The Clinical Research E-News

Volume 4: ISSUE 7: October 3, 2012

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 AML Clinical Trial Announcement: A Multi-Center, Open-Label, Phase Ib Study of Escalating Doses of RO5045337 Administered Orally, with Cytarabine Administered A) Subcutaneously, or B) Intravenously, in Patients with Acute Myelogenous Leukemia (AML)
   a. **Eligibility:** Patients with histological or cytological documented AML (except APL) appropriate for cytarabine therapy.
   b. **Study Design:** Arm A will include patients deemed not suitable for standard induction chemotherapy, Arm A patients will receive cytarabine subcutaneously at 20 mg/m2 daily for 10 days with escalating doses of RO5045337 beginning at 500 mg po daily x 10 days in a 28 day cycle. Arm B will include patients who have relapsed or are refractory after at least one cytarabine/anthracycline containing induction regimen. Arm B patients will receive Cytarabine intravenously at 1 gm/m2 IV daily for 6 doses in combination with escalating doses of RO5045337 administered orally beginning at 1000 mg/d for 5 days (QD or 500 mg BID if patient cannot tolerate multi-tablet dosing). Each arm will escalate separately.
   c. **Contact:** Briana Shields at 877-656-7116 or briana.shields@jefferson.edu

2. New Metastatic Pancreatic Clinical Trial Announcement: A Phase I-II Open Label Study to Assess the Efficacy and Safety of Gemcitabine + nab-Paclitaxel (Abraxane®) With or Without ODSH (2-0, 3-0 desulfated heparin) as First Line Treatment of Metastatic Pancreatic Cancer
   a. **Eligibility:** Patients must have histologically confirmed adenocarcinoma of the pancreas that is metastatic and for which potential curative measures, such as resection of an isolated metastasis, are not available. Patients with islet cell neoplasms
are excluded. Patients must have measurable disease. Patients who have received radiotherapy or chemotherapy as adjuvant or neoadjuvant therapy for locally advanced disease six months or more prior to enrollment into this study are eligible.

b. **Study Design:** Open label, randomized study with two arms: **Treatment A:** 25 subjects: Nab-paclitaxel + Gemcitabine + ODSH: Nab-paclitaxel at a dose of 125 mg/m2 administered IV over 30 minutes followed by gemcitabine IV 1000 mg/m2 over 30 minutes. Nab-paclitaxel and gemcitabine will be given weekly for 3 weeks followed by one week of rest. ODSH IV bolus at 4mg/m2 will be administered immediately after the completion of gemcitabine administration. ODSH 48-hour IV continuous infusion at .375 mg/kg/h should be started immediately after the ODSH bolus has been administered. **Treatment B:** 25 subjects: Nab-paclitaxel + Gemcitabine: Nab-paclitaxel at a dose of 125 mg/m2 administered IV over 30 minutes followed by gemcitabine IV 1000 mg/m2 over 30 minutes. Nab-paclitaxel and gemcitabine will be given weekly for 3 weeks followed by one week of rest.

*subjects randomized to the ODSH arm must be started on a Monday or Wednesday due to Heparin/PF4 antibody and Anti-Factor Xa processing.

c. **Contact:** Deborah Kilpatrick at 877-656-7115 or deborah.kilpatrick@jefferson.edu

---

**Now Open to Network Participation:**

**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)*

**Pending Studies for Network Participation:**

**N0949,** *Randomized Phase III Trial of mFOLFOX7 or XELOX Plus Bevacizumab Versus 5-Fluorouracil/Leucovorin or Capecitabine Plus Bevacizumab as First-line Treatment in Elderly Patients with Metastatic Colorectal Cancer*

**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*
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

RTOG1119, Phase II Randomized Study Of Whole Brain Radiotherapy In Combination With Concurrent Lapatinib In Patients With Brain Metastasis From HER2-Positive Breast Cancer- A COLLABORATIVE STUDY OF RTOG AND KROG

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:
S1007- Revision #4  R0937- Amend
S0931- Revision #1  E2408- Update #4
E2208- Addendum #5  JOG61- Amend
R1012  R0813- Amends #4/5
R0815- Amend #3  E2809- Amend #4
R0912- Amend #4  R1021- Amend #2 re- consent
R1106-new study  E1609- Addendum #5
R1016- Amend #2  S0518- Closure

*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:
Mandatory electronic submission of CALGB legacy data forms:
Beginning October 1, 2012, the Alliance will require that all data forms for legacy CALGB studies available in electronic format are submitted electronically using the “Print and/or Submit to CALGB” button located at the bottom of each form. After September 30, only amended forms and supporting documentation will be accepted by fax or surface mail. Data not sent electronically will not be entered and will be returned to the site. As with any CALGB form submission, please print a copy of the form for your records. Additional information about this policy and instruction for using E-Submit is available at: https://www.calgb.org/Private/COOP_Groups/CALGB/resources/cra/cra_documents/ESubmit_JA_09252007.pdf

Reporting of Pregnancies in AdEERS: Effective immediately, the NCI requires the reporting of all pregnancies and outcomes of pregnancies in female subjects or female partners of male subjects enrolled on protocols utilizing an investigational agent to be reported via AdEERS. This applies to all protocols activated after March 28, 2011, and ongoing protocols ONLY if the reporting of a pregnancy is already a requirement.

When submitting AdEERS reports for pregnancy or outcome of a pregnancy, the CTEP 'Pregnancy Information Form' should be completed and faxed along with any additional medical information CTEP (301-230-0159). This form is available on CTEP's website: (http://ctep.cancer.gov/protocolDevelopment/electronic_applications/docs/PregnancyReportForm.pdf)
Please consult your IRB regarding the process of collecting medical information on a pregnant partner of a male subject and a fetus/newborn.

C10403, *An Intergroup Phase II Clinical Trial for Adolescents and Young Adults with Untreated Acute Lymphoblastic Leukemia (ALL)*, has met its accrual goal and has permanently closed to accrual.

Please contact Joshua Schoppe with any CTSU related issues.

**ECOG Update:**

**ECOG-ACRIN Members and Constituents:** The ECOG-ACRIN Cancer Research Group is debuting a new digital newsletter this week. Visit the ECOG-ACRIN website via the link below to read the latest organizational news and information: [http://ecog-acrin.org/news-and-info/newsletters](http://ecog-acrin.org/news-and-info/newsletters)

**ECOG-ACRIN Fall Group Meeting - REGISTRATION NOW OPEN!!!**

Please use the follow link to register and download information for the upcoming ECOG Fall Group Meeting in Hollywood, FL on Friday, November 9, 2012 - Sunday, November 11, 2012: [https://www.regonline.com/ECOG_Fall2012](https://www.regonline.com/ECOG_Fall2012)

**ECOG Coordinating Center:** The ECOG Coordinating Center will be closed on Monday, October 8, 2012 in observance of Columbus Day. However, the Randomization Office will have staff available during normal business hours.

**The ECOG Data Monitoring Committee (DMC) met on September 27, 2012 to review all ongoing phase III studies coordinated by ECOG. Their recommendations have been posted on the ECOG website.**

[http://www.ecog.org/ecoginst/notices/ECOG_DMC_20120927.PDF](http://www.ecog.org/ecoginst/notices/ECOG_DMC_20120927.PDF)
**E2208**, Randomized Phase II Study of Paclitaxel With or Without the Anti-IGF-IR mAb Cixutumumab (IMC-A12) as Second Line Treatment for Patients With Metastatic Esophageal or GE Junction Cancer, will close to accrual on October 15, 2012, effective at 5pm. This study will terminate as it has reached its accrual goal.

Please contact Joshua Schoppe with any ECOG related issues.

**NSABP Update:**

**B-43:** A Phase III Clinical Trial Comparing Trastuzumab Given Concurrently with Radiation Therapy and Radiation Therapy Alone for Women with HER2-Positive Ductal Carcinoma In Situ Resected by Lumpectomy, A B-43 email blast dated September 21, 2012 can be found at this link: [https://members.nsabp.pitt.edu/B43_Email_Blast_0912.pdf](https://members.nsabp.pitt.edu/B43_Email_Blast_0912.pdf)

This communication contains important and helpful trial coordination details.

**Changes in Data Collection Procedures:** There will be changes in data collection procedures for the following protocols beginning October 1, 2012: B-30, B-31, B-32, B-34 and C-07. Please go to this link to view the details: [https://members.nsabp.pitt.edu/Changes_in_Data_Collection_Procedures.pdf](https://members.nsabp.pitt.edu/Changes_in_Data_Collection_Procedures.pdf)

**RTOG Update:**

The current accrual listed on the RTOG Website on the Protocol Information Page for RTOG 1010 reflects the total accrual to STEP 1 (HER2 screening). This study will continue to accrue until 160 cases have completed STEP 2 registration. The current accrual to RTOG 1010 - STEP 2 registration is 44 as of 9/30/12. Please continue to screen your patients for this very important study and we appreciate all of your efforts.
RTOG Data Management is pleased to announce that all data queries (Z1’s and ZV’s) that were previously sent via regular mail will be sent via electronic email as of Monday, October 1, 2012. If the response to the query cannot be addressed via Revisit (RTOG’s online data collection form correction system), please document your response on the query and email it to rtog-queries@acr.org.

**RTOG 0929, Randomized Phase I/II Study of ABT-888 in Combination with Temozolomide in Recurrent (Temozolomide Resistant) Glioblastoma** - Accrual of new patients is suspended immediately and cannot resume until the IRB of record has reviewed and approved a CTEP-approved amendment created in response to this Action Letter. RTOG will submit an amendment to CTEP in the near future and will broadcast it to sites upon CTEP approval.

**Jefferson Oncology Group (JOG) Update:**
Please contact Joshua Schoppe if you have a JOG related question.

**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:**
- **Annual JOG Investigators Meeting**, Loews Hotel - 33rd floor: Philadelphia October 4, 5:30pm
- **ECOG-ACRIN Semiannual Meeting**, Hollywood, FL: November 9-11
- **CRA Quarterly Meeting**, Jefferson Campus: December 19
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