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

New Trials Opened at the Kimmel Cancer Center at Jefferson:

1. New Ovarian Cancer Clinical Trial Announcement: Randomized Phase 2 Study of MLN8237, an Aurora A Kinase Inhibitor, plus Weekly Paclitaxel or Paclitaxel Alone in Patients with Recurrent Ovarian, Fallopian Tube or Primary Peritoneal Cancer, Proceeded by a Phase I Portion in Patients with Ovarian or Breast Cancer
   a. Eligibility: Women 18 years or older with ECOG performance status of 0 or 1 with a histologically confirmed diagnosis of ovarian, fallopian tube or primary peritoneal cancer. Up to 4 prior regimens is permitted as long as at least one of them contained a platinum agent and a taxane. Patients must be less than 12 months out from their last platinum based therapy.
   b. Treatment: Arm 1 (Combination Arm) Alisertib 40 mg PO BID 3 days on, 4 days off for 3 weeks w/ Paclitaxel 60 mg/m2 on Days 1, 8, 15 or Arm B-(single agent), weekly paclitaxel at 80 mg/m2 on days 1,8, 15
   c. Contact: Melisa Mordenti at 215-955-8979 or Melisa.Mordenti@jefferson.edu

2. New Pancreas Cancer Clinical Trial Announcement: A Phase Ib Study of Fractionated 90Y-hPAM4 with or without Gemcitabine in Patients with Metastatic Pancreatic Cancer Who Received at Least Two Prior Treatments
   a. Eligibility: Stage IV (metastatic) disease, including patients who underwent surgery but had incomplete resections with histologically or cytologically confirmed pancreatic adenocarcinoma. Previously treated and received two prior treatment regimens for advanced disease and have a greater than 3 month survival expectation.
   b. Treatment: At enrollment, patients will be assigned in alternating fashion to one of two treatment arms: Treatment Arm A: Four-week treatment cycle: 200 mg/m2
gemcitabine administered weekly for 4 weeks plus 3 doses of 90Y-hPAM4 administered once-weekly beginning week 2 of each cycle. Treatment Arm B: Three-week treatment cycle: 3 doses of 90Y-hPAM4 administered once-weekly each cycle (no gemcitabine)

c. Contact: Briana Shields, RN, BSN at 877-656-7116 or Briana.Shields@jefferson.edu

Now Open For Network Participation:

**N107C/R1270**, *A Phase III Trial of Post-Surgical Stereotactic Radiosurgery Compared with Whole Brain Radiotherapy (WBRT) for Resected Metastatic Brain Disease*

**SWOG0931**, *EVEREST: EVErolimus for Renal Cancer Ensuing Surgical Therapy, A Phase III Study.*

**RTOG1012**, *A Phase II Randomized Trial of Prophylactic Manuka Honey for the Reduction of Chemoradiation Therapy Induced Esophagitis-Related Pain During the Treatment*

**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.*

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*

**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

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)

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

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:
ECOG 2408- Add 4/Update 3
GOG 273-Amendment # 3 & 4
RTOG 1114- Amendment #1, 2
ECOG E3F05- addendum #5
ECOG 5508-Addendum#7
SWOG 0819-Revision #12
R-04- Amendment #8
SWOG 0931-New full approval
ECOG 7208
RTOG 0524
ECOG 2108
RTOG 0848
JOG61
RTOG 0912- Amendment #3

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

CTSU Update:
C90202, A Randomized Double-Blind, Placebo-Controlled Phase III Study of Early versus Standard Zoledronic Acid to Prevent Skeletal Related Events in Men with Prostate Cancer Metastatic to Bone, closed to patient accrual on April 4, 2012. Per the recommendation of the Alliance Data and Safety Monitoring Board, protocol treatment and data collection for CALGB 90202 is
to be terminated. Therefore, AFTER JULY 2, 2012, patients enrolled to CALGB 90202 should no longer be treated per protocol and data collection will no longer be required.

**C80405**, *A Phase III Trial of Irinotecan/5FU/Leucovorin or Oxaliplatin/5FU/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*, effective immediately, as a result of a change in drug distributor, a new order form for Cetuximab must be used. The form can be found on CTSU under the protocol CALGB80405. If you have any questions related to this notice, please contact Shivani Shah, Protocol Coordinator, sshah11@uchicago.edu.

Please contact Joshua Schoppe with any CTSU related issues.

**ECOG Update:**
**E1505**, *A Phase III Randomized Trial of Adjuvant Chemotherapy With or Without Bevacizumab for Patients with Completely Resected Stage IB (>4cm) – IIIA NSCLC*, Update #4 has been retracted from the ECOG website. An addendum to the protocol, which will incorporate the changes contained in Update #4 is currently in process and will be circulated upon completion.

**E1305 STUDY CHAIR TO HOST AN UPCOMING WEBINAR: E1305:** *A Phase III Randomized Trial of Chemotherapy With or Without Bevacizumab in Patients with Recurrent or Metastatic Head and Neck Cancer*. The educational webinar will provide an overview of the study by the study chair, Dr. Argiris, as well as a question and answer session at the conclusion of the presentation. This is a great opportunity for sites to learn more about this important protocol! Webinar Date: Friday, July 27, 2012 at 3pm ET
The ECOG Pathology Coordinating Office (PCO) will be closed on Wednesday, July 4th, but will have skeleton crews available. Ambient specimens must get shipped the day of collection, please ship by Tuesday, July 3rd, DO NOT HOLD. Frozen specimens must get shipped out by Monday, July 2nd. If unable to ship out then hold off until Thursday, July 5th. Do not ship specimens on Tuesday, July 3rd.

NSABP Update:
**R-04:** A Clinical Trial Comparing Preoperative Radiation Therapy and Capecitabine with or without Oxaliplatin with Preoperative Radiation Therapy and Continuous Intravenous Infusion of 5-Fluorouracil with or without Oxaliplatin in the Treatment of Patients with Operable Carcinoma of the Rectum, Amendment #8 was released on 6/05/12. It includes a Quality of Life (QOL) assessment to evaluate the long term QOL of R-04 rectal cancer survivors. It will be added to the 5-year follow-up visit.

**P-5:** Statin Polyp Prevention Trial in Patients with Resected Colon Cancer:
An email blast for P-5 was released on 6/26/12:
[https://members.nsabp.pitt.edu/P5_Email_Blast_0612.pdf](https://members.nsabp.pitt.edu/P5_Email_Blast_0612.pdf)

RTOG Update:
The RTOG Operations & Statistical/Data Management Centers will be closed on Wednesday, July 4th, for the Independence Day holiday. The office will reopen at 8:30 a.m. ET on Thursday, July 5th. Sites may access web registration 24/7.

The Summer 2012 edition of the RTOG Newsletter has been posted to the Web site. Download your copy today at:
[http://www.rtog.org/LinkClick.aspx?fileticket=QZXypnKlj0%3d&tabid=360](http://www.rtog.org/LinkClick.aspx?fileticket=QZXypnKlj0%3d&tabid=360)
R1102, 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, temporarily closed to accrual effective June 28, 2012 for protocol-specific toxicity analysis.

R1005, A Phase III Trial of Accelerated Whole Breast Irradiation with Hypofractionation plus Concurrent Boost Versus Standard Whole Breast Irradiation plus Sequential Boost for Early-Stage Breast Cancer, has a revised protocol with the release of amendment #1. Timing for completion of chemotherapy prior to study entry was revised; Timing of bone, CT, and PET/CT scans and negative post-excision mammogram was revised; Clarifying text for how to contour the contra lateral breast and heart was added; Dose volume constraints for Arm 1 and Arm 2 were modified: Text was added to clarify the administration of chemotherapy in relation to surgery and radiotherapy.

R0631, A Phase II/III Study of Image-Guided Radiosurgery/SBRT for Localized Spine Metastasis, is a landmark randomized study testing a new technology. The phase II component showed feasibility and safety, and the phase III component (now open) is our opportunity to provide evidence based medicine in this setting. RTOG has asked sites to encourage enrollment. If your site is interested please contact Joshua Schoppe.

**ALL INSTITUTIONS PARTICIPATING IN RTOG 0618 and 0915 (LUNG TRIALS)**, statistical analyses are being planned for these studies. Please review the OPS tool and patient calendars and submit all outstanding data due through June 30th, 2012 to RTOG Headquarters by July 15th, 2012. Please contact Jeff Serianni with any questions regarding this important data submission at jserianni@acr.org
Please contact Joshua Schoppe with any RTOG related issues.

**Jefferson Oncology Group (JOG) Update:**
No studies, please check back next month

**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:**
GOG Semiannual Meeting, Boston, MA: July 26-29  
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