The Clinical Research E-News

Volume 3: ISSUE 4: March 2, 2011

Now Open:
E1608, A Phase II Trial of GM-CSF Protein Plus Ipilimumab in Patients with Advanced Melanoma

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

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

E2108, A Randomized Trial of the Value of Early Local Therapy for the Intact Primary Tumor in Women with Metastatic Breast Cancer

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

E2906, Phase III randomized trial of Clofarabine as induction and post-remission therapy vs. standard Daunorubicin and Cytarabine induction and intermediate dose Cytarabine post remission therapy, followed by Decitabine maintenance vs. observation in newly diagnosed acute myeloid leukemia in older adults (age >60 yrs)
**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 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*

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

**RTOG 0724**, *Phase III Randomized Study of Concurrent Chemotherapy and Pelvic RT With or Without Adjuvant Chemotherapy in High-Risk Patients with Early-Stage Cervical Carcinoma Following Radical Hysterectomy*

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:
ACOSOG Z1071 amendment #2 R0436
E1508 ADDENDUM 6 & 7 C80405
E1305 ADDENDUM #5 E1608 NEW STUDY LETTER
E5501 FINAL LETTER E2208 NEW STUDY LETTER
R9712 FINAL LETTER SELECT FINAL LETTER
R9708 FINAL LETTER SEE (SELECT ANCILLARY STUDY) FINAL LETTER
R0625 FINAL LETTER

Patients on E1508 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:**
**E1508,** *A Randomized Phase II Study of Cisplatin and Etoposide In Combination with Either Hedgehog Inhibitor GDC-0449 or IGF-1R MOAB IMC-A12 for Patients with Extensive Stage Small Cell Lung Cancer (E1508),* has a recent TJUH IRB mandated re-consent with the approval of addendums #6-7. These changes to the consent include changes to the study chart on page 5 and 6 as well as risks to GDC-0449 on pages 12-13. **All patients currently receiving protocol related treatment or have received treatment within the last 30 days will need to be re-consented.**

**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,* has closed to accrual effective on February 28, 2011. Thank you for your diligent hard work in accruing to this trial. Our network accrued 57 patients to trial since its opening in May, 2008.

**ECOG Spring Meeting** being held in Boston, MA from June 10th-12th. Registration for the meeting is now OPEN and will be done completely online. To register for the Group Meeting, please use the following link: [https://www.regonline.com/ECOG_spring2011](https://www.regonline.com/ECOG_spring2011)

**Performance Monitoring:** The next Performance Monitoring data cut-off date of March 31, 2011 is approaching. Any data received on or before March 31
will be included in the upcoming Performance Monitoring. Data received after March 31 will be considered late. It is important to remember that data timeliness will be evaluated by assessing two 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.

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

**NSABP Update:**
**B-42, A Clinical Trial to Determine the Efficacy of Five Years of Letrozole Compared to Placebo in Patients Completing Five Years of Hormonal Therapy Consisting of an Aromatase Inhibitor (AI) or Tamoxifen Followed by an AI in Prolonging Disease-Free Survival in Postmenopausal Women with Hormone Receptor Positive Breast Cancer:** Frequently Asked Questions (FAQs) have been revised to correspond to the B-42 Protocol Version Date: December 7, 2010. If you have any questions about the revised FAQs or clinical questions about the B-42 Protocol, contact the Clinical Coordinating Division at 1-800-477-7227 or email ccd@nsabp.org

In observance of the University of Pittsburgh Spring Holiday on Friday, March 11, 2011, the NSABP Biostatistical Center offices will be closed. Patient entry for each NSABP protocol will be available as specified in the Patient Entry Guidelines.

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

**RTOG Update:**
**RTOG Launches New Web Site:** The wait is finally over – RTOG has launched its redesigned Web.
New features include:

- Protocol Table – Sort protocols by disease site, phase, or status. Click on the protocol number to view a Protocol Summary Page (http://www.rtog.org/ClinicalTrials/ProtocolTable.aspx)
- Protocol Summary Pages – Each protocol has its own summary page featuring: A summary of the primary objective and patient population, the target accrual and the number accrued, the sites with IRB approval, headquarters contacts for the protocol, protocol forms, broadcast announcement archive, case credits and reimbursement information, regulatory Information and current version date of the protocol

Patient enrollment and data entry is still accessed via the Data Center Logon button at the top of the Home page. If you experience any problems please contact the web support team at: websupport@acr.org.

**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 closed to patient accrual on February 25th, as the study will not meet design requirements for the number of skeletal related events needed for the protocol-specified statistical analysis.

**RTOG Elects New Vice-Chairs and Members-at-Large:** Maria Werner-Wasik, M.D., professor in the department of radiation oncology at Thomas Jefferson University in Philadelphia and an institutional RTOG principal investigator, was elected as the RTOG Vice-Chair for Publications. Dr. Werner-Wasik is a member of the RTOG Lung Cancer Steering Committee. Dr. Werner-Wasik will chair the RTOG Publications Committee which is responsible for the oversight of publication quality and timeliness of the results of the group’s trials. Join me in congratulating Dr. Werner-Wasik.

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:
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, 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
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