THE CANCER LETTER

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An Old Drug's 21st Century Makeover Begins With 84-Fold Price Increase

By Paul Goldberg

The generation-old drug Matulane (procarbazine hydrochloride) has acquired at least one attribute of a cancer therapy of the 21st century: the price.

For years, a bottle of 100 pills of procarbazine cost $66. Then, last September, the average wholesale price increased almost tenfold—to $650. On March 19, the price went up again—to $5,568.

As a result, a procarbazine pill that used to cost 66 cents less than a year ago sells for $56.

Procarbazine was approved in 1969 as a treatment for Hodgkin's

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In Brief:

Univ. of Pittsburgh Honors Bernard Fisher With Lecture And Portrait Unveiling

BERNARD FISHER, a pioneer in the biology and treatment of breast cancer, was honored by the University of Pittsburgh with a special lecture and portrait unveiling. **Mary-Claire King**, who discovered the first genetic link to breast cancer, presented the 2005 Bernard Fisher Lecture on March 29.

Fisher, a 1943 graduate of the University of Pittsburgh School of Medicine, serves as distinguished service professor of surgery at the university and scientific director of the Pittsburgh-based National Surgical Adjuvant Breast and Bowel Project, the research consortium he chaired from 1967 to 1994.

"It was an honor to give Bernard Fisher the acknowledgement he truly deserves for his seminal research and the contributions his research has made to the health of all women," said **Arthur Levine**, senior vice chancellor for the health sciences, and dean of the School of Medicine, University of Pittsburgh.

Fisher overturned the belief that breast cancer spreads in an orderly and sequential fashion. He proposed that breast cancer is a systemic disease that metastasizes unpredictably, and would best be treated with conservative local treatment plus systemic chemotherapy.

"His work changed the course of treatment, the rate of survival and the quality of life for women with breast cancer," said Levine. "At a time when radical mastectomy was the standard treatment for breast cancer, Dr. Fisher's landmark research found that less extensive and less disfiguring procedures were just as effective. His findings set a revolutionary new course for the

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Price Hike Of Procarbazine Astonishes Oncologists

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lymphoma. Its U.S. sponsor—Sigma-Tau Pharmaceuticals Inc. of Gaithersburg, Md.—said the increases were needed because the company had to find a new manufacturer of the active agent and make new regulatory filings.

"We are confident that, even with the impact of this price increase, Matulane remains competitively priced, in line with similar cancer therapies," Sigma-Tau Chief Operating Officer Gregg Lapointe said in a press release that was sent out twice—to explain each of the two price increases.

It's not easy to defend increasing the price of an old drug to the level of new agents, said Jim Koeller, professor and member of the Center for Pharmacoeconomic Studies in the College of Pharmacy at the University of Texas at Austin. "It would be like saying the price of 5-FU should go up from $3 a bottle to $3,000, to keep it in line with oxaliplatin, which is also given in colon cancer," Koeller said.

Doctors and pharmacists are used to seeing drug price increases of about 5 percent at a time. The 84-fold price hike astonished brain tumor expert Henry Friedman. "If this company can charge $5,568 for procarbazine, anyone can charge anything for anything," said Friedman, the James B. Powel Jr. Professor of Neuro-Oncology and co-director of the Clinical Neuro-Oncology Program at the Duke Brain Tumor Center. "With procarbazine at $5,568, what's prednisone worth? $9,568?"

With the federal government taking a hands-off approach to prices, industry observers expect that starting on Jan. 1, 2006, the newly priced procarbazine would be eligible for reimbursement under the Medicare Part D prescription drug benefit.

According to IMS Health, pharmacies in the U.S. bought between $255,000 and $365,000 worth of procarbazine a year between 2001 and 2004. If doctors keep prescribing despite the price increase, sales of the drug would rise from the $250,000 range to a more formidable $20 million-plus.

"Now it's a real product," Sigma-Tau executive Lapointe said in an interview. "Now we can keep doing it."

In lymphoma, the drug stands for the first P in the MOPP regimen—a combination of nitrogen mustard, vincristine, procarbazine and prednisone. MOPP has been largely abandoned in the U.S., but one of its variations is used in Germany.

Brain tumor specialists have used procarbazine as a single agent and as part of the PCV regimen, in combination with CCNU and vincristine. The regimen is being edged out by temozolomide, brain tumor experts say.

"It still does have a role in selected patients, until we get more choices to fight brain tumors, so I would hate to see it disappear," said Glenn Lesser, a brain tumor expert at Wake Forest University Comprehensive Cancer Center. "It does represent an option for patients who might not have very many—or any—other options."

Koeller said he wouldn't expect the makers of widely used cancer drugs to try to increase prices dramatically. In a large market, competitors would jump in and undercut the price. Niche products like procarbazine are another matter, he said.

"This kind of a pricing strategy works best if it stays under the radar," Koeller said. "It's such a small number of patients that they figure they would be off the screen. It's simple business."

A History of a Small Market

In 1998, Sigma-Tau, a firm that specializes in drugs for small populations, bought a license to procarbazine and a stockpile of the product from Roche.

"We acquired this product not knowing much about it, but just understanding that the product was essentially on its last legs," Lapointe said to The Cancer Letter. "Perhaps somewhat naively, we took the

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product on, thinking, 'This is what we do. We can fix this problem.'"

From the start, Sigma-Tau planned to find a new supplier of the bulk product and only then decide how the drug should be priced.

Experts in drug manufacturing say that making a new version of an existing cancer drug is usually a straightforward process, which includes establishing a drug master file, qualifying a manufacturer, and, finally, producing the pills.

These steps are analogous to filing an Abbreviated New Drug Application and launching a generic drug. This can cost between $2 million and $3 million, and take about two years. Procarbazine's molecular structure is related to rocket fuel, and the process involved in its manufacturing is not unusual, industry experts say.

"These days, it takes almost nothing to have a drug like this made," said Bruce Ross, a pharmaceutical industry consultant and former executive at Bristol-Myers Squibb who directed the development and initial production of Taxol.

Lapointe said his company's experience was different.

The process took six years, in part because the company couldn't find a manufacturer of the bulk product, he said. "Typically, when we'd find someone, they'd say, 'Okay, we are interested, how many hundreds of thousands of kilos will you need?' and we'd say, 'Maybe 60 kilos should do us for a long time.' And they are not interested."

Lapointe declined to discuss the company's investment in procarbazine. "It certainly has cost us significantly more" than what industry insiders estimate, he said. "I've heard those numbers thrown around," he said. "I guess there are examples out there. I don't know that they are with a product like this."

Lapointe said an Italian manufacturer agreed to make the active ingredient, and the pills continue to be manufactured by AAI International of Wilmington, N.C. Sigma-Tau Inc. is owned by Sigma-Tau S.p.a. of Rome.

The company had narrowly averted a shortage, Lapointe said. "We knew how many bottles were sold, and we knew that there was a risk that there would be no Matulane anymore," he said. "As we started to see the stock dwindle, we got extremely concerned, and we didn't want a situation where you had a pharmacist with an open bottle who had 70 tablets left in California and no supply on the East Coast. So we started to not ship through wholesalers anymore, because that's what creates that problem."

By the time a new supply of the drug became available, the stockpile had dwindled to 400 bottles, he said.

The company didn't track how the drug was used. "We knew how it was being used in terms of stage III and IV [Hodgkin's disease],"he said. "We've been surprised in the last several months to hear from people who are using it in other ways. We are aware that it's being used on occasion in brain tumors, with some good success, too." The existence of veterinary use surprised Lapointe, too, he said.

Beating Temodar?

The drug's price was set in part based on comparison with other agents used to treat cancer, Lapointe confirmed.

"We looked at the average cost in a variety of chemo areas, to make sure that we are in line," he said. "There is a number of different drugs out there, rituximab, etoposide. I think we are still below them on a regimen basis. Temodar is way up there, from what I understand."

It makes no sense to compare procarbazine to newer agents, said Koeller. "That's truly comparing an apple to an orange," he said. "They don't have a new drug. They have a 40-year-old drug here. They are just taking the price up."

Howard Ozer, director of the cancer center at the University of Oklahoma Health Sciences Center, agrees.

"I can't understand why a drug that has been utilized in lymphomas for years, albeit with a decreasing usage with newer agents and combinations, is now priced at such an exorbitant rate," said Ozer, a lymphoma expert. "It can't be that this is the cost of manufacturing and development or R&D, as is usually argued by drug companies."

There is no valid price comparison for procarbazine in lymphoma, Ozer said. "There are so many preferable alternatives in existence already," he said. "This has to be based on the price of temozolomide in brain cancer. That's the only thing I can see. These kinds of things drive up the global cost of healthcare, they drive up the cost of caring for our patients, and this ought to be something that insurance companies and the federal government should look into."

A comparison with temozolomide is problematic, brain tumor expert Lesser said.

"From an efficacy standpoint, there is a growing body of data regarding efficacy of temozolomide, and there are relatively little historical data on procarbazine,"

Lesser said. "Temozolomide is on average better tolerated, and recent well-controlled studies suggest that it has some real efficacy in selected populations. I am not sure one can make that same claim for procarbazine, based on the published historical data. It is one of the few drugs that has been shown to have activity against gliomas, yet the activity has been relatively modest, and the best data is part of a multi-agent regiment for a rare form of gliomas, where the proportional activity of individual agents is impossible to ascertain.

"It's hard to make a case for even similar efficacy, and I think most oncologists in the field would believe it has inferior efficacy in most situations, and is certainly on average a bit more toxic to patients," Lesser said.

Surprisingly, after the price increase, procarbazine administered as a single agent costs more than temozolomide.

The average wholesale price of a bottle of 20 pills, each containing 100 milligrams of temozolomide, is $3,555. A patient with the body surface of 2 m^2 would take 40 pills over two months. This would cost $7,110.

An identical patient taking procarbazine as a single agent would take 140 pills, each containing 50 mg of the drug, over two months. This would cost $7,795. A patient treated with the PCV regimen would take $1,559 worth of procarbazine over six weeks.

This pricing structure prompted a backhanded compliment from Friedman: "I applaud the company for giving physicians the incentive to abandon single-agent procarbazine in favor of a less expensive, better studied and less toxic alternative: temozolomide," Friedman said. "Is this altruism or a calculator malfunction?"

Procarbazine's new price amounts to an invitation to competitors, Ross said. "A drug priced this high will inevitably draw generic competition very quickly; that's 100 percent certain," he said.

Likely, this will happen soon, Koeller said. "It's U.S. Economics 101," he said. "This is a free market, capitalistic society. I can guarantee you, if the word gets out and people find out that this drug has gone up in price this dramatically, other suppliers will come forward. You will find some guys who will cut that price because they can."

A "Moral Dilemma"

Lapointe said the comments he heard since the price increase have been mostly positive. "People call and say, 'I am so glad the product is still available,'" he said.

However, Lapointe said he recognizes that the magnitude of the increase surprised doctors and pharmacists.

"We are guilty of doing it this in one-shot," he said. "In this industry, all my colleagues are saying that you have to do 5 percent twice a year, every year forever, and that's not our model. We price according to what it requires so we can keep doing what we do."

Working with the National Organization for Rare Disorders, the company is giving out the drug to patients who can't afford it. NORD has been running the procarbazine assistance program for several years, but demand rose only after the price increase.

"We have had an influx of applications for assistance with it," said Maria Hardin, NORD vice president for patient services.

To determine eligibility, NORD reviews the patients' income, expenses, assets and insurance. The assistance program isn't limited to Hodgkin's disease and other lymphomas. For brain tumor indications, the group asks prescribing doctors to submit releases from liability. "Some companies don't make their products available for off-label indications," Hardin said.

After NORD determines that a patient is needy, the company sends out the drug.

According to 2003 tax forms, NORD took in $1.354 million for administering indigent care programs for drug companies. The group's revenues were $4.786 million.

NORD provides assistance for another Sigma-Tau drug, Carnitor, indicated for primary systemic carnitine deficiency, dyalisis, chronic fatigue syndrome, and several metabolic disorders. The group's other clients include Allergan, Aventis, Cell Therapeutics, Cephalon, INO Therapeutics, Medtronic, Orphan Medical, QOL Medical, Questar Pharmaceuticals, Rare Disease Therapeutics, Serono Laboratories, Teva Neuroscience, and Ucylyd Pharma.

Also, NORD ran an expanded access program for the AstraZeneca drug Iressa, and provided travel grants to needy patients who wanted to attend the September 2002, meeting of the FDA Oncologic Drugs Advisory Committee (The Cancer Letter, Nov. 8, 2002).

Administration of financial assistance programs represents a "moral dilemma" for NORD, Hardin said. "Our allegiance lies with the patients," she said. "If the barriers are there, we just try to figure out any which way to make the drug accessible to the patient. That is where our issue lies, not in bringing in profits to the companies. We always tell them, 'Drop your prices. Don't go this route.' But nobody drops their prices; not one company."

Is bowing out an option?

"Look who would suffer in the end," said Hardin. "It's the patients who suffer, because they can't access the drugs. That's what we are up against."

With the prices of new drugs routinely exceeding $10,000 a month, an increasing number of patients will have to rely on private charities to pay for deductibles. Over the past year, patient assistance groups including NORD have established programs that cover the patients' deductibles under the Medicare program.

This form of assistance can be a better deal for companies, because it allows them to help the needy with the co-payment, while still billing third-party payers.

Under Medicare Part B, such programs are permitted only if they are run by independent foundations, without involvement of the drug manufacturers. It's unclear how such programs would be structured under the Part D program, industry observers say.

No matter how aid to patients is distributed, drug companies have become beneficiaries of their own charity, Koeller said.

"If a company can make $5,568 instead of $66, they can afford to make the drug available to the indigent and still make a significant profit. " he said. "And then it would be hard to condemn them when they are being a good corporate citizen by providing the drug free to those who can't afford it.

"Who is to complain?"

NCI Programs:

NCI Provides $95 Million For Community Networks

NCI has funded $95 million in grants for the Community Networks Program to reduce the number of cancer deaths in minority and poor populations, according to the Department of Health and Human Services.

Up to 25 grantees will develop programs to increase the use of cancer interventions in underserved communities. Interventions will include proven approaches including smoking cessation, increasing healthy eating and physical activity, and early detection and treatment of breast, cervical and colorectal cancers.

"Our commitment to closing the health care gap among racial and ethnic minorities is unwavering," HHS Secretary Mike Leavitt said. "We will continue to support community-based approaches to help racial and ethnic minority populations experience the benefits of modern medicine."

Each CNP will form an advisory group to work with community members. A steering committee of community-based leaders, researchers, clinicians and public health professionals will provide additional support. CNP grantees and NCI will train investigators and identify potential research opportunities.

The CNP builds on a previous initiative called the Special Population Networks program. It will be administered through individual cooperative agreements between NCI and the CNP grantees and will be directed by NCI's Center to Reduce Cancer Health Disparities.

Awardees include: Terrance Albrecht, Wayne State University; Claudia Baquet, University of Maryland School of Medicine; Laura Beebe, University of Oklahoma Health Sciences Center; Dedra Buchwald, University of Washington; Moon Chen, University of California, Davis; Mark Dignan, University of Kentucky Research Foundation; Dione Farria, Washington University, St. Louis; Estevan Flores, University of Colorado at Denver and Health Sciences Center; Paul Godley, University of North Carolina, Chapel Hill; James Hebert, University of South Carolina Research Foundation; Ronda Henry-Tillman, University of Arkansas for Medical Sciences; Elmer Huerta, MedStar Research Institute; Howard Koh, Harvard University, School of Public Health; Grace Ma, Temple University; John Maupin Jr., Meharry Medical College; Edward Partridge; University of Alabama at Birmingham; Amelie Ramirez, Baylor College of Medicine; David Satcher, Morehouse School of Medicine; Sora Park Tanjasiri, California State University, Fullerton; and Beti Thompson, Fred Hutchinson Cancer Research Center.

Funding Opportunities:

Foundation Seeks Applicants For Mesothelioma Research

Application Deadline: Aug. 15

Mesothelioma Applied Research Foundation Inc. is accepting applications for pleural or peritoneal mesothelioma. Eligible projects may relate to either benchwork research or clinical research, must not be presently funded or pending review, and may be conducted through any not for profit academic, medical or research institution, in the U.S. or abroad. Grant amount is $100,000 over two years.

Encouraged projects include, but are not limited to, benchwork/ clinical investigations of: (1) Strategies for early detection of new or progressive disease; (2) Definition of targetable differences between normal and transformed mesothelium and development of novel strategies for treatment taking advantage of these targets; (3) Therapeutic

intervention, including; a.Gene therapy b. Immunotherapy c.Novel chemotherapeutic compounds d.Novel radiation techniques e.Novel mechanisms which inhibit angiogenesis or metalloproteinases; (4) Determination of clinical/molecular determinants for prognosis; (5) Pain management.

Information and applications are available at http://marf.org/marfFrames/GrantsFrame.htm.

RFA Available

RFA-HD-05-025: Global Network for Women's and Children's Health Research

Letters of Intent Receipt Date: Dec. 19

Application Receipt Dates: Jan. 19, 2006

National Institute of Child Health and Human Development, NCI, and NCCAM invite applications to participate under a cooperative agreement in an ongoing multi-center international research network to perform randomized clinical trials using common protocols, to reduce the major risk of maternal, neonatal, infant, and early childhood mortality and significant morbidity in resource-poor countries in Africa, Asia, Latin America, and the Middle East. The funding opportunity will use the NIH Cooperative Research Project Grant U01 award mechanism. The RFA is available http://grants.nih.gov/grants/guide/rfa-files/RFA-HD-05-025.html.

Inquiries: Scientific/Research Contacts, Linda Wright, NICHD, phone 301-402-0830; fax 301-480-7773; e-mail wrightl@mail.nih.gov.

Program Announcements

PA-05-103: Pilot and Feasibility Program Related to the Kidney

NIH institutes invite applications through the exploratory/developmental R21 grant mechanism for high-risk pilot and feasibility research by newly independent or established investigators, to develop ideas for subsequent submission of R01 applications on research problems relevant to both acute and chronic kidney diseases, and their complications, in both the adult and pediatric populations. The PA is available at http://grants.nih.gov/grants/guide/pa-files/PA-05-103.html.

Inquiries: For NCI-- Judy Mietz, DNA and Chromosome Aberrations Branch, phone 301-496-9326; fax 301-496-1224; e-mail jm166o@nih.gov.

NOT-CA-05-021: Amendment to PA-05-015 Research Supplements to Promote Diversity in Health-Related Research

NCI is amending its participation in the PA, as follows: the Comprehensive Minority Biomedical Branch, Office of Centers, Training and Resources, announces a change in the way Research Supplements to Promote Diversity in Health-Related Research will be managed by NCI. For fiscal year 2005 only, no supplement applications will be accepted by NCI after June 1. In the future, related funding decisions will only be made twice a year, in March and July. The notice is available at http://grants1.nih.gov/grants/guide/notice-files/NOT-CA-05-021.html.

Inquiries: Peter Ogunbiyi, program director, Comprehensive Minority Biomedical Branch, Office of Centers, Training, and Resources, Office of the Director, phone 301-496-7344; fax 301-402-4551.

RFP Available

N02-CP-61000-04: Inherited Bone Marrow Failure Systems Support Services

Response Due Date: July 15

NCI Clinical Genetics Branch, Division of Cancer Epidemiology and Genetics, is competing a new contract for interdisciplinary studies in clinical cancer genetics targeting families with inherited bone marrow failure syndromes, a model for familial cancer. The contract will establish a mechanism to provide all the services required to conduct a wide variety of family studies and field (case-control and cohort) studies.

The RFP may be accessed via the NCI Research Contract Branch Web site: http://rcb.cancer.gov/rcb-internet/.

Inquiries: Brian Goodger, contract specialist, phone 301-435-3781; fax 301-480-0241 and Sharon Miller, contracting officer, phone 301-435-3783; fax 301-480-0241.

In Brief:

Fisher Honored With Lecture; Kober Medal To David Nathan

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treatment not only of breast cancer but other types of cancer as well."

Fisher and his research team demonstrated the superiority of lumpectomy combined with adjuvant chemotherapy as a treatment for breast cancer. His later studies showed that the drug tamoxifen can substantially reduce the risk of breast cancer in high-risk women who have not yet developed this disease.

"It is entirely fitting that one pioneer in breast cancer research be invited to recognize the work of another," said **David Bartlett**, chief of the division of surgical oncology and director, David C. Koch Regional Perfusion Cancer Therapy Center at UPMC Cancer Centers. "I cannot think of a more appropriate tribute to Bernard Fisher and his legacy than to hear from Mary-Claire King."

King, the American Cancer Society Professor of Medicine and Genome Sciences at University of Washington, discovered that mutations in a single gene known as BRCA1 can cause hereditary breast cancer. King earned her doctorate from the University of

California, Berkeley, where she taught from 1976 until 1995 before moving to the University of Washington. She has recently been awarded the Peter Gruber Foundation's Genetics Prize, the Marion Spencer Fay Award from the Institute for Women's Health and Leadership at Drexel University, and an honorary doctorate from Harvard University. She is a member of the Institute of Medicine and the American Academy of Arts and Sciences.

The portrait of Fisher is part of a dedicated gallery of research and clinical innovators in University of Pittsburgh history, located in the University of Pittsburgh's Biomedical Science Tower.

* * *

DAVID NATHAN, president emeritus of Dana-Farber Cancer Institute, Robert A. Stranahan distinguished professor of pediatrics at Harvard Medical School, and former chair of pediatrics and physician-in-chief at Children's Hospital Boston, will receive the most distinguished award in academic internal medicine, the George M. Kober Medal, from the Association of American Physicians, the association said.

When presented with the award in April 2006, Nathan will become only the third physician honored with both the Kober medal and the John Howland Award of the American Pediatric Society, which he received in 2003. The other two physicians who have received both awards are **James Gamble**, of Children's Hospital Boston, and **Helen Taussig**, of Johns Hopkins Medical Center.

"An entire army of leading academic hematologists and oncologists, in both pediatrics and adult medicine, owe their career success to David Nathan," said Dana-Farber President **Edward J. Benz Jr**. "David has made huge contributions as an investigator, but his enduring legacy is that he transformed our field by nurturing the careers of so many outstanding leaders and directing them toward areas of research and clinical care most in need of their talents."

* * *

SUSAN HORWITZ, president of the American Association for Cancer Research in 2002-2003, was elected to the National Academy of Sciences. Horwitz holds the Rose C. Falkenstein Chair in Cancer Research at Albert Einstein College of Medicine of Yeshiva University, Bronx, N.Y., where she is associate director for drug development at Albert Einstein Comprehensive Cancer Center. Her laboratory described the structure and mechanism of action of Taxol. Other AACR members elected to the academy: **C. David Allis**, Rockefeller University; **Michael Karin**, University of California, San Diego; **Mary-Claire King**, University of Washington, Seattle; **Marc Tessier-Lavigne**, Genentech Inc.; and **Craig Thompson**, Abramson Family Cancer Research Institute, University of Pennsylvania. . . . **LYMPHOMA** Research Foundation awarded $1.3 million in research grants to **Frank Rosenbauer**, Beth Israel Deaconess Medical Center; **Jennifer Brown**, Dana-Farber Cancer Institute; **Ann LaCasce**, Dana-Farber Cancer Institute; **Eric Chen**, Fred Hutchinson Cancer Research Center, **Xin Yu**, Rockefeller University; **Wei Ai**, Stanford University School of Medicine; **Qinyan Yin**, Tulane Health Sciences Center; **Ramune Reliene**, University of California Los Angeles; and **Irene Ghobrial**, University of Pittsburgh. . . **ROBERT H. LURIE** Medical Research Center basic and clinical research and teaching facility at Northwestern University Feinberg School of Medicine was dedicated April 21. Space in the 12-story center will be devoted to research on cancer, neurodegenerative diseases, bionanotechnology, infectious diseases, regenerative medicine and genetics, said **Lewis Landsberg**, dean of the Feinberg School and vice president for medical affairs. . . . **ONCOLOGY NURSING** Society announced the 2005–2006 board of directors at its 30th Annual Congress. **Karen Stanley**, nursing consultant in Greenwich, Conn., continues in her second year as president; **Georgia Decker**, nurse practitioner at Integrative Care and The Braverman-Panza Medical Group in Albany, NY, joined the board as president-elect. Newly elected directors-at-large are **Ellen Matthews**, oncology/bone marrow transplant staff educator at Presbyterian/St. Luke's Medical Center and assistant professor at the University of Colorado School of Nursing in Denver, and **Lisa Schulmeister**, adjunct assistant professor of nursing at the Health Sciences Center School of Nursing, Louisiana State University and a consultant in New Orleans. Continuing as board secretary is **Laura Benson** of OSI Pharmaceuticals in Melville, NY. Continuing as treasurer is **Diane Otte** of Franciscan Skemp Healthcare Cancer Center in LaCrosse, Wisc. Continuing their three-year terms as directors-at-large are **Patricia Buchsel**, of the University of Washington in Seattle; **Ryan Iwamoto** of Genentech BioOncology; **Ruth Gholz** of the Veterans Administration Medical Center in Cincinnati, **Julie Painter** of the Community Hospital of Indianapolis; and **Bradley Agle** of the Katz Graduate School of Business at the University of Pittsburgh. . . . **RHODA ALANI** was elected to membership in the American Society of Clinical Investigation. Alani is associate professor of oncology, dermatology, and molecular biology and genetics at Johns Hopkins Kimmel Cancer Center.

A Notch-Signaling Pathway Inhibitor in Patients with T-cell Acute Lymphoblastic Leukemia/Lymphoma (T-ALL)

An investigational study for children, adolescents and adults with relapsed and refractory T-cell acute lymphoblastic leukemia/lymphoma is now accruing patients at various centers around the country.

This study's goal is to evaluate the safety and tolerability of a Notch inhibitor as a rational molecular therapeutic target in T-ALL, potentially uncovering a novel treatment for these cancer patients.

Eligibility criteria and treatment schema for the study include:

Notch-Signaling Pathway Inhibitor in Patients with T-ALL	
Eligibility Criteria	Patient must be ≥ 12 months with a diagnosis of T-cell acute lymphoblastic leukemia/lymphoma AND must also have: • Relapsed T-ALL • T-ALL refractory to standard therapy • Not be a candidate for myelosuppressive chemotherapy due to age or comorbid disease ECOG performance status ≤2 for patients >16 years of age OR Lanksy performance level >50 for patients 12 months to ≤16 years of age Fully recovered from any chemotherapy and >2 weeks from radiotherapy, immunotherapy, or systemic steroid therapy with the exception of hydroxyurea or intrathecal therapy Patient must be >2 months following bone marrow or peripheral blood stem cell transplantation No treatment with any investigational therapy during the preceding 30 days No active or uncontrolled infection
Treatment Plan	Open label and non-randomized, this study is conducted in two parts. Part I is an accelerated dose escalation to determine the maximum tolerated dose (MTD), and Part II is a cohort expansion at or below the MTD. MK-0752 will be administered orally. Plasma concentrations will be measured at defined time intervals.

For information regarding centers currently open for enrollment, please contact 1-888-577-8839.

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