The Clinical Research E-News

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Jefferson Kimmel Cancer Center Network: For urgent clinical trial questions or assistance please page: 877-656-9004

Now Open For Network Participation:
NSABP B-49, A Phase III Clinical Trial Comparing the Combination of Docetaxel Plus Cyclophosphamide to Anthracycline-Based Chemotherapy Regimens for Women with Node-Positive or High-Risk Node-Negative, HER2-Negative Breast Cancer

RTOG1102, A Phase I Study of Induction Ganitumab (IND #113278) and Gemcitabine, Followed by Ganitumab, Capecitabine, and 3D-Conformal Radiation Therapy (3D-CRT) With Subsequent Maintenance Therapy for Locally Advanced Pancreatic Cancer

RTOG1175/CALGB80803, A Randomized Phase II Trial of PET Scan-Directed Combined Modality Therapy in Esophageal Cancer.

Pending Studies for Network Participation:
N0148, A Phase II/III Trial of Neoadjuvant FOLFOX with Selective Use of Combined Modality Chemoradiation versus Preoperative Combined Modality Chemoradiation for Locally Advanced Rectal Cancer Patients Undergoing Low Anterior Resection with Total Mesorectal Excision

RTOG1106, A Randomized Phase II Trial of Individualized Adaptive Radiotherapy Using During-Treatment FDG-PET/CT and Modern Technology in Locally Advanced Non-Small Cell Lung Cancer (NSCLC)
RTOG1115, *Phase III Trial of Dose Escalated Radiation Therapy and Standard Androgen Deprivation Therapy (ADT) with a GNRH Agonist vs. Dose Escalated Radiation Therapy and Enhanced ADT with a GNRH Agonist and TAK-700 for Men with High Risk Prostate Cancer*

RTOG1122, *Phase II Double-Blinded Placebo-Controlled Study of Bevacizumab with or without AMG 386 in Patients with Recurrent Glioblastoma or Gliosarcoma*

If your site is interested in participating in any of these studies please contact Joshua Schoppe at 215-955-0448 or at Joshua.schoppe@jeffersonhospital.org.

**Regulatory Update:**
- RTOG 1102-NEW Study
- ECOG 5508-Amendment
- GOG 0258-Amendment #9
- RTOG 0920- Amendment
- RTOG 0622- Revisions
- C80803-RTOG 1175- NEW Study
- *ECOG 2809- Amendment #3*
- JOG 59- Amendment
- ECOG 2108- Addendum #2
- NSABP B49-NEW Study
- ECOG 1508-Amendment #10
- N107C/RTOG 1270-Change PI
- RTOG 0724-Amendment change PI
- RTOG 0815-Amendment change PI

*All studies bolded and italicized require a re-consent of patients currently receiving treatment or within 30 days of receiving their last study dose.*

Please contact Rashada Dawson at 215-955-2135 or Rashada.Dawson@jeffersonhospital.org with any repository related questions.

**CTSU Update:**
- *Nationwide Intravenous Leucovorin Shortage:* There currently is a nationwide shortage of intravenous (IV) leucovorin. Your institution may or may not be able to obtain sufficient leucovorin for patients enrolled on
CALGB trials. Please note this effects patients currently being treated and new enrollments on CALGB80405, *A Phase III Trial of Irinotecan / 5-FU / Leucovorin or Oxaliplatin / 5-FU / Leucovorin with Bevacizumab, or Cetuximab (C225), or with the Combination of Bevacizumab and Cetuximab for Patients with Untreated Metastatic Adenocarcinoma of the Colon or Rectum.* Please see the CALGB memorandum regarding the Leucovorin shortage. This document is available under the CALGB studies protocol pages on the CTSU members' website (http://www.ctsu.org/).

**S0819, A Randomized, Phase III Study Comparing Carboplatin/Paclitaxel or Carboplatin/Paclitaxel/Bevacizumab with or without Concurrent Cetuximab in Patients with Advanced Non-Small Cell Lung Cancer (NSCLC),** announces the recall of the study drugs carboplatin and paclitaxel due to particles embedded in the glass at the neck of the vial. Anyone with an existing inventory in the United States should stop use and distribution, quarantine the product immediately, and call Stericycle at 1-888-628-0734 between the hours of 8am to 5pm EDT, Monday through Friday, to arrange for the return of the product. Read the MedWatch safety alert, including a link to the Press Release, at: [http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm312048.htm](http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm312048.htm).

Please contact Joshua Schoppe with any CTSU related issues.

**ECOG Update:**
The National Cancer Institute’s Cancer Therapy Evaluation Program (CTEP) in conjunction with ECOG (lead group) would like your opinions about a new NCI clinical trial for metastatic renal cell carcinoma that will activate soon. This E2810 clinical trial is a ‘Randomized, Double-Blind Phase III Study of Pazopanib vs. Placebo in Patients with Metastatic Renal Cell Carcinoma Who Have No Evidence of Disease Following Metastatectomy’. It will require 180 patients with pathologically confirmed renal cell carcinoma
that have previously undergone nephrectomy/partial nephrectomy and surgical resection. First, please review the brief two-page E2810 trial concept overview at [http://www.ecog.org/ecoginst/notices/E2810_concept.pdf](http://www.ecog.org/ecoginst/notices/E2810_concept.pdf).

**NSABP Update:**

**P-5: Statin Polyp Prevention Trial in Patients with Resected Colon Cancer:** Site Initiation Visit Web cast is available in the Members' Area of the NSABP Web site under Prevention Trials Information / Protocols / P-5 / Training / Special Documents / Site Initiation Visit (SIV) for US Sites. This Web cast is available for US sites to use as an introduction to the NSABP P-5 Protocol and is for educational purposes only. NSABP-US sites are not required to view the Web cast in order to participate in this clinical trial.

**B-49, A Phase III Clinical Trial Comparing the Combination of Docetaxel Plus Cyclophosphamide to Anthracycline-Based Chemotherapy Regimens for Women with Node-Positive or High-Risk Node-Negative, HER2-Negative Breast Cancer,** released a memo for guidelines on rescheduling treatment for Non-Medical reasons. Please visit the Members' Area of the NSABP for more details.

**RTOG Update:**

**RTOG 1012, Phase II Randomized Trial of Prophylactic Manuka Honey for the Reduction of Chemoradiation Therapy Induced Esophagitis-Related Pain During the Treatment of Lung Cancer,** is temporarily closed to patient accrual effective immediately, due to unavailability of Manuka honey in lozenge form. RTOG will broadcast the re-opening of the trial as soon as the lozenges are available.

**Instructions for Consent Withdrawal (CW):** RTOG has updated the instructions for the consent withdrawal form (CW). If a patient chooses to no longer participate in the protocol, this form will need to be completed and
signed by both the patient and the institutional RTOG PI. After this form is received at RTOG Headquarters, forms that are due (per the patient’s calendar) subsequent to the date the Consent Withdrawal form (CW) is signed will be suppressed. The updated instructions for consent withdrawal are available at: http://www.rtog.org/LinkClick.aspx?fileticket=wignC-rx6H8%3d&tabid=308

**RTOG 0815, A Phase III Prospective Randomized Trial of Dose-Escalated Radiotherapy With or Without Short-Term Androgen Deprivation Therapy for Patients With Intermediate-Risk Prostate Cancer:** The quality of life component of this study has closed to patient accrual effective August 2, 2012.

Please contact Joshua Schoppe with any RTOG related issues.

**Jefferson Oncology Group (JOG) Update:**

1. **JOG62: LUX-Breast 1; An open label, randomized phase III trial of BIBW 2992 and vinorelbine versus trastuzumab and vinorelbine in patients with metastatic HER2-overexpressing breast cancer failing one prior trastuzumab treatment**
   a. **Eligibility:** Histologically confirmed diagnosis of HER2-overexpression breast cancer, Stage IV metastatic disease, Must have progressed on one prior trastuzumab treatment, no more than one prior trastuzumab based therapy regimen (either adjuvant or first-line), Must have received anthracycline and/or taxane based chemotherapy for adjuvant treatment of breast cancer or first-line treatment of metastatic breast cancer
   b. **Treatment:** Experimental: Arm A: BIBW 2992 with vinorelbine patients receive BIBW 2992 tablets once daily combined with weekly intravenous infusion of vinorelbine. Active Comparator: Arm B: trastuzumab with vinorelbine patients receive weekly intravenous infusion of trastuzumab and vinorelbine

Please contact Joshua Schoppe if your site is interested. Limited spots available.
Jefferson Kimmel Cancer Center Network Homepage: http://www.kimmelcancercenter.org/jkccn/. This page contains links to the Remote Access Portal as well as the clinical trial document repository.

Upcoming Events:
CRA Quarterly Meeting, Jefferson Campus: September 19
ECOG-ACRIN Semiannual Meeting, Hollywood, FL: November 9-11
CRA Quarterly Meeting, Jefferson Campus: December 19
NRG meeting January, San Diego, CA: Jan 24-27, 2013

The Clinical Research E-News Archive is now located on the Kimmel Cancer Center webpage under the JKCCN Member Area: http://www.kimmelcancercenter.org/jkccn/e-newsletters.html

Please provide feedback and any suggestions to Joshua Schoppe at 215-955-0448 or email Joshua.schoppe@jeffersonhospital.org