# Alliance for Clinical Trials in Oncology Fall 2013 Volume 3, No. 8 info@allianceNCTN.org

### **SPOTLIGHT ON TRIALS**

# Mesothelioma Trial Evaluates Maintenance Therapy

CALGB 30901 Randomized Phase II Study of Maintenance Pemetrexed versus Observation for Patients with Malignant Pleural Mesothelioma without Progression after First-Line Chemotherapy

Malignant pleural mesothelioma (or MPM) is an uncommon tumor afflicting up to 3,000 patients annually in the United States. Most patients present with advanced disease, and treatment is limited to palliative chemotherapy. Only recently has the first chemotherapy regimen for mesothelioma, pemetrexed and cisplatin, been approved by the U.S. Food and Drug Administration (FDA). In a randomized phase III trial, treatment with pemetrexed and cisplatin was better than cisplatin alone with regard to response rates (41 percent versus 17 percent), time to progression (six months versus four months), and overall survival (12 months) versus nine months).1 The combination of pemetrexed and carboplatin is a reasonable alternative for patients who cannot tolerate cisplatin, based on results from large phase II trials and the expanded access experience showing comparable response rates and survival times.<sup>2-4</sup>

The optimal duration of first-line chemotherapy has been a long-standing question in the treatment of many solid tumors. Many investigators have argued that if a patient's cancer is controlled and the toxicities of the treatment are manageable, then discontinuation of the therapy will only result in earlier tumor regrowth. On the other hand, solid tumors ultimately reach a response plateau at which time additional chemotherapy does not result in further tumor shrinkage. Furthermore, continuation of chemotherapy for prolonged periods results in cumulative toxicities.

The experience in non-small cell lung cancer highlights this issue with several clinical trials designed to address the optimal duration of chemotherapy.<sup>5-7</sup> However, current treatment guidelines for advanced non-small cell lung cancer recommend four to six cycles of first-line platinum-based chemotherapy and then monitoring for progression.

The primary objective of CALGB 30901 is to determine if maintenance therapy with pemetrexed improves progression-free survival in patients with MPM who have at least stable disease after completion of first-line therapy with pemetrexed plus cisplatin or carboplatin. In addition, the study aims to determine if maintenance therapy with pemetrexed improves overall survival; evaluate frequency of responses to maintenance therapy with pemetrexed; and assess toxicity of maintenance therapy with pemetrexed.

In this study, patients with MPM who have a response or stable disease after four cycles of pemetrexed and cisplatin or carboplatin will be randomized to continued treatment with pemetrexed alone or to observation. At the time of progression, the choice of chemotherapy will be at the discretion of the treating physician. Many patients in the observation arm are likely to receive pemetrexed again which will help address the question regarding immediate versus delayed therapy.

Eligible patients must have histologically documented malignant pleural mesothelioma, epithelial, sarcomatoid or mixed type, not amenable to surgical resection. Patients with complete response, partial response, or stable disease following four cycles of first-line chemotherapy with pemetrexed and either cisplatin or carboplatin are eligible. Patients who have received more or fewer than four cycles are not eligible. At least three weeks, and no more than six weeks, must have elapsed from the completion of four cycles of therapy to registration. Patients who also have had prior surgical treatment or radiation therapy are eligible.

Refer to the study protocol (CALGB 30901), which can be found on the CTSU menu (ctsu.org) for complete information on the trial design, treatment plan and patient eligibility. The Study Chair is Arkadiusz Z. Dudek M.D., Ph.D., University of Minnesota, e-mail: dudek002@umn.edu.

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### Breast Cancer Trial to Assess Surgical, Quality of Life Outcomes of Preoperative MRI

Alliance A011104/ACRIN 6694 Effect of Preoperative Breast MRI on Surgical Outcomes, Costs and Quality of Life of Women with Breast Cancer

Surgical planning and local-regional treatment of breast cancer relies on adequate assessment of the disease, including the size of the primary tumor and the presence or absence of multiple tumor foci, either within the same quadrant (multifocality) or in different quadrants of the breast (multicentricity).

Macroscopic multifocal or multicentric disease is considered to result in higher rates of local recurrence, and is generally, a contraindication to breast conservation.<sup>1,2</sup> Frequency estimates of multifocality and multicentricity in breast cancer vary widely, and depending on the criteria used, can range from 7 to 63 percent.<sup>3-6</sup> With the concern of high local failure rates, women with multifocal or multicentric disease (at presentation) may not be ideal candidates for breast conservation. Preoperative identification of these patients is important for appropriate surgical planning and treatment.

As a diagnostic procedure in breast cancer patients, magnetic resonance imaging (or MRI) of the breast has been shown to have high sensitivity.<sup>7.9</sup> MRI has proven helpful for breast conservation in patients with unusual presentations such as nipple discharge and axillary node metastases.<sup>10-11</sup> MRI has also shown efficacy over conventional surveillance methods for patients at high risk of developing breast cancer.<sup>12-13</sup> However, for most patients with breast cancer, the role of MRI remains controversial.

Several small studies have described changes in the treatment of their patient cohorts based on MRI findings.<sup>9, 14-17</sup> Recently, data from a large multicenter trial of MRI in patients with breast cancer demonstrated a nearly 10 percent increase in detection of multicentric/ multifocal disease in the index breast.<sup>18</sup> Furthermore, MRI also detected clinically and mammographically occult cancer in the contralateral breast in 3.1 percent of patients.<sup>19</sup> Such findings have led to changes in surgical management of breast cancer patients in nearly 20 percent of women who undergo preoperative MRI with most cases converting from breast conserving therapy to mastectomy.<sup>17</sup>

Despite the enhanced sensitivity of breast MRI, its clinical application for preoperative surgical staging of breast cancer patients has remained controversial. In part, this is due to high false positive rates that lead to additional biopsy procedures.<sup>16,20-21</sup> However, the primary reason for the continued debate regarding the utility of preoperative breast MRI stems from the lack of data demonstrating an oncologic benefit. Specifically, the biologic and thus clinical significance of additional foci of carcinoma detected only by MR imaging is unknown. Strikingly, the frequency of occult disease detected by MRI is two- to three-fold higher than the rates of local regional recurrence (LRR) among women who undergo breast-conserving therapy (BCT) without the benefit of preoperative breast MRI. Data from many clinical trials suggest that local recurrence following breast-conserving surgery and adjuvant systemic therapy is low, less than 10 percent at 10 years. In contrast, the results of MRI continued on next page

## Spotlight on Trials

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based studies demonstrate 15 to 20 percent conversion rate from BCT to mastectomy on the basis of greater extent of disease or additional foci detected by MRI.

At this point, it has become even more imperative to determine whether preoperative MRI improves clinical outcomes. Alliance A011104 is a phase III trial that will assess MRI and mammography to see how well it works compared to mammography alone in patients with stage I-II breast cancer. The primary objective of this study is to compare the rates of local-regional recurrence (LRR) following attempted breast conserving therapy in a cohort of women with triple negative or HER-2 amplified breast cancer randomized to preoperative staging with mammography (control arm) or mammography plus breast MRI (MRI arm).

A key component of this trial is the collaboration between the Alliance and the American College of Radiology Imaging Network (ACRIN), which is now part of ECOG-ACRIN. This collaboration will help ensure quality control of the MRI performed in the study. Additionally, there are currently no standards for how MRI findings should be clinically interpreted and implemented. Hence, a major emphasis of this effort will be to establish standards for structuring the image report data and creating guidelines for subsequent patient intervention.

This study will also include three substudies that will focus on patient-reported quality of life parameters and costs of breast cancer treatment among patients participating on both arms of the study, and translational research to predict LRR and determine if molecular changes correlate with outcome.

Refer to the study protocol (Alliance A011104), which can be found on the CTSU menu (ctsu.org) for complete information on the trial design, treatment plan and patient eligibility. Please note that this study is currently in pre-activation status and is not yet open to patient enrollment. It is anticipated to open in late-September 2013. The Alliance Study Chair is Isabelle Bedrosian, MD, of MD Anderson Cancer Center, e-mail: ibedrosian@ mdanderson.org, and the ECOG-ACRIN Study Chair is Christopher E. Comstock, MD, of Memorial Sloan-Kettering Cancer Center, e-mail: comstocc@mskcc.org.

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# A Closer Look at Who's Who in the Alliance

This article is the second in a four-part, monthly series that will feature an overview of the Alliance committee leadership, along with short biographies of leaders within each area of the Alliance. This month's series will introduce chairs of the Alliance modality committees.

Who's Who Alliance Modality Committees

#### **Clinical Research Professionals Committee Chair**



Kandie Dempsey, MS, RN, OCN, CCRP, Director, Cancer Research/Community Clinical Oncology Program (CCOP) at the Christiana Care Health System. Ms. Dempsey's career in oncology and hematology has spanned over 26 years, working at Christiana Care Health Services, Inc. She

Dempsey

initially served as an oncology nurse providing direct patient care for nearly 11 years, and has spent the past 15 years as a research administrator providing oversight to one of the highest accruing CCOPs in the nation.

#### **Experimental Therapeutics Committee Co-Chairs**



**Charles Erlichman, MD,** Professor of Oncology in the Mayo Clinic College of Medicine; Chairman, Department of Oncology and Deputy Director of Clinical Affairs at the Mayo Clinic. Dr. Erlichman's research interests include the study of novel therapeutics in the laboratory and trans

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lating data or results into clinical trials. His research has focused on the development of novel therapies in the treatment of cancer with a particular emphasis on malignancies of the gastrointestinal tract.



Schwartz

Gary K. Schwartz, MD, Professor of Medicine at Weill Cornell Medical College and Chief, Melanoma and Sarcoma Service at the Memorial Sloan-Kettering Cancer Center. Dr. Schwartz also directs the Laboratory of New Drug Development, which focuses on the identification of new targeted agents for cancer therapy, especially in the treatment of sarcoma and melanoma. These agents are not disease specific and hold promise in the treatment of all solid-tumor malignancies. These laboratory studies allow for a bridge between the laboratory and the clinic, and many of the drugs that originated in the lab are now being evaluated in clinical trials.

#### **Oncology Nursing Committee Chair**



Lisa A. Kottschade, RN, MSN, CNP, Nurse Practitioner, Melanoma and Symptom Management, Division of Medical Oncology and Assistant Professor of Oncology at the Mayo Clinic. Ms. Kottschade's primarily interest is in biomarkers as predictors of outcomes and response of patients

Kottschade

undergoing both adjuvant and systemic therapy for the treatment of malignant melanoma. She's currently investigating different methods to detect circulating BRAF in peripheral blood as a potential biomarker for monitoring patients on BRAF/inhibitor therapy, as well as a biomarker of recurrence.

#### Patient Advocate Committee Chair



**Patrick Gavin, RPh**, Founder of Patrick Gavin RPh Consulting LLC. Mr. Gavin, a registered pharmacist licensed in four states, currently focuses on his work as a patient advocate and a cancer research advocate. He is a fiveyear plus cancer survivor of both stage IV pharyngeal cancer and

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malignant melanoma. He credits the cure for his stage IV cancer "the grace of God and the fact that I participated in a cancer clinical trial."

#### Radiation Oncology Committee Chair

Jeffrey A. Bogart, MD, Professor and Chair of Radiation Oncology, Professor of Urology, Medical continued on next page

# Alliance Members on the Move



DeLuca

**Jo-Ellen DeLuca** was honored with the Caring For The Carolinas Award for her service and commitment to the community, and most notably for her support of patients with cancer. The monthly award, presented by CBS affiliate WSPA7 in Spartanburg, South Carolina, is a salute to special volunteers and

their service to the community that make a lasting impression on others. DeLuca is the recipient for the month of August. She works closely with patients affected by the disease and is actively involved in cancer research. DeLuca is Founding Executive Director of Colon Cancer Solutions and a member of the Alliance Patient Advocate Committee.



Perlmutter

Jane Perlmutter, PhD, has recently co-authored "Cancer Research Advocacy: Past, Present, Future," a paper that was published in the August 1, 2013 issue of Cancer Research: The Journal of Cancer Research. The paper presents a brief history of cancer advocacy while discussing ways in which advocates become

involved in cancer research and the principles of successful research advocacy. Dr. Perlmutter is a member of the Alliance Patient Advocate Committee. Her advocacy work also includes membership with the Clinical Trials Transformation Initiative (CTTI), Clinical Trials Summit's Informed Consent Steering Committee, Translational Breast Cancer Research Consortium (TBCRC), NCI Breast Cancer Local Regional Task Force (BOLD) and as a five-year faculty member at the AACR/ASCO Methods in Clinical Research Workshop.

### Spotlight on Leadership

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Bogart

Director of Radiation Oncology; Director of Prostate Cancer Program and Medical Director of University Radiation Oncology at the State University of New York Upstate Medical University Medical Center. Dr. Bogart's clinical interests include lung cancer, prostate cancer including Intensity Modulated Radiation Therapy (IMRT) and brachytherapy,

breast cancer, lymphoma and pediatric oncology. His research interests include lung and prostate cancer and clinical trials.

#### **Transplant Committee Chair**



Devine

Steven M. Devine, MD, Professor of Internal Medicine and Program Director, Blood and Marrow Transplant Program at the Ohio State University Wexner Medical Center. Dr. Devine's clinical and research interests include acute and chronic leukemia, non-Hodgkin's lymphoma,

myeloma, autologous and allogenic stem cell transplantation and mobilization of stem cells.

Next month, this series will feature chairs of the Alliance odministrative committees, including Audit, Conflict of Interest, Constitution and Bylaws, Data and Safety Montioring Board, Ethics, Institutional Performance Evaluation, Membership, Pharmacy and Publications.

# NIH Calls for Applicants for Trials on Multiple Chronic Conditions

NIH Health Care Systems Research Collaboratory - Demonstration Projects for Pragmatic Clinical Trials Focusing on Multiple Chronic Conditions (UH2/UH3)(RFA-RM-13-012)

The National Institutes of Health (NIH) has released a new Request for Applications (RFA) focusing on pragmatic clinical trials on multiple chronic conditions. The application deadline is December 2, 2013. Applications are for efficient, large-scale pragmatic clinical trials that must be conducted across two or more health care systems (HCS) and must be conducted as part of the NIH HCS Research Collaboratory supported through the NIH Common Fund.

Awards made through this funding opportunity will initially support a one-year milestone-driven planning phase (UH2), with possible rapid transition to the implementation phase (UH3) for a pragmatic trial Demonstration Project. UH3s will be awarded after administrative review of eligible UH2s that have met the scientific milestone and feasibility requirements necessary for the UH3 implementation phase, depending on the availability of funds. The UH2/UH3 application must be submitted as a single application.

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For more information about how to apply, visit the NIH website at http://grants.nih.gov/grants/guide/rfa-files/RFA-RM-13-012.html.

# **ACS Offers New Clinical Trials Course**

The American College of Surgeons' Surgical Research Committee offers its 2013 Clinical Trials Methods Course at ACS office and headquarters and Hyatt Chicago Magnificent Mile Hotel in Chicago, IL, December 6-10.

The course provides a five-day, intensive course based on four successfully conducted and published clinical trials that are used to teach the methodology of design and implementation of a controlled clinical trial. It is recommended for surgeons who plan to engage in clinical research at a leadership level. The course is designed to provide surgical investigators with the concepts necessary to: develop a protocol for a clinical trial that is fundable by a peer-reviewed agency; understand the statistical concepts necessary to design a clinical trial; understand the design and implementation issues unique to performing surgical trials; and foster collaborative efforts necessary to conduct a clinical trial

Expert faculty will use a combination of didactic lectures and hands-on approaches, such as break-out sessions, to apply concepts learned throughout the course. Key topics will include the development of concepts and skills in the design, implementation, and analysis of randomized clinical trials' funding mechanisms and budget development; outcomes (medical, patient-centered); and dissemination of results through publications. Small teams will also work closely with experienced surgeons and biostatisticians to develop group proposals for clinical trial.

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For more information about the course, contact Carla Manosalvas, Administrator, Committees and Educational Programs, Division of Research and Optimal Patient Care - Continuous Quality Improvement, at CTMCourse@facs.org or (312)202-5319.

### Position Opens on Oncology Nursing Committee

The Alliance Oncology Nursing Committee (A-ONC), chaired by Lisa A. Kottschade RN, MSN, CNP, announces the availability of one position on the A-ONC. The positions is for a Surgical Liaison. A job description for the position as well as instructions on how to apply are listed below.

#### A-ONC Surgical Liaison Job Description

Responsibilities of the A-ONC Surgical Liaison include but are not limited to:

- 1. Mandatory attendance at all committee and group meetings. (Two meetings/year and participation in quarterly teleconferences.)
- 2. Review of all new protocols/forms/amendments for the Alliance American College of Surgeons Clinical Research Program (ACS CRP), act as a resource for other Alliance nurses regarding protocol execution within surgically-related protocols (available by phone and/or e-mail).
- 3. Collaboration across committees on projects, publications, educational initiatives, research, etc.
- 4. Provision of nursing perspective and expertise regarding study design and methods; as well as patient education.
- 5. Serving as a principal and/or co-investigator on Alliance trials.
- 6. Publication/dissemination of Alliance-related research findings.
- 7. Active participation at surgical meetings by tumor group for protocol development; assist in the education of other nurses and CRCs and others of the multidisciplinary team.

Minimum requirements for position include:

- 1. Registered Nurse
- 2. Employment at an Alliance institution
- 3. Demonstrated commitment to the Alliance (letter of interest)
- 4. Minimum of one-year experience working with research protocols within the cooperative group setting
- 5. Main employer will allow time to fulfill position requirements as well as financial support (documented by letter or e-mail)
  - a. Anticipated time commitment (two to four hours/month)
  - b. Two to four days away with each Alliance meeting (two meetings/year)
- 6. Experience with surgical oncology preferred

edu) no later than October 15, 2013.

How to Apply: Those interested in A-ONC membership should submit a CV/resume and a one-page letter of interest by October 15, 2013. Decisions regarding A-ONC membership will be made by October 25, 2013. Specifically, your letter should address the following points:

- 1. Please provide a letter of financial support from your PI or supervisor, or indicate other sources.
- 2. Your area of expertise (clinical, education, administrative, research). Please be specific. For example, if you possess clinical expertise, describe your specific disease or modality-focus (breast cancer, prevention, symptom control etc.);
- 3. Explain what contributions you will make to the committee and
- 4. Provide evidence that your current supervisor will support your participation (an e-mail communication from your supervisor addressed to Lisa Kottschade is satisfactory).

All application materials should be sent to Lisa Kottschade RN, MSN, CNP (Kottschade.lisa@mayo.

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# 2013 Meeting Abstract Submission Deadlines

All draft abstracts from Alliance for Clinical Trials in Oncology (including all three legacy groups: ACOSOG, CALGB and NCCTG) must be submitted to the Alliance by the date indicated in the table below. Please submit by e-mail to **Publications@AllianceNCTN.org**. This deadline is firm, and is required to ensure time for central review of content, as well as review of author lists. Adherence to the deadline will allow sufficient time for the each lead author to submit to the association.

All Alliance abstracts must follow this process. Independent submission of work related to the Alliance without this proper review is not permitted.

Meeting/Association	Deadline to Submit to the Alliance ( <u>Publications@AllianceNCTN.org</u> )	Deadline to Submit to Meeting/Association	Meeting Date
ASCO Genitourinary (GU) Cancers Symposium	Sept 17, 2013	Oct 1, 2013	Jan 30-Feb 2, 2014
European Breast Cancer Conference (EBCC)	Oct 25, 2013	Nov 15, 2013	Mar 19-21, 2014
European Society for Radiotherapy & Oncology	Oct 25, 2013	Nov 14, 2013	Apr 4-8, 2014

### Abstract Requirements

An Alliance abstract should contain the following information:

### Study number(s)

- For an Alliance study X, the study number should appear in the title as "Alliance X"
- For a legacy study, the study number should appear in the title as "[Legacy Group Name] X (Alliance)" (e.g., "CALGB 40101 (Alliance)")
- If multiple studies are involved and the title cannot accommodate all of the numbers, the study numbers must appear in the text of the abstract.

#### Authors

- · The Alliance statistician must appear in the list of authors, usually as second author
- The list of authors should reflect study participation, including patient accrual and scientific input

### Affiliation and grant support

• Provide institutional affiliation for each author

### **Corresponding author**

• Provide the name and contact information of the corresponding author

### **Accepted Abstracts**

Send the publications coordinator the acceptance notification and final accepted abstract within one week after hearing from meeting or association.

**Questions:** If you have questions about the abstract review process, contact the publications coordinator at Publications@AllianceNCTN.org.

# **Reminder** Due Now: ACOSOG/CALGB/Alliance PSAs

This is a reminder that all CALGB Purchase Service Agreement (PSA) modifications, ACOSOG PSAs and PSA modifications, and Alliance PSAs are due. Your institution will not receive per-case payments (for 2013 and future accruals) for participation in NCI-sponsored studies until the appropriate agreement is received and executed. If your institution has not submitted the partially executed agreement(s), or to check the status of your agreements, please contact the appropriate e-mail below:

- For ACOSOG Purchase Services Agreement and modification questions BWHACOSOGContracts@partners.org
- For CALGB modification questions BWHCALGBContracts@partners.org
- For Alliance Purchase Services Agreement questions BWHAllianceContracts@partners.org

### **Future Meeting Dates**

### 2013 Group Meeting

November 7-10, 2013 Open to Alliance members

\*Breast Committee will meet Sunday, November 10

ACCRU Group Meeting will be held in conjunction with the Alliance Group Meeting. \*ACCRU Operations will meet on November 8, 4p-6p \*ACCRU Scientific Program will meet on November 9, 7a-10a Visit the ACCRU website at www.accru.org for more information.

### 2014 Committee Meetings

May 8-10, 2014 Open to Alliance committee members only

### **Group Meeting**

November 6-8, 2014 Open to Alliance members

All meetings will be held at the InterContinental Chicago O'Hare 5300 N. River Road, Rosemont, IL

For meeting and travel inquiries, contact Holly DeSimone e-mail: hdesimone@partners.org phone: 617-525-3022

For more information on the Alliance and updates about meetings, visit AllianceforClinicalTrialsinOncology.org

### **Call for Posters**

The Alliance will sponsor a **poster session** at the Group meeting held November 7-10, 2013. If you presented at a meeting between November 2012 and November 2013, please contact Mary Cate Zipprich (mzipprich@partners.org) to express your interest in participating in the poster session and to obtain more details.