make the best sense now that the results from the ISEL trial were available," said Jeffrey Abrams, chief of the NCI Clinical Investigations Branch.

The Institute went back to the group chairmen and asked them to consult the Data and Safety Monitoring Boards.

SWOG Chairman Baker said that at a conference call March 31, NCI officials urged SWOG and NCIC to rethink their trials in view of the ISEL data. NCI argued that when information like the ISEL trial becomes available, the DSMBs should review the data and decide whether continuing the trials still makes sense.

However, Baker said that the group's decision to close the trial was its own.

The decision to examine the data was made by the DSMB, which met at the SWOG annual meeting in Denver, Baker said. The board decided to consider the data on April 7, reconvening four days later to perform the analysis.

The board's recommendation to stop the trial was reported to Baker on April 12.

"The DSMB voted on this unanimously," Baker said. "I then had a discussion with the lung committee, who agreed with closure. Also, I had a conversation with the scientific advisory board of SWOG, who agreed with closure, so I feel very confident about the decision."

Baker said the data confirmed favorable survival on the induction chemotherapy and radiation regimen used on both arms.

"The chemoradiation strategy that was employed in this study has approximately a 24-month median survival associated with it, which is the best that's ever been reported in the history of lung cancer investigation," he said. "This is a good step forward, and probably it will become the standard treatment for inoperable stage III lung cancer."

An earlier SWOG study, 9504, reported a median survival of 27 months.

Baker said the group is considering building on that regimen by testing it in combination with the Genentech antiangiogenesis agent Avastin. A recent study by Eastern Cooperative Oncology Group found that Avastin (bevacizumab) increased survival in frontline therapy for advanced NSCLC.

SWOG shared its data with CTEP and NCIC, prompting the Canadian group to suspend its Iressa trial on April 15. The NCIC Data and Safety Monitoring Committee met on April 20 to consider the SWOG data, and recommended permanent closure.

"The data will be presented at ASCO," said Paul Bunn, director of the University of Colorado Cancer Center. "I think it's unlikely that something definitive can be said. Given the number of events, I'd be surprised." Bunn, a lung cancer expert who has consulted with AstraZeneca in the past, hasn't seen the SWOG data.

"I don't think that all investigation of Iressa should be ended," he said. "It would be a sad day if all clinical trials came to a halt on a drug that has made a lot of people's lives a lot better, and it's a pill."

However, the unanswered questions about Iressa make it more appropriate for the advanced disease setting, Bunn said.

"There are many, many things about it we don't know," Bunn said. "Given the right dose and in a selected number of patients, the drug will be shown to be quite useful. What exactly the right dose is and who exactly these patients are remains to be determined.

"The adjuvant setting might not be the best place to answer those questions."

#### National Cancer Policy Board:

### Pediatric Cancer Drug R&D Needs Public-Private Effort

By Kirsten Boyd Goldberg

While oncologists are proud of their achievements over the past several decades to cure a majority of childhood cancers, further progress is threatened by the lack of a comprehensive research and development program, according to a report by the Institute of Medicine's National Cancer Policy Board.

Though childhood cancer is rare and most children survive with appropriate therapy, about 2,200 children died from the disease in the U.S. in 2001. But government, industry, and academic scientists aren't pursuing all the possible methods to develop new therapies, because their efforts aren't coordinated and supported, said the board's Committee on Shortening the Time Line for New Cancer Treatments.

"For high-risk childhood cancers, there is somewhat of a plateau in cures at a level no one is satisfied with, where everyone recognizes that we need novel therapeutic approaches," said Peter Adamson, chairman of developmental therapeutics for the Children's Oncology Group and a member of the committee that wrote the report. "We have learned how to use the drugs that we have had for the last 30 years in a better way, but we are now at a juncture where we have gotten about as much mileage as we are likely to get with the current armamentarium."

The traditional strategy of taking current treatments and increasing the dose can't result in breakthroughs, Adamson said. "The price that the children pay right now is, every time we intensify to get an incremental improvement, there are children who have to endure a greater and greater toxicity for that increment," said Adamson, who is also chief of clinical pharmacology at the Children's Hospital of Philadelphia.

In its report, the committee urged the formation of a "public-private partnership" involving government, industry, academic research institutions, advocacy groups, and philanthropies to lead pediatric cancer drug discovery and development. "The resources already in place for pediatric cancers are poised for this development," the report said.

"What appears to be missing in order to realize the potential for new childhood cancer drugs is an organized focus on childhood cancers to coordinate the pieces and drive a process toward shortening the developmental time line and multiplying the numbers of possible new agents," the report said. "Neither industry nor

government can be expected to play this role alone."

This type of "virtual research and development network" is working well for other diseases, including cystic fibrosis, tuberculosis, malaria, and other tropical diseases, the committee said. The report cited the Cystic Fibrosis Foundation Therapeutics Inc. and the Medicines for Malaria Venture as two "thriving" public-private partnerships.

"It would take a small group of motivated people who make it their focus to have it happen," Adamson said. "My sense is, academia, NCI, and industry would come to the table, but someone needs to drive it. That was the goal of this report, saying we need someone to take the lead on this, move it forward, because it's not going to happen on its own. That's pretty clear."

Besides R&D specifically for childhood cancers, treatment could be improved by testing in children the new drugs in development for adult cancers, the report said. Some drugs may fail to provide benefit to adults, but could help children. However, companies might not be able to recoup these development costs. If companies drop development of a promising drug, the government should take over, either directly or by funding external research, the report said.

Therefore, NCI "should assume responsibility as the developer of last resort for agents that show promise only in children if companies decide not to proceed with full-scale development," the report said in its second major recommendation.

In the past, there have been long delays between drug testing in adults and testing in children, the report said. Because these cancers are rare, clinical trials for children can take years longer than they do for adults. As a result of a mandate by the Best Pharmaceuticals for Children Act of 2002, NCI has begun to encourage faster testing by funding the first coordinated preclinical testing program for pediatric cancers, the report said. The initial five-year contract was awarded last fall to St. Jude Children's Research Hospital.

Greater steps should be taken to encourage companies to begin pediatric clinical trials earlier, the report said. The pharmaceutical industry, NCI, and FDA "should act to reduce the delay in beginning pediatric clinical studies of agents in development for adult cancers," said the report in its third major recommendation.

#### "No Major R&D Programs"

About 11,900 children and adolescents in the U.S. under age 20 were diagnosed with cancer in 2001, the report said. This represents an incidence rate of about

16 per 100,000 per year (roughly 1 per 6,400 children per year).

"Between birth and 20 years of age, about 1 in 333 Americans develops cancer," the report said. Cancer is the third leading cause of death among children ages 1 to 4, and second to accidents among children ages 5 to 14.

The major childhood cancers include leukemias, tumors of the brain and nervous system, the lymphatic system, kidneys, bones, and muscles. These cancers tend to be distinct biologically and clinically from adult cancers.

Basic research in pediatric cancer has identified unique molecular abnormalities, which could lead to new targeted treatments, the report said.

"However, there are no major R&D programs in either industry or the government devoted to developing new drugs for childhood cancers," the report said. "Even with incentives such as orphan drug provisions, the market for pediatric cancer drugs is too small for pharmaceutical companies to recoup their investments in developing new products, and full-scale drug development is not considered a government function."

The components of a comprehensive R&D program exist, but are scattered across universities, academic medical centers, industry and within NCI, the report said. "Companies maintain state-of-the-art, high-throughput screening technology and large "libraries" of compounds—major companies have libraries that number in the millions—that could become lead compounds to be developed into drugs, if they show activity when screened against relevant molecular targets," the report said. "There may well be useful agents for pediatric cancers in these libraries, including some in development for adult cancers, but by and large, compounds are not screened against known pediatric cancer targets."

Most of the drugs and biologics currently used for pediatric cancers were approved before 1990, about half before the mid-1980s, the report said. The drugs were used to treat adults before being tested for children.

Last December, for the first time in over a decade, FDA granted initial approval of a new pediatric cancer drug: clofarabine to treat refractory or relapsed acute lymphocytic leukemia in children.

PhRMA, the pharmaceutical industry trade group, lists 32 products in development for pediatric cancer in its publication, "Medicines in Development for Children 2004." Half of these are approved for adults. Two therapies are in phase III trials, and three are in

multiple-phase trials that include phase III.

Copies of the report, "Making Better Drugs for Children With Cancer," are available from <a href="www.nap.">www.nap.</a> edu.

# Pazdur Is "Excellent Choice," ASCO President Johnson Says

(Continued from page 1)

job—the National Coalition for Cancer Survivorship and the American Society of Clinical Oncology--said they were pleased with FDA's decision.

"NCCS commends the FDA for its attention to choosing a director of oncology drug products, and congratulates Dr. Richard Pazdur on his appointment to this position," said Ellen Stovall, NCCS president and CEO. "NCCS has long advocated for the consolidation of review and approval of new treatments for cancer, and, in particular, has advocated for Dr. Pazdur's leadership.

"Dr. Pazdur has all the credentials and vision to lead this new office," Stovall said. "We know from his longstanding career that he is knowledgeable and forthright, and will ensure that FDA's review process for new cancer products is transparent, predictable, and takes the best interests of patients to heart in meeting high efficacy and safety standards."

ASCO President David Johnson said Pazdur has done an "outstanding" job at FDA. "He has demonstrated over the course of the last several years that he has the insight, the experience, and wisdom to judge the quality of applications and steer companies toward the right trials that need to be done in order to approve drugs," said Johnson, deputy director of the Vanderbilt-Ingram Cancer Center.

"I think he has attempted to hold companies to high standards, which I think is the appropriate thing for the director to do," Johnson said. "By the same token, I think he has done it in a way that has been helpful, for those companies that listen. For those studies that are not well conceived, he has tried to steer companies towards a much better plan of action.

"He has also brought some pragmatism to the system," Johnson said. "With his experience and background as a physician, a drug development expert, and a clinical trialist, he recognizes when there are issues that are related to human nature that one can never overcome. I personally think he's an excellent choice. I think he has all the qualifications that we would want in someone who directs such an office."

Pazdur obtained his M.D. from Loyola Stritch School of Medicine, where he also trained in internal medicine. He was a fellow in oncology at Rush Presbyterian-St. Luke's Medical Center and the University of Chicago. He served as a practicing oncologist, researcher. and teacher at Wayne State University, prior to joining M.D. Anderson.

#### NCI Programs:

#### Paulette Gray Named Director, Div. of Extramural Activities

Paulette Gray, acting director of the NCI Division of Extramural Activities since 2003, was appointed director of the division on April 17.

Gray has served deputy director for the division since 1997. The division coordinates NCI extramural programs and grants by conducting peer review and oversight of extramural research, coordinating the National Cancer Advisory Board and the Board of Scientific Advisors, and establishing policies and procedures for extramural research, research integrity, and grant applications. Gray is responsible for the oversight of the more than 7,000 awards in NCI's extramural research portfolio.

Gray came to NCI in 1984 as the first special review officer with the Division of Extramural Activities. She held positions as a health scientist administrator, the first chief of the Review Logistics Branch (now the Special Review and Resources Branch), and served as the division's first associate director for extramural applications.

She received a B.S. in biology from Tuskegee University, as well as an M.S. in mycology and a Ph.D. in cellular and developmental biology from Atlanta University. She completed postdoctoral studies as a Josiah Macy Jr. Fellow at Woods Hole Marine Biological Laboratory. She was a Fulbright Scholar at the University of Kaiserlautern, Germany.

### <u>Funding Opportunities:</u> **Program Announcements**

PA-05-086: Stem Cells and Cancer

NCI is interested in stimulating research on all aspects of stem cell biology, including research into the molecular and biochemical regulation of embryonic and adult stem cell behavior. Investigators working on the cell and molecular biology of embryonic stem cells, adult stem cells, and tumor stem cells are encouraged to apply for R01 and R21 support under this funding opportunity.

The following questions illustrate areas of high interest, but other relevant innovative projects are also encouraged. What governs the proliferation rate of normal and tumor stem cells? Can oncogenes and their associated mutations affect

asymmetric versus symmetric divisions in stem cells? Stem cell quiescence versus growth must ultimately be understood in terms of progression through the cell cycle. Which stem cell-specific genes alter the cell cycle pathway proteins? Do tumor stromal cells constitute a unique tumor stem cell niche? Does the tumor stromal niche act as a constituent of a feedback mechanism with tumor stem cells to control their growth? Are the phenotypes of invasion and metastasis uniquely connected to the tumor stem cell phenotype? Are normal resident adult tissue stem cells a special target for carcinogenic insults? Can new and/or better markers and assays for the isolation and enrichment of tumor stem cells be developed? Can new and/or better in vivo functional assays to identify tumor initiating cells (e.g. engraftment of leukemic stem cells into immunodeficient NOD/SCID mice) be developed? The PA is available at <a href="http://grants.nih.gov/grants/guide/pa-files/PA-">http://grants.nih.gov/grants/guide/pa-files/PA-</a> 05-086.html.

Inquiries, for NCI: R. Allan Mufson, chief, Cancer Immunology Hematology Branch, Division of Cancer Biology, phone: 301-496-7815; fax 301-480-2844; e-mail am214t@nih.gov.

### PAS-05-085: Understanding and Treating Tuberous Sclerosis Complex

Participating NIH Institutes and centers invite R01, R21, and R03 research grant applications aimed at understanding or treating TSC. Studies to identify new therapeutic targets or that involve preclinical testing of candidate therapeutics are particularly encouraged. The PA is available at <a href="http://grants.nih.gov/grants/guide/pa-files/PAS-05-085.html">http://grants.nih.gov/grants/guide/pa-files/PAS-05-085.html</a>.

Inquiries, for NCI: Mary Ellen Perry, program director, Division of Cancer Biology, phone 301-496-7028; e-mail mp372j@nih.gov.

### PA-05-090: Methodology and Measurement in the Behavioral and Social Sciences

The goal of this PA is to encourage research that will improve the quality and scientific power of data collected in the behavioral and social sciences. Research that addresses methodology and measurement issues in diverse populations, issues in studying sensitive behaviors, issues of ethics in research, issues related to confidential data and the protection of research subjects, and issues in developing interdisciplinary, multimethod, and multilevel approaches to behavioral and social science research is particularly encouraged, as are approaches that integrate behavioral and social science research with biological, physical, or computational science research or engineering.

This initiative will use the R01, R03 and R21 mechanisms and competitive supplements to funded R01, R37, U01 and P01 projects. The PA is available at <a href="http://grants.nih.gov/grants/guide/pa-files/PA-05-090.html">http://grants.nih.gov/grants/guide/pa-files/PA-05-090.html</a>.

Inquiries, for NCI: Louise Mâsse, Health Promotion Research Branch, Behavioral Research Program, Division of Cancer Control and Population Sciences, phone 301-435-3961, e-mail: <a href="massel@mail.nih.gov">massel@mail.nih.gov</a>.

#### In Brief:

### AACR Inducts Peter Jones As President For 2005-06

**PETER JONES**, director of the University of Southern California Norris Comprehensive Cancer Center, assumed the presidency of the American Association for Cancer Research at the association's annual meeting in Anaheim, Calif., on April 18. Jones, Distinguished Professor of Urology and Biochemistry and Molecular Biology at the Keck School of Medicine of USC, holds the H. Leslie Hoffman and Elaine S. Hoffman Chair in Cancer Research. He joined USC in 1977 as an assistant professor of pediatrics and biochemistry at Children's Hospital Los Angeles. In 1984, he moved his laboratory to USC/Norris. Jones became director of urologic cancer research, leading the department's basic science investigations. His research focuses on DNA methylation. In 1993, he was named director of the Norris center. Jones was born in South Africa, raised and attended school in Rhodesia (now Zimbabwe), and received his doctor of philosophy degree from the University of London in 1973. "Obviously, it is a great honor to have the opportunity to lead the premier cancer research organization not only in the United States, but in the entire world," Jones said. "This is a critical time in cancer research because the application of molecular breakthroughs to cancer treatment and prevention holds so much promise, while funding for cancer research remains flat."... ARCHIE **BLEYER** has returned to the Pacific Northwest after 15 years at the University of Texas M.D. Anderson Cancer Center. He will serve as medical advisor to the Cancer Treatment Center at the St. Charles Medical Center in Bend, Ore., and continue to lead national initiatives to assist young adults with cancer. At M.D. Anderson, Bleyer was division head and chairman of pediatrics, and director of community oncology. For 10 years, he served as chairman of the Children's Cancer Group, during which he developed the national adolescent and young adult oncology program. . . . ALEX ADJEI was appointed vice chairman of the North Central Cancer Treatment Group, said **Jan Buckner**, group chairman. Adjei is director of the Mayo Clinic Cancer Center Phase I Program and Lung Cancer Program. Axel **Grothey** was appointed director for cancer treatment for NCCTG. Grothey is a medical oncologist at Mayo Clinic in Rochester, Minn., and co-director of the NCCTG GI Malignancies Program. . . . DANA-FARBER Cancer Institute produced an educational video that gives cancer patients the tools to make an informed

choice about clinical trials, said Faye Austin, senior vice president for research at Dana-Farber. "Entering a Clinical Trial: Is It Right for You?" is a 21-minute video with interviews with doctors, nurses, and patients. The video is free and is available in VHS and DVD formats, and can be viewed with a broadband Internet connection at www.dana-farber.org/res/clinical/trialsinfo/. The Health Improvement Institute named the video a winner of its 2004 Award for Excellence in Human Research Protection for Innovation. Christina Parker. of Dana-Farber, oversaw the production of the video and booklet, developed in collaboration with Brigham and Women's Hospital, Massachusetts General Hospital, and Beth Israel Deaconess Medical Center. . . . M. D. ANDERSON Cancer Center and Baylor College of Medicine are developing a joint neurosurgery program. "This brings together the best of the Texas Medical Center," said Raymond Sawaya, chairman of the Department of Neurosurgery at M.D. Anderson and chairman of the BCM Department. Sawaya will oversee the neurosurgery programs at the BCM affiliated hospitals: St. Luke's Episcopal Hospital, Ben Taub General Hospital, Texas Children's Hospital, and the Michael E. DeBakey Veteran's Affairs Medical Center, in addition to the M. D. Anderson program. Sawaya will continue as director of the Brain Tumor Center at M. D. Anderson. . . . REBECCA AND JOHN MOORES University of San Diego Cancer Center was officially opened last week. The building consolidates clinical, research and administrative services on the UCSD east campus. John Moores, the majority owner of the San Diego Padres and regent of the University of California, gave a \$20 million for the new building. **Jerome** and Miriam Katzin, supporters and volunteers at UCSD, gave \$15 million. The Katzin Research Laboratories, part of the new building, are named on their behalf. . . . ALFRED KNUDSON Jr. received the American Association for Cancer Research Award for Lifetime Achievement in Cancer Research. Knudson, a geneticist and physician, is being honored for the two-hit theory describing the role that genes and heredity play in causing cancer. He is senior advisor to the president of Fox Chase Cancer Center. . . . RESEARCH! AMERICA named John Porter and Mary Hendrix to its board of directors. **Porter**, the former Illinois Congressman who is a partner in the Washington, D.C., office of Hogan & Hartson, was named board chairman. Hendrix, president and scientific director of Children's Memorial Research Center at Northwestern University, also serves on the NCI Board of Scientific Advisors and the National Human Genome Research Institute Advisory Council.





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The Compendium neither represents an all-inclusive listing of every drug and biologic nor every appropriate use and indication for drugs and biologics. Any clinician seeking to apply or consult this Compendium is expected to use independent medical judgment in the context of individual clinical circumstances to determine any patient's care or treatment.

### ANNOUNCING

### NCCN Drugs and Biologics Compendium™

The National Comprehensive Cancer Network announces the authoritative source for determinations about the appropriate use of drugs and biologics in the care of cancer patients — The NCCN Drugs and Biologics Compendium™ — The Compendium defines appropriate uses as recommended in the NCCN Clinical Practice Guidelines in Oncology™ — the standard for clinical policy in cancer care. These uses include FDA-approved disease indications and additional uses deemed appropriate based upon sound scientific evidence and the expertise of the multidisciplinary NCCN Guidelines Panels. The Compendium is designed for easy reference by decision-makers in health care and continues the tradition of the NCCN Guidelines as the most up-to-date source of treatment recommendations in the field of oncology. The Compendium's includes:

- FDA-approved disease indications and specific NCCN uses, including beyond FDA-approved labeling
- generic and brand names
- pharmacologic class
- category of NCCN recommendation
- diagnostic and treatment codes
- and much more

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