The Clinical Research E-News

Volume 4: ISSUE 9: December 6, 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 Bladder Cancer Clinical Trial Announcement: Phase II Trial of Neoadjuvant Dose Dense Gemcitabine and Cisplatin in Muscle Invasive Bladder Cancer
   a. Eligibility: Patients must have histologically confirmed urothelial carcinoma of the bladder or urethra. Patients with urothelial carcinoma of the prostatic urethra only may be included at PI discretion. T-stage must be T2 to T4a. Patients with clinical N0 disease or cN1 disease are eligible for the study. Patients should have no radiographic evidence of metastatic disease. Mixed histologies which are predominantly urothelial, such as with squamous or micropapillary differentiation, are allowed so long as there is no component of small cell histology. Histology must be confirmed by a pathologist at an institution involved in this study. Patients must be candidates for radical cystectomy with the goal of cure. Patients who have undergone prior radiation to greater than or equal to 25% of the bone marrow within the past year are excluded due to risk of life threatening myelosuppression. Patients who have received any previous systemic chemotherapy or radiation therapy for urothelial carcinoma within 1 year of study entry are ineligible.
   b. Treatment: Every 2 weeks x 3 cycles Gemcitabine 1200mg/m2 Cisplatin 70 mg/m2 Pegfilgrastim 6 mg
   c. Contact: Debbie Kilpatrick at 215-955-0017 or deborah.kilpatrick@jefferson.edu

2. New Breast Cancer Clinical Trial Announcement: LUX-Breast 1: An Open Label, Randomized Phase III Trial of BIBW 2992 and Vinorelbine versus Trastuzumab and Vinorelbine in Patients with Metastatic Her-2 Over expressing Breast Cancer Failing One Prior Trastuzumab Treatment
a. **Eligibility:** Histologically confirmed diagnosis of HER2-overexpressing breast cancer. Stage IV metastatic disease. Must not have received and failed 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. Prior treatment with EGFR/HER2-targeted small molecules or antibodies other than trastuzumab is not allowed. Prior treatment with vinorelbine is also not allowed.

b. **Treatment:** **Arm A:** Patients receive BIBW 2992 tablets once daily combined with weekly intravenous infusion of vinorelbine. **Arm B:** Patients receive weekly intravenous infusion of trastuzumab and vinorelbine.

c. **Contact:** Melisa Mordenti at 215-955-8979 or Melisa.Mordenti@jefferson.edu

3. **New Melanoma Cancer Clinical Trial Announcement:** *Phase I Study of Ipilimumab Combined with Whole Brain Radiation Therapy or Radiosurgery for Melanoma Patients with Brain Metastases*

   a. **Eligibility:** A pathological diagnosis of melanoma is required, from either the primary or a metastasis. This also includes uveal melanoma. A radiological diagnosis (CT or MRI) of one or more brain metastases is required. Patient with leptomeningeal carcinomatosis is allowed in the WBRT arm. Resolution of all acute toxic effects of prior chemotherapy or radiotherapy or surgical procedures to NCI CTCAE Version 4.0 grade <= 1. Patient with leptomeningeal carcinomatosis are excluded If patients are receiving chemotherapy or other investigational drugs (including Ipilimumab), they must be discontinued 4 weeks prior to enrollment.

   b. **Treatment:** This is an open label phase I multi-site clinical trial with two arms, representing single and fractionated radiation therapy. Within each arm the radiation dose is pre-determined and not escalated. Ipilimumab will be administered intravenously once every 3 weeks for a total of 4 times. Ipilimumab will be dose-escalated independently in each arm. There is no intra-patient dose escalation. The starting dose of 3 mg/kg is currently FDA approved dose for Ipilimumab. And final dose level of ipilimumab is 10 mg/kg.

c. **Contact:** Kelly Shipman at 215-955-8619 or Kelly.Shipman@jeffersonhospital.org

**Now Open for Network Participation:**
**NCCTG0148,** *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*

**Pending Studies for Network Participation:**
**CALGB80702**, *A phase III trial of 6 versus 12 treatments of adjuvant FOLFOX plus celecoxib or placebo for patients with resected stage III colon cancer*

**SWOG1207**, *Phase III Randomized, Placebo-Controlled Clinical Trial Evaluating the Use of Adjuvant Endocrine Therapy +/- One Year of Everolimus in Patients with High-Risk, Hormone Receptor-Positive and HER2/neu Negative Breast 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](mailto:Joshua.schoppe@jeffersonhospital.org).
The E3805 amendment requires a re-consent of all patients currently receiving treatment or who have finished being treated in the last 30 days.

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

CTSU Update:
Future of CTSU: The CTSU trials portfolio has undergone a number of changes since the program launched in September 1999, expanding to include coordination of services for a broader range of trials and collaborators. The CTSU’s initial focus was on phase 3 adult Cooperative Group treatment trials in the most common cancer types. While these will continue to be a large portion of the trial offerings (53% of the current menu of trials active or under development), the direction of the CTSU menu has gone beyond the phase 3 treatment genre to incorporate trials in earlier phases and less common disease types as well as trials that employ new approaches to cancer control, prevention, and treatment. Over the past several years the CTSU has supported an increasing number of early phase trials, including seven Phase 2 Consortia (P2C) studies with enrollment restricted to P2C sites. Approximately 71% of accruals to these P2C trials (512/726) are attributed to non-lead P2C sites participating through the CTSU. Look for more phase 2 studies on CTSU!

CTSU Help Desk: A reminder – the Help Desk hours now extend to 8:30 pm (Eastern Time). Don’t hesitate to call in the evening if you need support.
TAILORx Follow-up Form Submission: Refer to the TAILORx/ PACCT-1 Site memorandum “TAILORx Follow-Up Form Reminders” dated October 22nd, 2012 on the CTSU PACCT-1 document page for details on appropriate submission of follow-up data, inclusive of Lost-to-Follow-up patients, withdrawn patients, and deceased patients.

S1207, Phase III Randomized, Placebo-Controlled Clinical Trial Evaluating the Use of Adjuvant Endocrine Therapy +/- One Year of Everolimus in Patients with High-Risk, Hormone Receptor-Positive and HER2/neu Negative Breast Cancer, has been granted the status of “Group Activation” by CTSU. This study will open to accrual shortly. If your site is interested, please submit your site’s regulatory paperwork at your earliest convenience.

Please contact Joshua Schoppe with any CTSU related issues.

ECOG Update:
The November issue of “News from ECOG-ACRIN” is now available. We invite you to visit the ECOG-ACRIN website via the link below to read the latest organizational news and information: http://archive.constantcontact.com/fs156/1110677545555/archive/1111468565907.html All members and constituents are invited to sign up to receive future newsletters directly via email by completing a brief, confidential registration form on the ecog-acrin.org website. A shortcut to the sign-up form is accessible at the following link: http://ecog-acrin.org/newsletter-signup

Performance Monitoring: The next Performance Monitoring data cut-off date of December 31, 2012 is approaching. Any data received on or before December 31, 2012 will be included in the upcoming Performance Monitoring. Data received after December 31, 2012 will be considered late. It is important to remember that data timeliness will be evaluated by assessing 2 components: The rate of CRF submitted and the rate of survival follow-up. To avoid
penalties, each evaluable ECOG institution must have a score of 90% or better on each component.

Please contact Joshua Schoppe with any ECOG related issues.

NSABP Update:
The deadline for **NSABP registration** for the NRG Group Meeting is December 21st. Hotel rooms are filling fast, so you are encouraged to register as soon as possible.  [http://www.meetingsinfo.com/HotelInformation/san-diego-13/home.html](http://www.meetingsinfo.com/HotelInformation/san-diego-13/home.html)

The NSABP has announced endorsement of the following protocols:
**PROSPECT (N0148)** - the intergroup trial for locally advanced rectal cancer
**RTOG 1005** - a trial comparing accelerated vs standard whole breast radiation for early stage breast cancer

**NSABP P-5**: *Statin Polyp Prevention Trial in Patients with Resected Colon Cancer*: An e-mail blast dated November 29, 2012 contains important information regarding this trial, including a coming amendment to expand eligibility to include stages 0 and 3.

**Holiday Schedule**
There are documents posted for guidance through the coming holidays:
*For Clinical Coordinating Division:*
[https://members.nsabp.pitt.edu/CCD_Holiday_Memo_111212.pdf](https://members.nsabp.pitt.edu/CCD_Holiday_Memo_111212.pdf)

*For Biostatistical Center:*
[https://members.nsabp.pitt.edu/Holiday_Schedule_2012.pdf](https://members.nsabp.pitt.edu/Holiday_Schedule_2012.pdf)

*For scheduling of treatment:*
[https://members.nsabp.pitt.edu/Scheduling_Therapy_During_Holidays_2012.pdf](https://members.nsabp.pitt.edu/Scheduling_Therapy_During_Holidays_2012.pdf)
Please contact Vicki Squire with any NSABP related issues at 215-503-5641.

**RTOG Update:**  
**RTOG 1203, A Randomized Phase III Study Of Standard vs. IMRT Pelvic Radiation For Post-Operative Treatment Of Endometrial And Cervical Cancer (TIME-C),** has been approved for group activation. This trial is not yet open to patient enrollment. If you are interested in opening this trial at your institution, please contact Josh Schoppe.

**RTOG 1122, Phase II Double-Blinded Placebo-Controlled Study of Bevacizumab with or without AMG 386 in Patients With Recurrent Glioblastoma or Gliesarcoma,** is temporarily closed to accrual until the phase II design is finalized. Expect it to re-open sometime in December 2012.

The January 2013 RTOG semiannual meeting will be held in conjunction with the semiannual meetings of our NRG Oncology partners, NSABP and GOG. Many scientific sessions and committee meetings will be joint sessions and are highlighted in red on our agenda. RTOG members are welcome to attend the GOG and NSABP open sessions and links to their agendas can be found on our website. Note however that a separate registration may be required if you wish to attend GOG or NSABP sessions. Hotel reservations must be made by December 28th to ensure availability.

Investigators participating in **RTOG 1021/ACOSOG Z4099, A Randomized Phase III Study of Sublobar Resection (+/- Brachytherapy) versus Stereotactic Body Radiation Therapy in High Risk Patients with Stage I Non-Small Cell Lung Cancer (NSCLC):** ACOSOG (the coordinating group for this trial) has developed laminated pocket cards describing the trial for use with patients in the clinic. Sites can request a set of the cards, by e-mailing Susan C. Budinger, Clinical Trials Manager, susan.budinger@duke.edu. The e-mail should include the street address to which the cards should be mailed.
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:
CRA Quarterly Meeting, Jefferson Campus: December 19, 2012
NRG meeting January, San Diego, CA: Jan 24-27, 2013
CRA Quarterly Meeting, Jefferson Campus: March 13, 2013
ECOG-ACRIN Meeting, Atlanta, GA: May 14-16, 2013
CRA Quarterly Meeting, Jefferson Campus: June 26, 2013
CRA Quarterly Meeting, Jefferson Campus: September 11, 2013
ECOG-ACRIN Meeting, Fort Lauderdale, FL: November 15-17, 2013

CRA Quarterly Meeting, Jefferson Campus: December 18, 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