

## VETERANS DAY CLOSURE

The HCC-CTO will be closed on **Monday, November 12th** in observance of Veterans' Day. If you anticipate any drug orders or other protocol assistance during this time, please contact the Network Office to make prior arrangements.

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## Clinical Trial Updates: October 2007

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## INVESTIGATOR-INITIATED STUDIES

Contact Information and Regulatory Updates within the month of September 2007.

### → ACTIVE STUDIES

#### **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, PA](#)

[Spartanburg Regional Healthcare System](#)

[University of California at Irvine](#)

#### **Regulatory Updates:**

- **Amendment 6, issued 9/25/2007:**  
Please Note that due to the significance of this amendment, **patient enrollment has been temporarily suspended effective October 1**. Enrollment can be reactivated after your IRB approvals for Amendment 6 have been received.

- For participating sites only: [please log in to the Workbench to view this update](#)

**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 Member:**

[Spartanburg Regional Healthcare System](#)

→ **PENDING STUDIES**

**Phase II Study of Neoadjuvant Gemcitabine/Oxaliplatin and Cetuximab followed by Surgery or concurrent External Beam Radiation with Capecitabine for Patients with Locally Advanced Unresectable Nonmetastatic Pancreatic Cancer**

**CTO:** 100918

**PI:** Uzair Chaudhary, MD

**Network Member Reviewing Study:**

[McLeod Regional Medical Center](#)

**Multicenter Randomized Phase II Study of Erlotinib, Cisplatin, and Radiotherapy versus Cisplatin and Radiotherapy in Patients with Stage III and IV Squamous Cell Carcinoma of the Head and Neck**

**CTO:** 100949

**PI:** Anand Sharma, MD

**Network Member Reviewing Study:**

[McLeod Regional Medical Center](#)

**Phase II Trial of Dasatinib [Sprycel (R)] in Subjects with Hormone-Refractory Prostate Cancer, Previously Treated with Chemotherapy**

**CTO:** 101137

**PI:** Andrew Kraft, MD

**Network Member Reviewing Study:**

[McLeod Regional Medical Center](#)

→ **STUDY CLOSURES**

**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, PA](#)  
[Spartanburg Regional Healthcare System](#)

**Regulatory Information:**

-Study closed on July 18, 2007

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## CTN PROTOCOL 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-IIIC 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) (Hercept<sup>™</sup>).
- 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 One of Our Participating Sites in South Carolina:**

[Medical University of South Carolina](#)

Principal Investigator: Alberto J. Montero, MD

Study Coordinator: Shanta Salzer, [salzers@musc.edu](mailto:salzers@musc.edu).

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## 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 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](#)

### → STUDY CLOSURES

**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](#)

**Regulatory Information:**

-Study closed on August 30, 2007

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## MUSC Cooperative Group Affiliates

### [NSABP](#)

Carolina Regional Cancer Center

Georgetown Hospital System

The Regional Medical Center of Orangeburg and Calhoun Counties

### [SWOG](#)

Lexington Medical Center

The Regional Medical Center of Orangeburg and Calhoun Counties

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## COOPERATIVE GROUP TRIAL ACTIVATIONS

Below is a listing of newly activated cooperative group trials activated between **August 15, 2007** and **September 1, 2007**. If you would like to review any of the protocols listed below, please view the information on the cooperative group websites or contact the Network Office.

### [ACOSOG](#)

No newly activated studies.

### [CTSU](#)

No newly activated studies.

### [GOG](#)

No newly activated studies.

### [NSABP](#)

No newly activated studies.

### [RTOG](#)

No newly activated studies.

### [SWOG](#)

No newly activated studies.

## Cooperative Group Information:

Sites that have affiliate cooperative group memberships through HCC may access all available studies as offered by their affiliated cooperative group or through CTSU.

If you would like to review any of these protocols, please review the information on the cooperative group websites or contact the Network Office at 843.792.1753 or [hccrnet@musc.edu](mailto:hccrnet@musc.edu).

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## Patient Education: October 2007

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#### CURE Patient Items

Thanks to you Bag, Certificate, Bumper Sticker, Document Holder, Stress Star, Pill Box, Pin, and Flashlight.

## CURE INITIATIVE: ITEMS FOR CTN PATIENTS

As a part of the CURE Initiative (Clinical Trials, Understanding,

Research, Education), HCC has launched tokens of appreciation for clinical trials patients.

Patient journals, memo pads, highlighters, and pens are among the items available to our patients.

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

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.

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

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

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## 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 Inf** 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](http://cancer.org).

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

**Shipping Inf** 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 Inf** Call 877.520.4457, visit [cancertrialshelp.org](http://cancertrialshelp.org), or contact Arlene Felipe at 843.792.6394 or [felipe@musc.edu](mailto:felipe@musc.edu).

**Ordering Inf** Place orders over internet or phone. No minimum charges apply.

**Shipping Inf** 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 Inf** Call 800.4.CANCER, visit [cancer.gov/publications](http://cancer.gov/publications), or contact Arlene Felipe at 843.792.6394 or [felipe@musc.edu](mailto:felipe@musc.edu).

**Ordering Inf** Place orders over internet, phone, fax, or mail. \$8 min. charge

**Shipping Inf** 15 cents/ copy for bulk orders beyond 20 copies.

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## CANCER CARE SERIES

A listing of featured programs is available by calling 888.337.7533 or logging on to [cancercare.org](http://cancercare.org). Register by calling Cancer Care at 800.813.HOPE or logging on to [cancercare.org](http://cancercare.org).

### **Moving Forward: Breast Cancer Survivorship**

**When: Wednesday, October 3, 1:30 p - 2:30 p EST**

**Free Telephone Workshop Will Include:** Current standard of care, weight gain and other side effects, sticking with your treatment, nutrition and exercise guidelines, body image and intimacy, the importance of a support network, and questions for our panel of experts.

### **The Importance of Taking Your Pills Everyday**

**When: Friday, October 19, 1:30 p - 2:30 p EST**

**Free Telephone Workshop Will Include:** overview of compliance: taking your pills on schedule, the important role of compliance in the management of cancer, barriers to taking your pills, practical tips to overcome these barriers, planning ahead for traveling, refills and weekends, communicating with your health care team, the importance of a support network, resources for finding help, and questions for our panel of experts.

### **Caring for Your Bones when You have Breast Cancer**

**When: Friday, October 26, 1:30 p - 2:30 p EST**

**Free Telephone Workshop Will Include:** Screening for bone health and risk factors, prescription medication to promote bone health, the role of nutrition, exercise, and calcium supplements, breast cancer and bone metastases, clinical trials, controlling pain and discomfort, doctor-patient communication, and questions for our panel of experts.

### **Living Each Day with Lung Cancer**

**When: Wednesday, November 7, 1:30 p - 2:30 p EST**

**Free Telephone Workshop Will Include:** Overview of lung cancer, clinical trials, coping with lung cancer, its treatment and side effects, practical tips to help you, getting support from your health care team, the importance of a support network, and questions for our panel of experts.

### **For Caregivers: Coping with a Loved One's Cancer During the Holidays**

**When: Wednesday, November 14, 1:30 p - 2:30 p EST**

**Free Telephone Workshop Will Include:** Definition of a Caregiver, taking

on this role, caring for the person with cancer, coping with caregiving during the holidays, managing family, friends, partners, and traditions, long-distance caregiving, tips for taking care of yourself and questions for our panel of experts.

**The Latest Developments Reported at the 30th Annual San Antonio Breast Cancer Symposium**

**When: Wednesday, December 19, 1:30 p - 2:30 p EST**

**Free Telephone Workshop Will Include:** An overview of breast cancer, new treatment approaches reported at the symposium, the role of systemic adjuvant therapies, how clinical research affects your care, symptom management, quality-of-life issues and questions for our panel of experts.

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