The Clinical Research E-News

Volume 5: ISSUE 1: January 10, 2013

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 Prostate Cancer Clinical Trial Announcement: Phase I Trial of High Dose Rate Brachytherapy Combined with Stereotactic Body Radiation Therapy for Intermediate Risk Prostate Cancer Patients

   a. Eligibility: Inclusion Criteria: Adenocarcinoma of the prostate with locally advanced prostate cancer without distant metastatic with intermediate risk disease defined as PSA between 10 and 20, Gleason score 7, or clinical stage T2b. Karnofsky Performance Status > 70. No history of previous pelvic irradiation. Exclusion Criteria: History of urological surgery or procedures predisposing to GU complications after radiation (will be determined by radiation oncologist), history of prior pelvic irradiation, documented distant metastatic disease or prior radical prostatectomy or cryosurgery for prostate cancer

   b. Treatment: Patients will be accrued in a standard 3+3 dose-escalation design during ongoing dose exploration. Dose escalation will continue until the maximum tolerated dose (MTD), the appropriate dose for Phase II study. During dose exploration, cohorts of 3-6 patients will be treated as a cohort. The initial cohort will be treated at Dose Level 1. If 0/3 or 1/6 patients initially treated at Dose Level 1 have DLT at the first treatment cycle, the SBRT dose per fraction will be escalated, and the next cohort of 3-6 patients will be treated at Dose Level 2. In like manner, depending on cohort toxicity, the SBRT dose/fraction will be escalated as needed to determine the highest level for which 2 of 6 patients has DLT. The dose level below this level will be declared the MTD. Dose level 4 will be the highest dose for this study and no further dose escalation will be performed. We will allow for an expansion cohort of an additional 30 patients at the MTD dose level.

   c. Contact: Kelly Shipman at 215-955-8619 or Kelly.Shipman@jeffersonhospital.org
Now Open for Network Participation:
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

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.

Regulatory Update:
R0232-Amend- new PI
R0933-Amend-closed to accrual
R1119-New Study

E1609-Amend pt. letter
B-46-I- Amend #5

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

NCI Revises Clinical Trials Audit Guidelines:
Effective January 1, 2013, the National Cancer Institute’s Clinical Trials Monitoring Branch (CTMB) will institute guidelines revised in October 2012
for auditing of clinical trials for cooperative groups, community clinical oncology program research bases, and the Cancer Trials Support Unit (CTSU). Complete guidelines, along with other support materials, can be found on the NCI website:

http://ctep.cancer.gov/branches/ctmb/clinicalTrials/monitoring_coop_ccop_ctsu.htm

CTSU Update:

**Regarding Change in CTSU Patient Transfer Process:**

To support cross-organizational communication on subject transfers between sites and investigators, the CTSU will begin processing transfer requests for all studies in OPEN and for legacy studies for non-lead protocol organization (LPO) sites posted to the CTSU website beginning Tuesday, January 8, 2013. The table below this text outlines transfer processing responsibilities.

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<thead>
<tr>
<th>Enrollment Initiated/Protocol Owner</th>
<th>Applies to:</th>
<th>Transfer Request Submitted to:</th>
</tr>
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<tbody>
<tr>
<td>Transfers for all OPEN Protocols</td>
<td>All Sites</td>
<td>Submit transfer documents to CTSU</td>
</tr>
<tr>
<td>Transfers for GOG Protocols</td>
<td>All Sites</td>
<td>GOG online transfer system</td>
</tr>
<tr>
<td>Non OPEN / Non Lead Group Transfers</td>
<td>CTSU Sites</td>
<td>Submit transfer documents to CTSU</td>
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**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:

**E3611**, *A Randomized Phase II Study of Ipilimumab at 3 mg/kg or 10 mg/kg Alone or in Combination with High Dose Interferon-α in Advanced Melanoma*, was activated on December 27, 2012. This study is available only to ECOG members. Please contact Josh Schoppe if your site is interested in participating.

**E2905**, *Randomized Phase III Trial Comparing the Frequency of Major Erythroid Response (MER) to Treatment with Lenalidomide (Revlimid®) Alone and in Combination with Epoetin Alfa (Procrit®) in Subjects with Low- or Intermediate-1 Risk MDS and Symptomatic Anemia*, has been suspended to new accrual effective December 29, 2012. Due to changes in the supply of Epoetin Alfa for E2905, new accrual has been suspended. E2905 will re-open to new accrual once an amendment is processed to allow patients registered after December 31, 2012 to receive Erythropoietin, recombinant human (Epoetin alfa, Procrit-Ortho-Biotech) commercially.

Please contact Joshua Schoppe with any ECOG related issues.

NSABP Update:

**P-5: Statin Polyp Prevention Trial in Patients with Resected Colon Cancer**

Amendment #3 which adds stages 0 and III to the eligibility criteria has been activated and submitted to the IRB for approval. Please note the amendment generated revised patient-directed brochures, forms and a physician pocket card. These may not be used until IRB approved. Approval of the amendment is expected in early February, so screening for stages 0 and III can begin.

**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**:

An email blast focused on this trial was posted on 12/12/12: [https://members.nsabp.pitt.edu/B43_Email_Blast_1212.pdf](https://members.nsabp.pitt.edu/B43_Email_Blast_1212.pdf)
**Closed to Follow Up**
Effective December 31, 2012 the following NSABP protocols were closed to follow up: **B-30, B-34, C-07, C-08, C10**. The final reports for these trials are being submitted to the IRB. "Dear Patient" letters and closure approval letters will be posted on our repository in the coming weeks. Many thanks to all coordinators who have been committed to submitting data for these trials. Please use the approved patient letter to communicate appreciation to all the patients for their very important participation.

Please note there will be limited coverage of the NSABP Clinical Coordinating Division (CCD) January 23-28 due to the group meeting. Details are at [https://members.nsabp.pitt.edu/Treatment_News.asp](https://members.nsabp.pitt.edu/Treatment_News.asp)

Please contact Vicki Squire with any NSABP related issues at 215-503-5641 or [Vicki.squire@jeffersonhospital.org](mailto:Vicki.squire@jeffersonhospital.org)

**RTOG Update:**
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. The meeting will take place in San Diego, CA from Jan 24-27.

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/](http://www.kimmelcancercenter.org/jkccn/) This page contains links to the Remote Access Portal as well as the clinical trial document repository.
Upcoming Events:
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