

## SPOTLIGHT ON TRIALS

# Alliance Trials Evaluate Breast Conservation, Drug Efficacy

## ACOSOG Z11102 Impact of Breast Conservation Surgery on Surgical Outcomes and Cosmesis in Patients with Multiple Ipsilateral Breast Cancers (MIBC)

Of the more than 200,000 women newly diagnosed with breast cancer in the United States each year, studies have reported that between 14 and 51 percent will undergo preoperative MRI.<sup>1-4</sup> In an era of increasing breast MRI usage and improved radiographic imaging, the incidence of preoperatively identified multiple ipsilateral primary breast cancers (MIBC), including multicentric and multifocal breast cancer, is increasing.<sup>5-10</sup> The prevalence of MIBC reported in several studies ranges from 13 to 75 percent, and the presence of MIBC is one of many factors contributing to increases in mastectomy rates in the United States.<sup>11-16</sup>

Based on historic, retrospective studies from the late 1980s and early 1990s, most surgeons are reluctant to proceed with breast conservation therapy (BCT) for women with multicentric or multifocal breast cancer due to a perceived high risk of local recurrence. However, no scientific evidence supports performing mastectomies in MIBC patients.<sup>17-20</sup> The emotional impact of mastectomy on body image and quality of life is well documented.<sup>21-23</sup> The emotional benefit of breast conservation has driven surgeons in the U.S. and Europe to recommend breast conservation to more than 50 percent of women with a single, early

stage malignant focus for three decades.<sup>24-25</sup> BCT is associated with improved patient satisfaction and quality of life and has been shown to be cost effective.<sup>26-28</sup>

The present diagnosis of MIBC includes patients with two small foci of disease detected on screening digital mammogram and/or MRI compared to decades ago when MIBC was often detected as one or two palpable masses. Introduction of routine screening mammography and increased patient awareness has led to identification of breast cancer when tumors are smaller in size and early stage breast cancer has better survival compared to more advanced disease. Therefore, more MIBC patients are now eligible for BCT at time of diagnosis due to the smaller tumor size and disease burden, as compared to the 1980s and 1990s when most women with MIBC presented with larger, palpable tumors. Moreover, in women with newly diagnosed breast cancer who undergo MRI for surgical planning, additional malignant lesions that alter the surgical plan (multicentric/multifocal lesions) are detected in 8 to 27 percent of patients. These factors make it important for investigators to reassess the indications for BCT versus mastectomy in women with MIBC.

ACOSOG Z11102 is a study that will prospectively evaluate whether breast conservation is a safe surgical approach for patients with MIBC. It is

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a single-arm trial with a primary objective of assessing the local recurrence rate. Secondary objectives include evaluating the rate of conversion to mastectomy due to persistently positive margins, inability to satisfy radiation dose constraints due to volume of boost, or poor cosmesis. Additional objectives include patient perceptions of breast cosmesis, incidence of breast lymphedema, and adverse effects of surgery and radiation given larger or multiple lumpectomy cavities and boost areas.

This trial also provides a unique opportunity for the radiation oncology community to prospectively study the feasibility, efficacy and outcome of delivering boost treatment to more than one site in the breast. It incorporates specific target volume definitions and dosimetric constraints developed by the Radiation Therapy Oncology Group (RTOG), allowing for a detailed analysis of dosimetric parameters which may impact local control and cosmetic outcome. Data collected in this trial will not only determine whether breast conservation is possible in multicentric disease, but will also help to better define optimal dose-volume constraints useful for all future trials investigating breast radiotherapy.

Patient eligibility includes women older than 40 years old who have two or three foci of biopsy-proven breast cancer separated by greater than 3 cm of normal breast tissue on preoperative imaging. Foci must include at least one focus of invasive breast carcinoma with another focus of either invasive breast carcinoma or ductal carcinoma in situ (DCIS), and no more than two quadrants with biopsy-positive breast cancer. Ultrasound cannot be used to determine patient eligibility; eligibility to be determined by both bilateral mammogram and MRI.

About 230 women will take part in this study, which includes substudies that will evaluate the similarities and differences of multiple foci of disease within the breast.

The study protocol for ACOSOG Z11102 is available on the CTSU menu ([ctsu.org](http://ctsu.org)). Refer to the protocol for complete information about the trial design and patient eligibility.

The Study Co-Chairs are Judy C. Boughey, MD, of the Mayo Clinic, e-mail: [boughey.judy@mayo.edu](mailto:boughey.judy@mayo.edu); and Kari Rosenkranz, MD, of Dartmouth-Hitchcock Medical Center, e-mail: [kari.m.rosenkranz@hitchcock.org](mailto:kari.m.rosenkranz@hitchcock.org).

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## NCCTG N1174 Phase I/Comparative Randomized Phase II Trial of TRC105 plus Bevacizumab versus Bevacizumab in Bevacizumab-Naïve Patients with Recurrent Glioblastoma Multiforme

Malignant gliomas are the most common primary brain tumor in adults. Glioblastoma Multiforme (GBM) represents the most common glioma histology. GBM has a bleak prognosis despite the use of multimodality treatment with a median survival of 12 to 16 months.<sup>1-4</sup> There is an urgent need for better therapies. High-grade gliomas and glioblastoma in particular are characterized by intense angiogenesis, a key event in tumor growth and progression.<sup>5-6</sup> Tumor angiogenesis is mediated by small cell-signaling protein molecules (or cytokines) that promote endothelial migration and proliferation through activation of corresponding cytokine receptors on endothelial cells, with vascular endothelial growth factor (VEGF) playing a key role in GBM neoangiogenesis.

Bevacizumab has recently received U.S. Food and Drug Administration (FDA) accelerated approval for treatment of recurrent GBM on the basis of durable response rate.<sup>7</sup> Six month progression-free survival rates ranged from 29 percent to 43 percent with a median overall survival of 7.8 months to 9.2 months. The survival benefit is modest and novel approaches that result in a sustainable benefit are needed.<sup>8-9</sup>

CD105 (endoglin), a member of the transforming growth factor- $\beta$  (TGF- $\beta$ ) receptor superfamily, is expressed on angiogenic endothelial cells and in gliomas.<sup>10-12</sup> Its potential importance in glioma progression and angiogenesis is highlighted by the fact that CD105 is expressed in GBM-derived cancer stem cells, circulating endothelial cells, and endothelial progenitor cells.<sup>13-15</sup> TRC105 inhibits angiogenesis of proliferating endothelial cells by targeting an epitope on the extracellular domain of CD105. TRC105 acts to inhibit proliferation of endothelial cells and induce cell death via apoptosis. Finally, TRC105 can

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kill endothelial cells through antibody dependent cellular cytotoxicity.<sup>11</sup> By targeting a unique and important angiogenic pathway, TRC105 has the potential to complement existing anti-angiogenic therapies. CD105 is expressed at significantly higher levels following VEGF inhibition in animal models of human cancer. The increase in CD105 expression is likely an attempt to compensate for, or escape from, VEGF inhibition. This escape mechanism could be inhibited with a combination approach targeting both pathways simultaneously.

It is hypothesized that combining bevacizumab with the TRC105 antibody, blocking CD105 signaling, will increase the efficacy and duration of response to bevacizumab for patients with recurrent GBM and prevent the development of secondary resistance. This is also supported by preclinical data demonstrating that TRC105 and bevacizumab act together to inhibit VEGF-induced sprouting in vitro. Thus, this combination may be able to increase the response rate and extend overall survival in patients with glioblastoma.

NCCTG N1174 includes a phase I dose-escalation study and a randomized phase II study in patients with recurrent glioblastoma. The primary objective of the phase I study is to establish a maximum tolerated dose of TRC105 combined with bevacizumab in this patient population. The phase II study will assess the safety and adverse effects of TRC105 in combination with bevacizumab by randomizing patients into two groups. It will also determine the efficacy of TRC105 in combination with bevacizumab in recurrent glioblastoma as measured by progression-free survival and compare it with the efficacy of bevacizumab alone in this patient population. An addendum will announce the opening of the phase II study.

Patients who are eligible to participate in this study are those at least 18 years of age with recurrent high grade gliomas and any number of previous chemotherapy regimens for recurrent disease (for phase I). For the randomized phase II trial, patients should have recurrent glioblastoma with no more than one prior chemotherapy regimen for recurrent disease and be willing to provide mandatory blood and tissue samples.

About 18 people will take part in the phase I study, and 86 for the randomized phase II study. The phase I trial will also evaluate the pharmacokinetics of TRC105 immunogenicity of TRC105. Phase II correlative analysis will determine the relationship between tumor biomarkers, circulating biomarkers of vascular response and VEGF/VEGFR SNPs in predicting efficacy and/or toxicity of treatment. The utility of MRI imaging including apparent diffusion coefficient (ADC) and dynamic contrast enhanced (DCE) MRI as predictors of response to bevacizumab with or without TRC105 will also be assessed.

Study participation for the phase I trial is limited to only the following Alliance sites, Mayo Clinic Rochester, Mayo Clinic Florida, Dana-Farber Cancer Institute, University of Virginia, University of California-San Francisco and Memorial Sloan-Kettering Cancer Center. The phase II trial will be open to all Alliance sites.

The Study Co-Chairs are Evanthia Galanis, MD, of the Mayo Clinic, e-mail: galanis.evanthia@mayo.edu; and Patrick Y. Wen, MD, of the Dana-Farber Cancer Institute, e-mail: pwen@partners.org.

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## New Conflict of Interest Regulations in Effect

The U.S. Department of Health and Human Services issued a revision to regulation governing the federal Conflict of Interest (DHHS COI) policy which became effective August 24, 2012.

The revised DHHS COI policy will apply to the Alliance for Clinical Oncology clinical trials, and as a result, Alliance sites that receive federal funds from Brigham and Women's Hospital (Partners Healthcare, Inc.) will receive a modification to their Purchase Service Agreement (PSA).

Principal Investigators are encouraged to work closely with their institutions to ensure ongoing compliance with the DHHS COI policy. As a result, ACOSOG and CALGB institutions will be required to report financial conflict of interests that occur as a result of the ongoing Alliance clinical trials to Brigham and Women's Hospital within 45 days of the identified financial conflict of interest.

All legacy ACOSOG and CALGB institutions and their Principal Investigators will be required to sign and return the modifications in order to continue to receive federal payments. If you have any questions you may contact [BWHAllianceContracts@partners.org](mailto:BWHAllianceContracts@partners.org).

## ACOSOG Website De-Activation

Effective 5 pm (ET) March 7, 2013, the American College of Surgeons Oncology Group (ACOSOG) website will be de-activated. All current ACOSOG protocols and other documents will be available on the Alliance member website at [AllianceforClinicalTrialsinOncology.org](http://AllianceforClinicalTrialsinOncology.org). ACOSOG investigators and research staff may access the Alliance member website using CTEP-IAM usernames and passwords.

**How to Access ACOSOG Content:** On the Alliance website, simply click Member Login in the upper right corner and enter your CTEP-IAM username and password. On the Welcome page, select ACOSOG in the welcome box OR select Legacy Sites, then ACOSOG, from the navigation bar (bottom of page) to retrieve content from the de-activated website.

**Questions:** Send questions, comments or concerns to [info@allianceNCTN.org](mailto:info@allianceNCTN.org).

## On the Move: Alliance/ACOSOG Central Specimen Bank

The Alliance/ACOSOG Central Specimen Bank has moved to a new laboratory on the Washington University School Medicine campus. The bank's phone numbers and hours of operation will remain the same for all areas.

Beginning March 6, 2013, all samples should be shipped to: Dr. Sandra McDonald, Alliance/ACOSOG-CSB /TPC, 425 S. Euclid Ave, Rm 5120, BJC IOH/WUSM, St. Louis, MO 63110.

**Questions:** For additional information about the move, contact Vicky Holtschlag at 314-454-7605 or Sandra McDonald at 314-747-5773.

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## 2013 Richard L. Schilsky CALGB Achievement Award

The Alliance for Clinical Trials in Oncology Foundation is currently seeking nominations for the 2013 Richard L. Schilsky Cancer and Leukemia Group B Achievement Award. The annual award was established in 2010 to recognize the 15-year tenure of Dr. Schilsky as Group Chair of CALGB. It acknowledges the significant contributions of an individual to cooperative group research.

As an organization, it is vital for the Alliance to identify and honor the talented people responsible for its success. This award is made possible through generous donations from Alliance members and industry supporters. All Alliance members are welcome to submit nominations for the award. The award will be presented during the Plenary Session of the 2013 Alliance Group Meeting in November.

The deadline for nominations is April 22, 2013.

**What's the process?** If you're interested in nominating an Alliance member for this award, please submit a letter by e-mail that describes the contributions of the nominee to: Denise Brennan (Interim Treasurer, Alliance for Clinical Trials in Oncology Foundation) at [Dcollinsbrennan@partners.org](mailto:Dcollinsbrennan@partners.org).

## Foundation Extends Deadline for Alliance Scholar Award

The Alliance for Clinical Trials in Oncology Foundation has extended the deadline for applications for the Alliance Scholar Award. Applications must be submitted by May 6, 2103.

Applicants must be oncology junior faculty at Alliance institutions within five years of training (rank below Associate Professor), who have completed training in an oncology clinical specialty (e.g., medical, surgical, radiation, gynecologic). Applicants must submit a proposal, which includes a letter of support from the appropriate Alliance Scientific Committee Chair. This ensures that proposals are closely tied to the research agenda of the Alliance.

Award recipients will receive a two-year, non-renewable cancer research grant of \$40,000 direct costs per year, plus 10 percent overhead each year for two years. Successful applicants will be announced at the 2013 Alliance Group Meeting in November. Funding will begin approximately January 1, 2014.

A Scientific Review Committee, co-chaired by Phillip G. Febbo, MD, and John P. Leonard, MD, will review applications and select award recipients.

**How to apply:** Application requirements can be found on the Alliance website under Foundation (Awards) at [AllianceforClinicalTrialsinOncology.org](http://AllianceforClinicalTrialsinOncology.org). The Foundation is finalizing a new online submission portal. Directions for accessing the new site will be made available once the site has been launched.

## ASCO/AACR Workshop: Clinical Cancer Research

Vail Marriott / Vail, Colorado

July 27-August 2, 2013

**Course Co-Directors:** Jamie H. Von Roenn, MD; Neal J. Meropol, MD; and Mithat Gönen, PhD

Errors made in the design and conduct of a clinical trial can make it impossible for the trial to provide a definitive answer about the effectiveness of a new approach. Poor design can lead to the abandonment of promising avenues of research that are based on sound basic scientific work as well as to delays in the introduction of new treatments into the practice of oncology.

The American Association for Cancer Research (AACR) and the American Society of Clinical Oncology (ASCO) have designed this intensive workshop to increase the reliability and effectiveness of clinical trials by:

- Introducing clinical fellows and junior faculty in any oncology subspecialty to the principles of good clinical trial design. This workshop will give them the tools needed to conduct clinical trials that will yield clear results that investigators can use to move to the next level of research.
- Exposing early-career clinical scientists to the full spectrum of challenges in clinical research – from surgery, radiotherapy, conventional and investigational antineoplastic agents and multidisciplinary treatment regimens to gene therapy, biologic therapy, and multimodality and combination treatments. Workshop faculty seeks to inspire participants to devote all or a portion of their future careers to some aspect of clinical research.
- Developing a cadre of well trained, experienced clinical researchers whose expertise will foster better clinical trial design. Such expertise will hasten the introduction of improved regimens for cancer therapy and prevention into everyday medical practice and patient care.

All accepted applicants receive financial assistance to attend. The workshop is supported by a grant from the National Cancer Institute and educational grants from corporate supporters.

**How to apply:** The application deadline is March 18, 2013. Applications are available at <http://myaacr.aacr.org/Core/Workshops>. For more information about the workshop, contact Dean Post (Assistant Director, Program Development) at [dean.post@aacr.org](mailto:dean.post@aacr.org).

## Merrill J. Egorin Workshop in Cancer Therapeutics and Drug Development

Lansdowne Conference Center / Leesburg, Virginia  
October 11-14, 2013

The three-day workshop brings together 20 to 25 fellows and junior faculty (within five years of training completion) from the leading medical oncology, surgical oncology, radiation oncology, and surgical subspecialty fellowships in the United States. It has received national recognition for its focused and practical approach to preparing individuals to conduct cancer drug research.

Co-Chaired by Ross Donehower, MD, of Johns Hopkins School of Medicine, and Jeffrey Engelman, MD, of Harvard Medical School, the 16-member faculty includes researchers and educators from the National Cancer Institute, U.S. Food and Drug Administration, and the nation's leading cancer centers. The broad-based curriculum covers a range of topics related to new drug development and clinical evaluation. Expert speakers will lead discussions and present important didactic information regarding the preclinical and clinical evaluation of cytotoxic and targeted drugs, the identification and use of biomarkers, the special challenges of evaluating combination therapies, the problem of pharmacodynamic and pharmacokinetic drug interactions, and effects of organ dysfunction on drug disposition and toxicity.

**How to apply:** The application deadline is June 11, 2013. Visit the Cancer Education Consortium website at [www.cancereducationconsortium.org](http://www.cancereducationconsortium.org), call 201-338-2537 or e-mail [slisanti@cancereducationconsortium.org](mailto:slisanti@cancereducationconsortium.org) for more information about the workshop.

# Society for Clinical Trials 34th Annual Meeting

Sheraton Boston Hotel / Boston, Massachusetts  
May 19-22, 2013

Ideal learning opportunity for leading edge trialists, policy experts, biostatisticians, ethicists, epidemiologists, regulators, and students! The Society for Clinical Trials, created in 1978, is an international professional organization dedicated to the development and dissemination of knowledge about the design, conduct and analysis of government and industry-sponsored clinical trials and related health care research methodologies.

**Keynote Speakers:** “Transforming 300 Billion Points of Data into Diagnostics, Therapeutics, and New Insights into Disease” by Atul Butte, MD, PhD, Curtis Meinert Lecture and “Challenges for Health Behavior Trials from Design to Practice: The Example of Unhealthy Alcohol Use” by Richard Saitz, MD, MPH, FACP, FASAM, Founders Lecture

May 19: Full-day and half-day workshops

May 20-22: Engaging invited sessions; distinctive contributed papers and posters; and networking opportunities with others in the clinical trials community

**To register:** Visit [www.sctweb.org](http://www.sctweb.org). The SCT meeting is open to members and non-members. Non-members who register receive a one-year membership and a subscription to the SCT journal, *Clinical Trials: Journal of the Society for Clinical Trials*.

## Call for Photos / New Alliance Website

**Want to see your institution featured prominently on the new Alliance website?** If so, send us your photos. We welcome photos of all Alliance members and institutions. Just send them to us with a confirmation that all individuals pictured have given their consent for web posting to *Alliance News* at [jowens@uchicago.edu](mailto:jowens@uchicago.edu). Also, make sure to include a caption with the date, location, and names of individuals in the photos.

## Alliance Committee Meetings March 14-17, 2013 InterContinental Chicago O'Hare

Open to Alliance committee members only

### Invitations for the March Committee Meetings

were sent in early January. If you are a committee member and have not received an invitation, please contact Katherine Faherty at 617-525-3022 or [kefaherty@partners.org](mailto:kefaherty@partners.org). Also note that the Breast Committee will meet on Sunday, March 17. For the meeting schedule, visit the Alliance website.

## Future Meeting Dates

### 2013 Group Meeting

November 7-9, 2013

Open to Alliance members

### 2014 Committee Meetings

May 8-10, 2014\*

Open to Alliance committee members only

\*date changed from March 27-29, 2014

### Group Meeting

November 6-8, 2014

Open to Alliance members

All 2013-14 meetings will be held at the **InterContinental Chicago O'Hare**  
5300 N. River Road, Rosemont, IL

For meeting and travel inquiries, contact Katherine Faherty  
e-mail: [kefaherty@partners.org](mailto:kefaherty@partners.org)  
phone: 617-525-3022

For more information on the Alliance and updates about meetings, visit [AllianceforClinicalTrialsinOncology.org](http://AllianceforClinicalTrialsinOncology.org)