

Network Office News: July 2007

INDEPENDENCE DAY CLOSURE

The HCC-CTO will be closed on **Wednesday, July 4** in observance of Independence Day. If you anticipate any drug orders or other protocol assistance during this time, please contact the Network Office to make prior arrangements.

HCC CLINICAL RESEARCH ASSOCIATE SERIES

LCACRP SEMINAR: WARNING: IS YOUR MONITORING EFFECTIVE?

Guest Speaker: Deidra Poucher, RN, BSN, MSHS, CCRC, George Washington University, D. Poucher Consulting, LLC

Event Date/Time: Thursday, July 19, 6:00 p.m.

Continuing Education Credit: 2 Hours. As a CTN Member, you can participate and obtain credit hours for this event at no charge.

[Click here to view the July 17 LCACRP Event Flyer.](#)

Primary Location: MUSC Basic Science Building, Room 202, Charleston, SC

Videoconference Location: Palmetto Health, Two Medical Park Conference Center, Columbia, SC.

*Please see below for more information.

**To find more info for the Videoconference Location in Columbia, please contact Rosemary Faile at 803.255.3462 or 2MP_CONFERENCE_ROOM@gw.mp.sc.edu.*

For more information regarding this event in general or at MUSC, please contact Erica Ellington at 843.792.0299 or ellingte@musc.edu.

MEMBERSHIP CONTRACT RENEWALS

Membership Renewal Packets have been delivered to your site. If you have any questions about the Renewal Process, please contact Tricia Bentz at 843.792.1753 or adraleta@musc.edu.

CTN MEMBERSHIP WORKBENCH WEBSITE

The Membership Workbench Website is currently active. This secured portal allows network members to access important protocol documents and worktools. The protocol, model consent, case report forms, and regulatory documents can be downloaded here, as well as policy manuals and clinical research resources.

If you are a CTN Member and have not received your username and password, please contact Arlene Felipe at felipe@musc.edu

[Please click here to visit hollingscancercenter.org/network.](http://hollingscancercenter.org/network)



Dr. Anthony Murgo

Head, Early Clinical Trials Development, Div. of Cancer Treatment and Diagnosis, NCI.

Guest speaker for the **CTN Annual Retreat on Saturday, Sept. 8**

(photo from NCI website)

CLINICAL TRIALS NETWORK RETREAT

Save the Date!: Saturday, September 8, 2007

Time: 9:30am – 2:30pm

Location: Hollings Cancer Center, Conference Room 120

Keynote Speaker: **Anthony Murgo**, MD, MS, FACP, Head, Early Clinical Trials Development, Division of Cancer Treatment and Diagnosis, NCI

[Click here to view more details, including a tentative agenda, for the September 8th event.](#)

NEW NETWORK BULLETIN FEATURES

Archives: Back issues of the CTN Bulletin are now available online.

[Click here to visit the Archives.](#)

Press Releases: The Clinical Trials Network has been recognized by several regional publications, including US News & World Report, for its cancer care services throughout South Carolina.

[Click here to view the HCC Clinical Trials Network Advertisement in a regional page of US News & World Report.](#)

The HCC Website is proud to feature and archive such Press Releases online. [Click here to view the HCC Press Releases.](#)

Clinical Trials Network stories include: [McLeod Health joining the Network](#), [Coverage of the CTN and various services](#), and [HCC's affiliation with Carolina Regional Cancer Center](#).

If your site has any news you would like to share, please contact us.

Clinical Trial Updates: July 2007

INVESTIGATOR-INITIATED STUDIES

Contact Information and Regulatory Updates for the month of June 2007.

Velcade (Bortezomib) for Injection Therapy for Early Relapsed Prostate Cancer

CTO: 100822

PI: Andrew S. Kraft, MD

Participating Network Members:

[Loma Linda University Cancer Institute](#)

[South Carolina Oncology Associates, P.A.](#)

[Spartanburg Regional Healthcare System](#)

[University of California - Irvine](#)

Regulatory Updates:

- Velcade SAE set 6.27.07 posted on the CTN Members' Workbench.

Phase II Study of Xelox in Locally Advanced or Metastatic Gastric Cancer

CTO: 100829

PI: Uzair Chaudhary, MD

Participating Network Members:

[South Carolina Oncology Associates, P.A.](#)

[Spartanburg Regional Healthcare System](#)

Regulatory Updates:

- No regulatory updates.

Phase II Study of Neo-Adjuvant Cisplatin, Gemcitabine, and Bevacizumab, Followed by Radical Cystectomy for Patients with Muscle-Invasive, Resectable, Non-Metastatic Transitional Cell Carcinoma (TCC) of the Bladder

CTO: 100892

PI: Uzair Chaudhary, MD

Participating Network Members:

[Spartanburg Regional Healthcare System](#)

Regulatory Updates:

- No regulatory updates.



Dr. Alberto Montero, Principal Investigator for CTO # 101072

IIT HIGHLIGHT

Phase II Study of Neoadjuvant Treatment with NOV-002 in Combination with Doxorubicin and Cyclophosphamide Followed by Docetaxel in Patients with Stages IIB-IIIC Breast Cancer

CTO: 101072

PI: Alberto Montero, MD

Primary Objective:

To define the rate of pathologic complete response rate (pCR) in the affected breast after the preoperative administration of NOV-002 in combination with doxorubicin and cyclophosphamide followed by docetaxel in patients with stage IIB-IIIB breast cancer.

Inclusion Criteria:

- Females age 18 years or older
- The ability to provide written informed consent prior to study specific screening procedures, with the understanding that the patient has the right to withdraw from the study at any time
- Histologically confirmed infiltrating (invasive) breast cancer by core needle biopsy, with no evidence of metastatic disease except to the ipsilateral axillary lymph nodes
- Clinical stage IIB-IIIC (T2-4, N0 or N1, M0 or - any T, N1-3, M0) breast cancer. The primary tumor must be greater than or equal to 2cm (T2-4) or with pathologically proven axillary nodal involvement (N1-3).
- Patients with inflammatory breast cancer (T4) are permitted into the study.
- Clinically palpable tumor that meets the criteria of RECIST for palpable measurable disease. The primary tumor must be greater than or equal to 2cm (T2-4) or with pathologically proven axillary nodal involvement (N1-3). Bilateral synchronous breast cancers are allowed by one of the primary tumors should be selected as the target tumor.
- Primary tumor may be estrogen or progesterone receptor negative or positive, and HER-2/neu negative as determined by either Fluorescent In Situ Hybridization (FISH) or 0-2+ staining by immunohistochemistry (IHC) (Hercepttm).
- Normal cardiac ejection fraction (EF >50%) as determined by screening MUGA or echocardiogram
- No prior history of myocardial infarction, congestive heart failure, symptomatic coronary artery disease, or cardiac arrhythmias
- Patients must be ambulatory with ECOG Performance Status of 0-1.
- The patient or her caregiver must be able to self-administer daily subcutaneous injections.
- Life expectancy greater than 6 months

The protocol will be offered to approved Network Centers pending the approval of Amendment #1. If interested in activating the trial, please download the study request form and fax the completed form to the Network Office, 843.876.1963.

[Click here to download the study request form for this clinical trial.](#)

If You Have a Potential Patient, Please Contact Our Participating Site in South Carolina:

[Medical University of South Carolina](#)

- Principal Investigator: Alberto Montero, MD
- Study Coordinator: Shanta Salzer, salzers@musc.edu

COOPERATIVE GROUP STUDIES

Network Cooperative Group Studies

Randomized Phase III Study of Conventional Whole Breast Irradiation (WBI) vs. Partial Breast Irradiation (PBI) for Women with Stage 0, I, II Breast Cancer

Protocol ID: NSABP B-39

Participating Network Members:

[Carolina Regional Cancer Center](#)

[Georgetown Hospital System](#)

Phase III Comparison of Prophylactic Cranial Irradiation vs. Observation in Patients with Locally Advanced Non-Small Lung Cancer

Protocol ID: RTOG 0214

Participating Network Members:

[Carolina Regional Cancer Center](#)

[Lexington Medical Center](#)

Phase III Randomized Study of Hypofractionated 3D-CRT/IMRT vs. Conventionally Fractionated 3D-CRT/IMRT in Patient Treated for Favorable-Risk Prostate Cancer

Protocol ID: RTOG 0415

Participating Network Member:

[Carolina Regional Cancer Center](#)

Phase III Randomized Trial of Anastrozole vs. Anastrozole and Fulvestrant as First Line Therapy for Post-Menopausal Women with Metastatic Breast Cancer

Protocol ID: SWOG 0226

Participating Network Member:

[The Regional Medical Center of Orangeburg and Calhoun Counties](#)

COOPERATIVE GROUP TRIAL ACTIVATIONS

Below is a listing of newly activated cooperative group trials activated between **May 24, 2007** and **June 16, 2007**. If you would like to review any of the protocols listed below, please review the information on the cooperative group websites or contact the Network Office.

[ACOSOG](#)

No newly activated studies.

[CTSU](#)

CALGB-100104

CTSU Activation Date: 6/8/2007

Protocol Title: A Phase III Randomized, Double-Blind Study of Maintenance Therapy with CC-5013 (NSC# 703813, IND #70116) or Placebo Following Autologous Stem Cell Transplantation for Multiple Myeloma

[GOG](#)

GOG-0087M

Activation Date: 6/4/2007

Protocol Title: A Phase II Evaluation of Trabectedin (Yondelis, R279741, IND# 75,111) in the Treatment of Advanced, Persistent, or Recurrent Uterine Leiomyosarcomas

GOG-0126R

Activation Date: 6/4/2007

Protocol Title: A Phase II Evaluation of Abraxane® in the Treatment of Recurrent or Persistent Platinum-Resistant Ovarian, Fallopian Tube or Primary Peritoneal Cancer

GOG-0227E

Activation Date: 6/11/2007

Protocol Title: A Phase II Evaluation of Cetuximab (Erbix®), C225, NSC# 714692) in the Treatment of Persistent or Recurrent Squamous or Non-Squamous Cell Carcinoma of the Cervix

[NSABP](#)

NSABP B-41

Posted: 6/13/2007

Activation Effective: 7/16/2007

Protocol Title: A Randomized Phase III Trial of Neoadjuvant Therapy for Patients with Palpable and Operable HER2-Positive Breast Cancer Comparing the Combination of Trastuzumab Plus Lapatinib to Trastuzumab and to Lapatinib Administered with Weekly Paclitaxel Following AC Accompanied by Correlative Science Studies to Identify Predictors of Pathologic Complete Response

[RTOG](#)

No newly activated studies.

[SWOG](#)

S0521

Activation Date: 6/1/2007

Protocol title: A Phase III Randomized Trial of Maintenance versus Observation for Patients with Previously Untreated Low and Intermediate Risk Acute Promyelocytic Leukemia (APL)

S0600

Activation Date: 6/15/2007

Protocol title: A Phase III Trial of Irinotecan-Based Chemotherapy Plus Cetuximab (NSC# 714692) with or without Bevacizumab (NSC# 704865) as Second-Line Therapy for Patients with Metastatic Colorectal Cancer who have Progressed on Bevacizumab with either FOLFOX, OPTIMOX or XELOX

S0618

Reactivated: 6/15/2007

Protocol title: A Phase II Evaluation of E7389 (NSC# 707389) in Patients with Metastatic or Recurrent Squamous Cell Carcinoma of the Head and Neck

Patient Education: July 2007



[Click here to view the Clinical Trials Awareness Video.](#)

Other CURE Patient Items include: *Thanks to You Bag, Certificate, Bumper Sticker, Envelope, Stress Star, Pill Box, Pin, Flashlight*

CLINICAL TRIALS AWARENESS VIDEO

The Clinical Trials Awareness video includes five testimonies from former Clinical Trials patients. The video may be customized for your site and include contact information, logo, and photos of your facility and staff members.

[Please click here to view the Clinical Trials Awareness Video.](#)

Patient journals, memo pads, highlighters, and pens are among the items available to our patients. As a part of the CURE Initiative (Clinical Trials, Understanding, Research, Education), HCC has launched tokens of appreciation for clinical trials patients.

[Click here to view the goals of the CURE initiative as well as more detailed descriptions and list of our items.](#)

For more information regarding orders and pricing, please contact the Network Office.

FREE PATIENT EDUCATION MATERIALS

[ACS: American Cancer Society](#)

Examples of Materials: Brochure for Patients: Is a Clinical Trial the Right Choice for Me?; Brochure for Physicians: Referring Your Patient to a Clinical Trial.

Contact Info: Charleston Office: 843.744.1922, Columbia Office: 803.750.1693 and HCC Network Office 843.792.1753. To find your local ACS chapter, visit cancer.org.

Ordering Info: Contact your local Materials Coordinator. 100 of each publication will be sent at a time. No minimum charges apply.

Shipping Info: Free shipping!

[CCCG: Coalition of Cancer Cooperative Groups](#)

Examples of Materials: Knowledge is Power: featuring Lance Armstrong, Cokie Roberts; Myths and Facts about Clinical Trials Brochure.

Contact Info: Call 877.520.4457, visit cancertrials-help.org, or contact Arlene Felipe at 843.792.6394 or felipe@muscc.edu.

Ordering Info: Place orders over internet or phone. No minimum charges apply.

Shipping Info: Free shipping!

[NCI: National Cancer Institute](#)

Examples of Materials: Clinical Trials workbooks, notebooks, booklets, videos with discussion guides, and slide programs (also available in Spanish).

Contact Info: Call 800.4.CANCER, visit cancer.gov/publications, or contact Arlene Felipe at 843.792.6394 or felipe@muscc.edu.

Ordering Info: Place orders over internet, phone, fax, or mail. \$8 min. charge
Shipping Info: 15 cents/ copy for bulk orders beyond 20 copies.

CANCER CARE SERIES

A listing of featured programs is available by calling 888.337.7533 or logging on to cancer.org. Register by calling Cancer Care at 800.813.HOPE or logging on to cancer.org.

Colorectal Cancer: Report from the 2007 American Society of Clinical Oncology (ASCO) Annual Meeting

When: Wednesday, July 25, 1:30 p - 2:30 p

Free Telephone Workshop Will Include: an overview of colorectal cancer, new treatment approaches reports at ASCO, the important role of clinical trials, controlling symptoms and pain, communicating with your health care team, quality-of-life considerations, and questions for our panel of experts.

Medical Update on Lung Cancer from the 2007 American Society of Clinical Oncology (ASCO) Annual Meeting

When: Thursday, July 26, 1:30 p.m. - 2:30 p.m.

For more information, please visit cancer.org.

Emerging Treatments for Mantle Cell Lymphoma

When: Wednesday, August 15, 1:30 p - 2:30 p

Free Telephone Workshop Will Include: an overview of Mantle Cell Lymphoma, diagnosis and staging, current standard of care, new treatment approaches, clinical trials, side effect and pain management, working with your health care team, quality-of-life considerations, and questions for our panel of experts.