Advances in Chemotherapy Dramatically Benefit Women with Estrogen Receptor-Negative Breast Cancer

Fifty years ago, when CALGB was founded, researchers were just beginning to explore and develop hormonal therapies and chemotherapy to treat breast cancer. Early single agent chemotherapy trials were just being launched. Biological selection of patients for therapies did not yet exist. The estrogen receptor (ER) had not yet been discovered.

Fast-forwarding to the present, researchers are focusing on the biological subtypes of breast cancer and their response to various therapies, in order to offer patients more precisely tailored treatments. Recently CALGB investigators have demonstrated that advances in adjuvant chemotherapy have substantially improved prognoses for women with ER-negative breast cancer, whereas women with ER-positive tumors were not as greatly affected by newer chemotherapy regimens.

Previously it was believed that women with ER-negative breast cancer were not benefitting fully from the huge strides in research, such as the tremendous success of tamoxifen and other hormonal therapies available only to ER-positive patients. With increasingly effective chemotherapy, however, expectations for the ER-negative subgroup now approach cancer-free survival rates of patients with ER-positive disease.

Previously it was believed that women with ER-negative breast cancer were not benefitting fully from the huge strides in research, such as the tremendous success of tamoxifen and other hormonal therapies available only to ER-positive patients. With increasingly effective chemotherapy, however, expectations for the ER-negative subgroup now approach cancer-free survival rates of patients with ER-positive disease.

These findings come from a retrospective analysis of 3 consecutive randomized chemotherapy trials coordinated by CALGB, spanning 14 years and including 6644 women with node-positive breast cancer. Results were published in the Journal of American Medical Association, April 12, 2006.

“We were able to show consistently that ER-positive and ER-negative breast cancers have different natural histories, and that fine-tuning chemotherapy has the biggest impact on the fastest growing cancers that recur earlier,” comments Clifford Hudis, MD, Breast Committee Co-Chair and one of the study authors.

Study results

The differences in benefits of sequential improvements in chemotherapy according to ER status are striking. The CALGB analysis revealed that:

- Five-year disease-free survival increased by 22.8% for ER-negative patients, compared to 7% for ER-positive patients.
- Overall survival improved by 16.7% for ER-negative patients and only by 4% for women with ER-positive disease.
- Both the risk of recurrence and the overall risk of death were reduced by 55% in women with ER-negative breast cancer, whereas women with ER-positive tumors were not as greatly affected by newer chemotherapy regimens.

The authors point out that for ER-negative patients, the benefits are primarily due to the dramatically lowered risk of disease recurrence in the early years after treatment with newer chemotherapy. In ER-positive patients treated with tamoxifen, the risk of recurrence in the first few years is quite low. Since chemotherapy has its most substantial impact in the first several years after diagnosis, this may partially explain why the more current regimens led to a less dramatic effect in patients with ER-positive disease.

The findings do not mean, however, that women with ER-positive breast cancer do not need chemotherapy in addition to hormonal therapy. “All patients in the trials we analyzed received chemotherapy, so we did not look at data on how ER-positive patients would do with only tamoxifen,” explains Hudis. “One of our jobs going forward will be to discover what defines different subtypes of breast cancer in terms of chemotherapy benefit.”

continues on page 3
Happy 50th anniversary to CALGB! In recent columns, I have briefly recounted the origins of CALGB and discussed the first CALGB clinical protocol. Our theme for the 50th Anniversary Meeting is “Honor the Past...Look to the Future.” We have structured the meeting agenda accordingly, with 2 plenary sessions that honor our founders and pioneers (Friday afternoon) and provide a glimpse of CALGB research in the years ahead through the eyes of some of our up-and-coming leaders (Saturday afternoon). Many special guests have been invited, so please seek out old friends and colleagues, many of whom have played important roles in CALGB over the years.

At this meeting we will officially roll out the CALGB tagline, Tomorrow’s Cancer Treatments Today, submitted by Mike Perry and selected by a vote of the membership. This tagline will be incorporated in the CALGB logo and will appear on all official CALGB documents and publications henceforth. I think it reflects perfectly what CALGB is all about...providing innovative therapies to today’s patients through our clinical trials, with the goal that these treatments become the standard of care for tomorrow’s patients.

During the past 50 years, nearly 700 unique institutions in North America and Europe have participated in CALGB and our Statistical Center has recorded more than 112,000 (and counting!) registrations to more than 600 CALGB studies. The scientific output of the Group has been prodigious, with more than 1500 published papers since the first CALGB report in 1958 (an average of 30 publications/year!) and countless abstracts presented at scientific meetings.

The many accomplishments of the Group are summarized in a special supplement to Clinical Cancer Research (CCR, June 1, 2006 issue) devoted entirely to CALGB. Each meeting registrant will receive a copy of this journal along with a DVD that contains lectures by Jim Holland and me describing the early and more recent accomplishments of the Group. Among the CALGB accomplishments highlighted in the CCR issue are the following:

- Development of combination chemotherapy for acute leukemia
- Role of high dose cytarabine in treatment of AML
- Benefit of fludarabine in CLL
- Demonstration of the efficacy and FDA approval of 5-azacytidine in MDS
- FDA approval of nelarabine in T-cell leukemia and lymphoma
- Description of new cytogenetic and molecular abnormalities in AML that refine prognosis and enable risk-adapted therapy
- Demonstration of the superiority of ABVD chemotherapy for Hodgkin’s lymphoma
- Demonstration of the efficacy and FDA approval of paclitaxel in adjuvant chemotherapy for breast cancer
- Demonstration of the efficacy of dose-dense administration of adjuvant chemotherapy for breast cancer
- Superiority of combined chemotherapy and radiation therapy for stage IIIA NSCLC
- Role of adjuvant chemotherapy in early stage NSCLC
- Improved survival of colon cancer metastatic to the liver with hepatic artery infusion of chemotherapy
- CALGB studies to define the safety profile and dosing of new drugs in patients with organ dysfunction
- Introduction of quality of life assessments in cooperative group studies
- Development of clinical trials for older patients
- Development of quality control assessments for radiation therapy and surgery

An often unrecognized, but vitally important contribution of CALGB, is the mentoring provided by the Group to young investigators. There is no other venue where young investigators can have such ready access to world experts in clinical oncology, cancer biology, health outcomes research, biostatistics, and clinical trial design. One of our colleagues recently wrote to me about his experiences in CALGB and put it this way: “I have been a part of the CALGB since my first year on the faculty at [my institution] and have built a close camaraderie [with CALGB], which to date is one of the most collegial and influential groups in my career and way of thinking.” I must say that I feel much the same way, having been introduced to CALGB in 1981 by Patrick Henry and Mike Perry and immediately being exposed to luminaries such as Tom Frei, Jim Holland, Clara Bloomfield, Larry Norton, Bob Mayer, and Mark Green.

In responding to an invitation to attend this special meeting, a former member of the CALGB Central Office staff wrote: “In 16 years I still haven’t gotten CALGB out of my system. Nothing I’ve done since has been nearly as satisfying.” I hope all CALGB members share these sentiments. But as grand as our history may be, we still have work to do and our focus must be the challenges of the future rather than the accomplishments of the past.

So happy 50th anniversary to CALGB and remember the words of Dr. Jonas Salk on the occasion of receiving the Congressional Medal for Distinguished Civilian Achievement in 1958: “I feel that the greatest reward for doing is the opportunity to do more.”
Lymphoma

50303 Phase III Randomized Study of R-CHOP versus Dose-Adjusted EPOCH-R with Molecular Profiling in Untreated De Novo Diffuse Large B-Cell Lymphomas

Rationale
This is a phase III randomized comparison of rituximab (R)-CHOP, the de facto standard for diffuse large B-cell lymphoma (DLBCL), to dose-adjusted (DA)-EPOCH-R, a regimen developed from studies on drug schedule and resistance and pharmacokinetics. Importantly, this study will incorporate tumor microarray analysis using Affymetrix genome arrays in all patients to identify molecular mechanisms of drug resistance, develop molecular prognostic models, and to assess microarray tissue diagnosis. Retrospective microarray results with CHOP-based treatment in DLBCL have already identified that tumor proliferation and the Activated B-cell signature are the most important adverse molecular prognostic features. Results with DA-EPOCH show that it can abrogate tumor proliferation as an adverse prognostic factor, making the testing of DA-EPOCH a rational next step approach based on the microarray.

Trial design
This trial is available on the CTSU menu. Patients will be randomized to receive either R-CHOP or DA-EPOCH-R for 6 cycles. The primary objectives are to compare the event-free survival of R-CHOP versus DA-EPOCH-R chemotherapy in untreated CD20+ DLBCL, and to develop a molecular predictor of outcome of R-CHOP and DA-EPOCH-R chemotherapy using molecular profiling. The secondary objectives are: 1) to compare the response rates, overall survival, and toxicity of R-CHOP and DA-EPOCH-R; 2) to define the pharmacogenomics of untreated DLBCL and correlate clinical parameters with molecular profiling; 3) to assess the use of molecular profiling for pathological diagnosis; and 4) to identify new therapeutic targets using molecular profiling. All patients must be offered participation in the correlative science substudy, CALGB 60405, Pharmacogenomics in CALGB 50303.

Eligibility
Eligible patients must have histologically documented de novo stage I or higher mediastinal DLBCL or any stage II, III, or IV DLBCL, and must have 1 of the following WHO histologic subtypes without evidence of indolent histologic features in the tissue biopsy or bone marrow: 1) CD20+ DLBCL (includes centroblastic; immunoblastic; T-cell/histiocyte rich; and anaplastic); 2) CD20+ mediastinal LBCL; 3) CD20+ intravascular LBCL. Patients should have had no prior cytotoxic chemotherapy or rituximab.

Treatment plan
Patients randomized to CHOP-R will receive rituximab 375 mg/m² IV infusion on day 1 prior to CHOP chemotherapy; cyclophosphamide 750 mg/m² IV day 1; doxorubicin 50 mg/m² IV day 1; vincristine 1.4 mg/m² IV day 1; and prednisone 40 mg/m²/day PO on days 1-5. Filgrastim or pegfilgrastim is allowed. The cycle is repeated every 21 days for 6 cycles, and patients are restaged after cycles 4, 6. Patients randomized to DA-EPOCH-R will receive rituximab 375 mg/m² IV infusion on day 1 prior to EPOCH chemotherapy; (dose level 1) doxorubicin 10 mg/m²/day CIVI days 1-4; etoposide 50 mg/m²/day CIVI days 1-4; vincristine 0.4 mg/m²/day CIVI days 1-4; cyclophosphamide 750 mg/m² IV day 5; and prednisone 60 mg/m² PO on days 1-5. Filgrastim is required (use of pegfilgrastim requires study chair approval). Doses of doxorubicin, etoposide and cyclophosphamide are increased 20% over the previous cycle if the neutrophil nadir is over 500 cells/ul. The cycle is repeated every 21 days for 6 cycles and patients are restaged after cycles 4, 6.

The study chairs are Wyndham H. Wilson, MD, PhD, National Cancer Institute, email: wilsonw@mail.nih.gov, and Andrew D. Zelenetz, MD, PhD, Memorial Sloan-Kettering Cancer Center, email: a-zelenetz@ski.mskcc.org.
Transplant

**CALGB 100001 Autologous Followed by Non-Myeloablative Allogeneic Transplant for Multiple Myeloma**

**Rationale**

Although high complete response rates (30%–40%) can be achieved in patients with multiple myeloma (MM) using high-dose therapy and autologous hematopoietic stem cell transplant (HST), almost all patients are destined to relapse, and few, if any, are cured. Major obstacles to attaining a cure are the presence of contaminating tumor cells within the autologous stem cell product, excessive toxicity associated with allogeneic transplant, and the persistence of minimal residual disease despite maximally tolerated doses of chemotherapy (MRD). CALGB 100001, a phase II trial of autologous followed by non-myeloablative allogeneic transplant with post-transplant donor lymphocyte infusion, is intended to capitalize on recent advances to overcome these obstacles.

Evidence strongly suggests that post-transplant, donor immunologic factors may play a role in elimination of residual disease and the prevention of relapse. This immunologic effect is referred to as the graft-versus-myeloma (GVM) effect. This immune reaction, however, has the potential to attack not only the myeloma cells, but also the normal tissues in the recipient, which results in graft-versus-host disease (GVHD). In the past, the high transplant-related mortality (40%–50%) after allogeneic transplantation in MM due to treatment-related toxicity, including GVHD and infectious complications, precluded clinical exploitation of the potential benefit of GVM.

**Trial design**

After a traditional autologous transplant to cytoreduce patients with multiple myeloma, CALGB 100001 employs a non-myeloablative conditioning regimen to establish donor cell engraftment and microchimerism, thereby avoiding the morbidity and mortality associated with conventional high-dose ablative therapy and allogeneic transplant. Once donor cell engraftment has been achieved, adoptive immunotherapy with donor lymphocyte infusions (DLI) may be used, as needed, to induce GVM activity. Data have demonstrated that patients with MM who relapsed after an allogeneic bone marrow transplant can achieve complete and partial responses after treatment with DLI.

The primary objective of this phase II study is to assess the safety and feasibility of coupling an autologous HST with a subsequent allogeneic HST, and to determine whether GVM induced by DLI can improve disease-free survival outcomes. Ultimately, the hope is that this treatment strategy can cure some of these high risk patients.

**Eligibility**

Eligible patients will include those with active multiple myeloma requiring treatment (Durie-Salmon stage ≥1), who have not had more than 12 months of prior alkylating agent therapy, not more than 18 months of all prior therapy, and no more than 1 prior progression after initial therapy. Prior chemotherapy, radiotherapy, and surgery must have been completed 4 or more weeks before registration. Patients must have an HLA identical sibling donor, and patients must be 65 years or younger with an ECOG PS 0-1. DLCO must be >40% predicted with no symptomatic pulmonary disease, and LVEF by MUGA must be ≥30%. Patients must have neither uncontrolled diabetes mellitus nor active serious infection. Patients with HIV are excluded due to significantly higher risk of toxicity from intensive immunosuppressive therapy employed in the study.

**Treatment plan**

Patients will undergo stem cell mobilization with cyclophosphamide. High-dose melphalan 200 mg/m² will be used as the preparative regimen for autologous transplant. Approximately 2-4 months later, a non-myeloablative allogeneic transplant will be performed. The preparative regimen will consist of fludarabine and cyclophosphamide. Tacrolimus and low-dose methotrexate will be administered for GVHD prophylaxis. Patients with progressive or stable disease while off immunosuppressive therapy for a minimum of 30 days and who show no signs of active GVHD are eligible to receive DLI from the original HLA-identical sibling donor. The sibling donor may agree to undergo leukapheresis for lymphocyte collection, or, alternatively, cells from the initial stem cell collection that have been stored frozen may be used for DLI.

The study chair is Ken Anderson, MD, Dana Farber Cancer Institute, e-mail: kenneth_anderson@dfci.harvard.edu. The study co-chair, Philip McCarthy, MD, Roswell Park Cancer Institute, should be contacted with questions at e-mail: philip.mccarthy@roswellpark.org.
In 1956, I was 4 years old. The world was changing and, had I been interested in anything other than my dolls or pester ing my younger brother, I might have witnessed a number of milestones in American history:

- Ed Sullivan introduced TV viewers to Elvis Presley – shocking reluctant parents into the realization that rock and roll was, indeed, here to stay.
- Dwight D. Eisenhower was re-elected to a second term as president.
- Julie Andrews and Rex Harrison were starring on Broadway in the smash hit My Fair Lady.
- People were flocking to theaters to see The King and I, Giant, and the classic thriller Invasion of the Body Snatchers.
- Jackie Robinson retired from baseball.
- The New York Yankees beat the Brooklyn Dodgers in the World Series.
- The Acute Leukemia Group B was established by the clinical studies panel of the Cancer Chemotherapy National Service Center. (It was to be renamed the Cancer and Leukemia Group B in 1976.)

Nursing in the mid 1950s was changing too. The post World War II era ushered in a time when patient care was moving from a home-based setting to the hospital and the construction of new hospitals resulted in a higher demand for nurses. With inevitable critical shortages, however, hospitals began to utilize nurse aides and other ancillary staff. Many nurses, therefore, began to transition away from the role of care providers to that of care supervisors and administrators – and researchers.

The American Nurses Foundation was founded in 1955, and one of its goals was to advance the nursing profession through nursing research. Many nursing questions have been answered through research in the past 50 years, but in the early days of cooperative groups, nurses primarily functioned as assistants to the investigators. They played a minor, albeit important, behind-the-scenes role in the management of protocols.

In the ensuing decades, nurses began to play a much broader role in protocol development and management. Eventually CALGB added an Oncology Nursing Committee (ONC) to the modality committee roster. Initially, the committee focused on providing educational programs and networking to support nurses in their evolving roles as members of the research team. As the science of the profession advanced, the CALGB medical and nursing leadership began to support the efforts of member nurses to identify research issues, develop concepts, and conduct their own studies.

Today CALGB has 500 nurse members and ONC continues to encourage and support nurses and nursing research. The committee’s mission statement, which is posted on the nurses’ page of the CALGB web site states:

The Oncology Nursing Committee has and will continue to be a valuable resource within CALGB, making significant contributions to cancer research through attaining the following objectives:

1. Education of nurses, patients, and other health care professionals regarding issues relevant to CALGB trials
2. Integration of nursing care and science into CALGB studies
3. Advancement of oncology nursing science through the development of CALGB nursing studies in the areas of education and support, symptom management, and survivorship

To this end, the Oncology Nursing Committee was restructured in recent years and now includes several nurse researchers who assist nurse investigators with projects. Currently, ONC supports nurses as either principal investigators or co-investigators on 6 nursing-specific protocols that are in various stages of development. The committee sponsored a Cooperative Group Nursing Summit to discuss the state of the science of nursing research, an event that was attended by representatives from 8 other cooperative groups. Committee members also serve as liaisons to the disease committees and several of the modality committees, providing valuable insight into nursing issues that affect patient care, protocol management, and the ultimate success of the studies. Unfortunately, CALGB can only fiscally support a limited number of nurses to serve on the committee, but ONC leadership encourages the general nursing membership to participate in committee projects that enhance the roles of nurses in CALGB, and promote the health and well-being of our patients through all stages of their disease course.

Monumental changes have occurred in the last 50 years and are continuing to occur. How will cancer research and treatment evolve by 2056? Will cancer even be the acute process that it is today, or will it become a chronic condition that can be easily managed? As science continues to advance, nurses, undoubtedly, will continue to actively participate and add their unique contribution to oncology research.

Barbara Kleiber, R.N.
CALGB 1956 - 2006: 50 YEARS OF HISTORY

1956 - Acute Leukemia Group B established

1957 - Study of chemotherapy alone or chemotherapy plus irradiation in poor risk stages I & II Hodgkin’s disease patients started

1956 - Adult Solid Tumor Committee divided into several disease committees (Breast, GI, Respiratory and Other Tumors)

1957 - Chemotherapy Committee formed

1958 - First study published in Blood

1959 - Dr. Bernard Gehan became Group Statistician

1960 - Certain adult solid tumors first studied

1961 - Gastric cancer was first investigated

1962 - Study of respiratory cancer began

1963 - Dr. Paul Shaha became Group Statistician

1963 - Dr. Ted Fried became the first Group Chair

1964 - Dr. Oliver Goldblatt became Group Statistician

1966 - Breast cancer first studied

1967 - Data Management Committee was renamed CMA Committee

1967 - Radiation Oncology Committee was formed

1970 - New England Journal of Medicine published an article from Protocol 6601

1971 - Dr. Edwin Holland became the first Group Chair

1972 - Cancer and Leukemia Group B (CALGB) name changed to the Cancer and Leukemia Group B (CALGB)

1973 - Radiation Oncology Committee was formed

1975 - Dr. James Holland became the Group Chair

1975 - Dr. James Holland on national panel of cancer consultants and helped produce “little green book” outlining what could be done in cancer research format

1976 - Data Management Committee was renamed CMA Committee

1976 - Radiation Oncology Committee was formed

1978 - Constitution submitted and adopted

1981 - Central Office moved to the Dana Farber Cancer Institute

1981 - Statistical Center moved to the Harvard School of Public Health

1981 - Frontier Science and Technology Research Foundation (FSTRF) in Amherst, NY was chosen as the data processing center for the group

1984 - Central Office moved to Dana Farber Medical School

1986 - CALGB became a research base for 7 CCCPs

1990 - Dr. H. Ross McLeod became the Group Chair

1991 - Dr. Stephen George became the Group Chair

1992 - Dr. Ronald Schiller became the Group Chair

1996 - CALGB web site initiated

1999 - CALGB pathology coordinating office opened at The Ohio State University

2001 - CALGB newsletter began
**JUNIOR FACULTY RESEARCH AWARD 2006**

Hyung L Kim, MD  
*Roswell Park Cancer Institute*  
Gene Profiling for Renal Cell Carcinoma

Mark Kirstein, PharmD  
*University of Minnesota*  
Optimizing Treatment with Gemecitabine and Cap-Dependent Translation Blockade

**CALGB ONCOLOGY FELLOW RESEARCH AWARD 2006**

Nicholas Choong, MD  
*University of Chicago*  
The Role of Eph A2 in Lung Cancer

Rebecca Petersen, MD  
*Duke University Medical Center*  
Gene Expression Signatures of Oncogenic Pathway Deregulation in Non-Small Cell Lung Cancer

Shannon Smiley, MD  
*Roswell Park Cancer Institute*  
The Molecular Mechanism of Low Molecular Weight Heparin (LMWH) Inhibition of Tumor Growth
Preparations are underway for the 2006 CALGB CRA Orientation, to be held November 3-4, 2006, in Raleigh, NC. Later this summer, all Lead Clinical Research Associates and Principal Investigators will receive invitations for their new CRAs. For purposes of this orientation, a new CRA is one who has been employed as a CALGB CRA for one year or less, and who devotes a minimum of 25% of their time to CALGB-related work.

All program information will be posted at: http://www.calgb.org/Private/COOP_Groups/CALGB/meetings/meeting_documents/cra_orientation/cra_orientation.php

To access this site, click on the Member Site tab of the CALGB web site at www.calgb.org. You will need to enter your CALGB User Name and Password to access the Member Site. Click on the “Meetings” tab and you will see a link to 2006 CRA Orientation. At this site, you will be able to access the agenda, the registration form, travel information, and other helpful information to be posted during the summer.

Registrations must be received by October 6, 2006. All registrations must be authorized by either the Lead CRA or PI at the Main or At-large member institution in order to be accepted.

The pre-requisite for attending the CRA Orientation is to view the New Member Orientation online, also located under the Meetings tab, under Meeting Presentations, 2005 June Group Meeting Presentations on the CALGB Member Site.

We look forward to meeting new clinical research associates in November.
Return of NCI-supplied Investigational Agents

The NCI Pharmaceutical Management Branch (PMB) has clarified the procedures for return of clinical supplies of NCI-supplied investigational agents that were previously dispensed as follows.

Question: What should I do when patients return clinical supplies of NCI-supplied investigational agents that were previously dispensed? Should I return them to the NCI Clinical Repository?

Answer: If the protocol is open label, destroy the returned clinical supplies locally according to your institution's local destruction policy. You can make a note in the patient's chart and/or on the back of the Drug Accountability Record Form if you want to track the return.

If the protocol is blinded, dispensed clinical supplies (opened and unopened kits, boxes, or bottles) returned by the patient should be documented in the patient-specific NCI Investigational Agent Accountability Record (i.e., logged in as 'returned by patient') and destroyed on site in accordance with institutional policy (i.e., logged out as 'destroyed on site').

Undispensed clinical supplies (kits, boxes, or bottles) should be documented in the NCI Investigational Agent Accountability Record (i.e., logged out as 'returned to NCI') and returned to the NCI Clinical Repository using the NCI Return Drug List available on the CTEP home page (http://ctep.cancer.gov) or by calling the PMB at (301) 496-5725. If blinded, patient-specific supplies are being returned, the assigned patient ID number and the patient initials should be entered in the "Lot Number" field. A separate line item is required for each patient ID and for each agent, but multiple bottles of the same agent for the same patient should be entered as a single line item.

In summary, when a patient returns NCI-supplied investigational agent

- For open label studies: All dispensed/returned agent is destroyed on site.
- For blinded studies: All dispensed/returned agent is recorded on the patient-specific DARF and destroyed on site.

Patients should return all dispensed, unused agent to the dispensing pharmacy.

Questions regarding return/destruction of clinical supplies can be directed to the Pharmaceutical Management Branch (PMB), CTEP, NCI by calling (301) 496-5725 Monday through Friday from 8:30 am to 4:30 pm Eastern Time or by sending an e-mail to PMBAfter Hours@mail.nih.gov at any time.

Institutions should ensure that their pharmacy staff are informed of this clarification. Appropriate dispensing, return, destruction and accountability of NCI-supplied investigational agents will be reviewed during CALGB institutional audits.

Source: Pharmaceutical Management Branch
PROTOCOL NEWS

GI COMMITTEE
CLOSED
80303 - Gem +/- bevacizumab in pts w/advanced pancreatic ca Study Chair: H. Kindler

CTSU - S0205: Ph III opn-lbl gem + cetux vs. gem as 1st line tx for adv pan ca Study Chair: E. O’Reilly

LEUKEMIA CORRELATIVE SCIENCES COMMITTEE
OPENED
20502 - LTB: Molecular genetic studies of AML with normal cytogenetics Study Chair: G. Marcucci

LYMPHOMA COMMITTEE
CLOSED
50205 - NHL: Rituxan and ASCT for B cell diffuse large cell lymph(E2499) Study Chair: C. Linker

RESPIRATORY COMMITTEE
CLOSED
30306 - Cis, CPT-11 & bev for untreated ESCLC Study Chair: N. Ready

TRANSPLANT COMMITTEE
OPENED
100102 - Nonmyelo transplant w/haplotype mismatched CD34 cells Study Chair: S. Farag

CLOSED
100002 - Min ablation & cellular immune tx in hem malignancies Study Chair: A. Bashey
109901: Minimal ablation & cellular immune therapy in CLL & NHL Study Chair: T. Shea

SUPPORT ACKNOWLEDGEMENTS

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Abbott Laboratories
Abraxis BioScience
Amgen, Inc.
AstraZeneca
Berlex Laboratories
BioNumerik
Breast Cancer Research Foundation
Bristol-Myers Squibb Oncology
Eli Lilly
Genentech BioOncology
GlaxoSmithKline
Health Learning Systems
Millennium Pharmaceuticals
Novartis Oncology
Ortho Biotech
OSI Pharmaceuticals
PDL BioPharma, Inc.
Pfizer, Inc.
Pharmion Corporation
Roche Pharmaceuticals
Sanofi-Aventis
Schering Plough
SuperGen, Inc.

Thank you for supporting CALGB.
Your generous gift will help us and will bring you closer to the vacation of a lifetime. In addition to the satisfaction you’ll get from knowing your gift made a difference, you’ll earn 500 miles with every $100 you give. Include your AAdvantage number in the space provided and we’ll take care of the rest.*

The Cancer and Leukemia Group B Foundation is a non-profit, tax-exempt foundation formed for the primary purpose of aiding the Cancer and Leukemia Group B, a group of 29 of the most prestigious medical centers in the U.S. and more than 250 affiliated institutions collaborating in large-scale clinical trials. The CALGB Foundation supports the clinical trials and laboratory research of the CALGB, as well as efforts to educate the medical community on methods of cancer diagnosis, treatment, and prevention.

Examples of recent initiatives supported by the CALGB Foundation:
• New chemotherapy treatments for breast, prostate, lung, and colorectal cancer.
• New surgical techniques for breast and colon cancer.
• Genetic studies of breast cancer risk.
• Molecular determinants of response to therapy for breast, colorectal and lung cancer as well as leukemia.
• Improving the quality of life of cancer patients and their caregivers.

Your contribution will support continuing efforts to find ways to prevent and cure many types of cancer, including leukemia, lymphoma, melanoma, and cancers of the breast, prostate, lung, and GI tract.

Gifts to the Foundation may be designated according to your wishes, and are tax-deductible to the extent permitted by law.

Please make checks payable to the Cancer and Leukemia Group B Foundation.

Thank you for your support.

Enclosed is my our contribution of $___________ to support the research of the Cancer and Leukemia Group B.
• In Memory of ____________________________
• In Honor of ____________________________
• Occasion ________________________________
• Please use my gift where needs are greatest
• Please use my gift for ____________________

Please send me information on how to include the Cancer and Leukemia Group B Foundation in my will or charitable trust.

American Airlines AAdvantage No. ____________________________

For information about major gift opportunities, for assistance regarding gifts of securities, gifts of appreciated property, or gifts-in-kind, please contact:

Mary A. Sherrell, M.A.
Treasurer, CALGB Foundation
(773) 702-9856 phone, (312) 345-0117 fax
email: msherrel@uchicago.edu

Please send my receipt to:

Name ____________________________
Address __________________________
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Name ____________________________
Address __________________________
City __________ State _____ Zip ________

* Gifts of $1000 or more earn 10 miles per dollar donated. Gifts of $100-$999 earn 5 miles per dollar donated. Gifts up to $99 earn 1 mile per dollar donated.