The Clinical Research E-News

Volume 3: ISSUE 3: February 16, 2011

Now Open:
RTOG 0631, Phase II/III Study of Image-Guided Radiosurgery/SBRT for Localized Spine Metastasis

RTOG 1010, A Phase III Trial Evaluating the Addition of Trastuzumab to Trimodality Treatment of HER2-Overexpressing Esophageal Adenocarcinoma

Coming soon:
CALGB 90802, Randomized Phase III trial comparing everolimus plus placebo versus everolimus plus bevacizumab for advanced renal cell carcinoma progressing after treatment with tyrosine kinase inhibitors

E1608, A Phase II Trial of GM-CSF Protein Plus Ipilimumab in Patients with Advanced Melanoma (Incorrectly listed as now open in the last issue, still pending).

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 (Incorrectly listed as now open in the last issue, still pending).

E2408, A 3-Arm Randomized Phase II Trial of Bendamustine-Rituximab (BR) Followed by Rituximab vs Bortezomib-BR (BVR) Followed by Rituximab vs BR Followed by Lenalidomide/Rituximab in High Risk Follicular Lymphoma
**E3108**, A Phase II Prospective Trial Correlating Progression Free Survival with CYP2D6 Activity in Patients with *Metastatic Breast Cancer* Treated with Single Agent Tamoxifen.

**E7208**, A Randomized Phase II Study of Irinotecan and Cetuximab with or without the Anti-angiogenic Antibody, Ramucirumab (IMC-1121B), in Advanced, K-ras Wild-type *Colorectal Cancer* Following Progression on Bevacizumab-Containing Chemotherapy.

**NSABP C-11**, A Phase III Study Evaluating the Role of Preoperative Chemotherapy and Bevacizumab in Patients with Potentially *Resectable Hepatic Colorectal Metastases*

**NSABP B-47**, A Randomized Phase III Trial of Adjuvant Therapy Comparing Chemotherapy Alone (Six Cycles of TC or Four Cycles of AC Followed by Four Cycles of Weekly Paclitaxel) to Chemotherapy Plus Trastuzumab in Women with Node-Positive or High-Risk Node-Negative HER2-Normal Invasive *Breast Cancer*

**RTOG 0839**, Randomized Phase II Study of Pre-operative Chemoradiotherapy +/- Panitumumab followed by Consolidation Chemotherapy in Potentially Operable Locally Advanced (Stage IIIA, N2+) *Non-Small Cell Lung Cancer*

**RTOG0912**, A Randomized Phase II Study of Concurrent Intensity Modulated Radiation Therapy (IMRT), Paclitaxel and Pazopanib/Placebo, for the Treatment of Anaplastic *Thyroid Cancer*

**RTOG 0929**, A Randomized Phase I/II Study of ABT-888 in Combination with Temozolomide in Recurrent (Temozolomide Resistant) *Glioblastoma*
RTOG 1008, *A Randomized Phase II Study of Adjuvant Concurrent Radiation and Chemotherapy Versus Radiation Alone in Resected High-Risk Malignant Salivary Gland Tumors*

If your site is interested in participating in any of these studies please contact Rolma Gano at 215-955-7954 or Rolma.gano@jeffersonhospital.org.

**Regulatory Update:**

- CALGB 40502
- **RTOG 0617 amendment #7**
- RTOG 0825 amendment #4
- RTOG 0522 amendment #5
- SWOG 0819 Revision #8
- JOG 57
- RTOG 0524
- RTOG 0831
- NSABP B-38 amendment #4
- GOG 249 revision #7

*Patients on R0617 who are currently being treated on study or within 30 days of receiving protocol related treatment should be re-consented.*

Please contact Rolma Gano with any repository or other regulatory related questions.

**CTSU Update:**

Please contact Joshua Schoppe with any CTSU related issues at 215-955-0448 or Joshua.Schoppe@jeffersonhospital.org

**ECOG Update:**

**E5202, A Randomized Phase III Study Comparing 5-FU, Leucovorin and Oxaliplatin versus 5-FU, Leucovorin, Oxaliplatin and Bevacizumab in Patients with Stage II Colon Cancer at High Risk for Recurrence to Determine Prospectively the Prognostic Value of Molecular Markers**, closed to accrual on February 11, 2011.
**E5103, A Double-Blind Phase III Trial of Doxorubicin and Cyclophosphamide Followed by Paclitaxel with Bevacizumab or Placebo in Patients with Lymph Node Positive and High Risk Lymph Node Negative Breast Cancer**, will close to new Step 1 accrual on February 28, 2011. Patients randomized to Arm C who meet the protocol requirements for treatment completion may continue to register to Step 2. Patients currently on this study should be followed according to the protocol. Quality of Life evaluations should continue as specified in the protocol.

The **ECOG Coordinating Center** will be closed on Monday, February 21, 2011, in observance of Presidents' Day. However, the Randomization Office will have staff available during normal business hours.

If you have an ECOG related question please contact Joshua Schoppe.

**NSABP Update:**

**C-11, A Phase III Study Evaluating the Role of Perioperative Chemotherapy in Patients with Potentially Resectable Hepatic Colorectal Metastases:** Amendment #1 has been released. It removes bevacizumab from the treatment schema. The trial will open soon at TJUH under this amendment.

**B-44-I BETH, A Multicenter Phase III Randomized Trial of Adjuvant Therapy for Patients with HER2-Positive Node-Positive or High Risk Node-Negative Breast Cancer Comparing Chemotherapy Plus Trastuzumab with Chemotherapy Plus Trastuzumab Plus Bevacizumab:** Amendment #2, recently released, adds a brief consent form addendum containing updated information on the use of bevacizumab in the adjuvant setting for colorectal cancer. All patients will be required to sign the addendum when it is approved and posted on our repository.
Below is the link for the Clinical Coordinating Connection, featuring NSABP B-43. Please utilize this document if you have B-43 open.

NSABP group meeting is March 24-27, 2011 in Boca Raton, FL. Go to the following link for meeting information and registration.
http://www.meetingsinfo.com/hotelinformation/Boca_Raton/home.html. Please note the deadline for registration is Monday, February 21st. Rooms at the resort are filling up quickly, so register ASAP.

If you have an NSABP related question please contact Vicki Squire at vicki.squire@jeffersonhospital.org or at 215-503-5641.

RTOG Update:
RTOG 0517, Randomized Phase III Trial To Evaluate Radiopharmaceuticals And Zoledronic Acid In The Palliation Of Osteoblastic Metastases From Lung, Breast, And Prostate Cancer, will close to patient accrual at 5 PM EST, Friday, February 25, as the study will not meet design requirements for the number of skeletal related events needed for the protocol-specified statistical analysis. A modified analysis plan is being developed based on the current patient enrollment. Institutions should continue to follow the treatment/follow-up guidelines provided in the protocol.

RTOG 0834, Phase III Trial on Concurrent and Adjuvant Temozolomide Chemotherapy in Non-1p/19q Deleted Anaplastic Glioma, just released Amendment #2 which include the addition of a screening consent for 1p19q deletion status for sites accruing to both NCCTG N0577 and RTOG 0834; and the ability for sites to submit slides for tissue analysis if a block is not available.
RTOG 0617, *A Randomized Phase III Comparison of Standard-Dose (60 Gy) Versus High-Dose (74 Gy) Conformal Radiotherapy with Concurrent and Consolidation Carboplatin/Paclitaxel +/- Cetuximab in Patients With Stage IIIA/IIIB Non-Small Cell Lung Cancer*, has undergone changes to the protocol and consent form with approval of Amendment #7. All patients currently being treated or within 30 days of being treated will need to be re-consented. The changes occurred on page 7, 11 and 15 of the new consent.

Please contact Joshua Schoppe or Vicki Squire with any RTOG related issues.

**Jefferson Oncology Group (JOG) Update:**
If your site has any JOG inquiries please contact either Joshua Schoppe or Vicki Squire.

**Jefferson Kimmel Cancer Center Network Homepage:**

**Upcoming Events:**
- **CRA Quarterly Meeting**, Philadelphia, PA: March 16th
- **NSABP Group Meeting**, Boca Raton, FL: March 24-27
- **JKCCN/KCC All Day Annual Scientific and Clinical Symposium Topic: Breast Cancer**, Philadelphia, PA: April 8th
- **JOG Annual Investigators Meeting**: Philadelphia, PA: April 11th
  Topic: Treatment in Thoracic Malignancies
- **ECOG Semiannual Meeting**, Boston, MA: June 10-12
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