

## CLINICAL TRIALS NETWORK ANNOUNCEMENTS

November 2006

### **Hollings Cancer Center's 6th Annual Research Retreat**

You are cordially invited to attend the HCC annual Research Retreat on **Friday, November 17, 2006** from 8:00 AM to 5:00 PM at the Citadel's Holliday Alumni Center. The retreat is being planned for members of the Cancer Research Programs, Hollings Cancer Center members, and MUSC faculty, Network Investigators, graduate and postdoctoral students interested in cancer research.

Breakfast and lunch will be provided. Visit the following website, <http://hcc.musc.edu/research/annualretreat>, for more info.

### **CLINICAL TRIALS NETWORK WEBSITE**

The Network members' Worktools website has been under construction. If you need access to frequently used forms or tools or other protocol documents or tools, please contact the Network office. More information about the updated member's website will be released.

### **November 10th Holiday**

The HCC-CTO office will be closed on Friday November 10th in observance of Veteran's Day.

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## CLINICAL TRIALS NETWORK CLINICAL TRIAL ACTIVATIONS

Protocol: **RTOG-0214 A Phase III Comparison of Prophylactic Cranial Irradiation versus Observation in patients with Locally Advanced Non-Small Cell Lung Cancer**

Participating Network Members:

- Lexington Medical Center
- Carolina Regional Cancer Center

Protocol: **VELCADE (bortezomib) for Injection Therapy for Early Relapsed Prostate Cancer, CTO 100822**, Andrew S. Kraft, MD

Participating Network Members:

- Loma Linda University Cancer Institute
- South Carolina Oncology Associates, P.A.
- Spartanburg Regional Healthcare System

Protocol: **A Phase II Study of XELOX in Locally Advanced or Metastatic Gastric Cancer, CTO 100829**, Uzair Chaudhary, MD

Participating Network Members:

- South Carolina Oncology Associates, P.A.
- Spartanburg Regional Healthcare System

Protocol: **NSABP-B 39- A Randomized Phase III Study of Conventional Whole Breast Irradiation (WBI) vs. Partial Breast Irradiation (PBI) for Women with Stage 0, I, II Breast Cancer**

Participating Network Member:

- Georgetown Hospital System Radiation Therapy Center

Protocol: **Phase II Study of Gemcitabine and CPT-11 (Irinotecan) in Locally Advanced and Metastatic Bladder Cancer, CTO 100730**, Uzair Chaudhary, MD  
Participating Network Member:  
•Spartanburg Regional Healthcare System

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## **CLINICAL TRIALS NEWS**

Clinical Trials Network members may access a number of research studies through the HCC Network. Below are links to the current clinical trials available. Sites that have affiliate cooperative group memberships through HCC may access all available studies as offered by the cooperative group. For more information about activating a Network clinical trial, please contact the Network Office at 843-792-1753 or email at [hccrnet@musc.edu](mailto:hccrnet@musc.edu)

### **HCC Investigator Initiated Trials**

#### **IIT Highlights**

##### **CTO# 100855**

##### **A Phase II trial of Arsenic Trioxide and 5-Azacitidine in Patients with Myelodysplastic Syndrome**

*Principal Investigator: Dr. Robert Stuart*

##### *Primary Objectives:*

To determine the response rate to therapy with 5-azacitidine 75mg/m<sup>2</sup> administered subcutaneously (SC) once daily for 5 days every 4 weeks for a minimum of 4 cycles and arsenic trioxide (ATO) 0.25mg/kg administered intravenously (IV)

##### *Eligibility Highlights:*

- Patients must have MDS or chronic myelomonocystic leukemia (CMML)
- International Prognostic Scoring System (IPSS) = INT-1. Patients with Low IPSS score will be enrolled if they meet one or more of the following criteria: required packed RBS transfusions within 4 weeks of study; have platelet counts  $\leq 50.0 \times 10^9/L$ ; required platelet transfusions within 4 weeks of study; or have been neutropenic (ANC  $< 1.0 \times 10^9/L$ ) with infections requiring treatment with antibiotics.

If you are interested in participating in any of the trials listed, please contact the Network Office at [hccrnet@musc.edu](mailto:hccrnet@musc.edu) or 843-792-1753.

*To request more information about a clinical trial, please contact the Network Office at 843-792-1753 or [hccrnet@musc.edu](mailto:hccrnet@musc.edu). A confidentiality agreement will be faxed to your site. Upon completion, protocol and model consents will be provided for review.*

#### **STORY- Sisters tell others and revive yourself**

A research study called STORY is being conducted at the Palmetto Health SC Cancer Center under the direction of Dr. Sue Heiney. STORY is being done to find out if support groups by telephone will improve quality of life and mood of African American women with breast cancer. Patients eligible for the study include African American women who

have been diagnosed with infiltrating/ invasive ductal carcinoma within the last 6 months.

Attached is a flyer regarding the research study. If you have any potential patients or want more information, please contact Hiluv Johnson at 803/434-3118 or 1-800-775-2287 (if you are calling long distance) or email at [story@palmettohealth.org](mailto:story@palmettohealth.org)

### **Cooperative Group Studies**

Below please find a listing of newly activated cooperative group trials activated between October 15, 2006 and November 1, 2006. 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 ([www.acosog.org](http://www.acosog.org))**

No newly activated studies

#### **CTSU ([www.ctsu.org](http://www.ctsu.org))**

S0500: A Randomized Phase III Trial to Test the Strategy of Changing Therapy Versus Maintaining Therapy for Metastatic Breast Cancer Patients Who Have Elevated Circulating Tumor Cell Levels at First Follow-up Assessment. CTSU Activation Date: 10/09/06.

NSABP-B-40: A Randomized Phase III Trial of Neoadjuvant Therapy in Patients with Palpable and Operable Breast Cancer Evaluating the Effect on Pathologic Complete Response (pCR) of Adding Capecitabine or Gemcitabine to Docetaxel when Administered Before AC with or without Bevacizumab and Correlative Science Studies Attempting to Identify Predictors of High Likelihood for pCR with Each of the Regimens. \*This protocol has been pre-activated and will open to patient enrollment on 11/20/06.\*

#### **GOG ([www.gog.org](http://www.gog.org))**

No newly activated studies

#### **NSABP ([www.nsabp.pitt.edu](http://www.nsabp.pitt.edu))**

S0500: A Prospective Randomized Trial to Evaluate Changing to an Alternate Therapy for Metastatic Breast Cancer Patients Who Have Elevated Circulating Tumor Cell Levels at First Follow-up Assessment (Breast Cancer Alternate Therapy - BRAT). Activation Date: 10/09/06.

#### **RTOG ([www.rtog.org](http://www.rtog.org))**

NCCTG 0574, "Phase III Randomized Trial of Whole Brain Radiation in Addition to Radiosurgery in Patients with One to Three Cerebral Metastases." Enrollment must occur via CTSU.

#### **SWOG ([www.swog.org](http://www.swog.org))**

CTSU/E2204 - Phase II: An Intergroup Randomized Phase II Study of Bevacizumab (NSC 704865) or Cetuximab (NSC 714692) in Combination with Gemcitabine and in Combination with Chemoradiation (Capecitabine and Radiation) in Patients with Completely-Resected Pancreatic Carcinoma. SWOG Activation Date: 10/15/06.

S0435: A Phase II Trial of BAY 43-9006 (NSC-724772) in Patients with Platinum-Treated Extensive Stage Small Cell Lung Cancer. \*Phase II Partial Reactivation; Effective Immediately.\*

### **All Active Clinical Trials at Hollings Cancer Center**

A current list of all active clinical trials available through the HCC Clinical Trials Office is now available on-line.

[http://hcc.musc.edu/patient/clinical\\_trials/active\\_clinical\\_trials.cfm](http://hcc.musc.edu/patient/clinical_trials/active_clinical_trials.cfm). The list includes all investigator-initiated, cooperative group and pharmaceutical sponsored studies. If you would like one of your patients evaluated, or if you would like additional information about a clinical trial, please contact the Network coordinator at [hccrnet@muscc.edu](mailto:hccrnet@muscc.edu)

You can also quickly view our most recently activated trials in the News/Events section of the web site: [http://hcc.musc.edu/news\\_events/news](http://hcc.musc.edu/news_events/news).

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### **EDUCATIONAL OPPORTUNITIES**

#### **Hollings Cancer Center's 6th Annual Research Retreat**

You are cordially invited to attend the HCC annual Research Retreat on Friday, **November 17, 2006** from 8:00 AM to 5:00 PM at the Citadel's Holliday Alumni Center. The retreat is being planned for members of the Cancer Research Programs, Hollings Cancer Center members, and MUSC faculty, Network Investigators, graduate and postdoctoral students interested in cancer research.

A detailed agenda will be forthcoming. Breakfast and lunch will be provided. Attendance is limited, so please visit the following website, <http://hcc.musc.edu/research/annualretreat> for retreat details and to register before the deadline of October 27.

#### **Patient Education**

##### ***Cancer Care Series***

A listing of featured programs is available by logging onto [www.cancercare.org](http://www.cancercare.org) or calling 1-888-337-7533. Register online at [www.cancercare.org](http://www.cancercare.org) or call cancer care at 1-800-813-HOPE.

##### **The Future Role of Cancer Vaccines**

Wednesday, November 15, 2006, 1:30p-2:30p EST

Free Telephone workshop to address overview, history and differences between targeted therapy and chemotherapy, understanding the roles of vaccines in medicine, how cancer vaccines work, their relationship with clinical trials, and the future role of cancer vaccines.

##### **New Trends in the Treatment of Head and Neck Cancer: Update from ASCO**

Friday, November 17, 2006, 1:30p-2:30p EST

Free Telephone workshop to address an overview of Head and Neck Cancer, the current standard of care, findings presented at ASCO, speech and swallowing rehabilitation, progress in pain and symptom management, and quality-of-life considerations.

##### **Difficult Side Effects of Breast Cancer Treatment**

Wednesday, November 29, 2006, 1:30p-2:30p EST

Free telephone workshop to address an overview of breast cancer treatment, memory and thinking changes, practical ways to compensate for them, recommended treatment approaches, multidisciplinary care plan for coping, and your health care team.

Advances in the Treatment of Lung Cancer

Tuesday, December 5, 2006, 1:30p-2:30p EST

Free telephone workshop will address an overview of lung cancer, current standard of care, new research and treatment approaches, symptom and pain management, the importance of a support network, and questions for Our Panel of Experts.