The Clinical Research E-News

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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 Head and Neck Squamous Cell Carcinoma Clinical Trial Announcement: A randomized, open label, phase III study to evaluate the efficiency and safety of oral afatinib (BIBW 2992) versus intravenous MTX in patients with recurrent and or metastatic head and neck squamous cell carcinoma who have progressed after platinum based therapy
   a. Eligibility: Histologically or cytologically confirmed squamous cell carcinoma of the oral cavity, oropharynx, hypopharynx or larynx, which has recurred/metastasized and is not amenable for salvage surgery or radiotherapy. Documented progressive disease based on investigator assessment according to Response Evaluation Criteria in Solid Tumors (RECIST) following receipt of cisplatin and/or carboplatin based regimen (minimum doses described below) administered for recurrent and/or metastatic disease independent of whether patient progressed during or after platinum based therapy.
   b. Treatment: Arm 1 Afatinib – starting dose (oral) 40 mg daily. Escalation to 50mg/m2 and or to reduce to 40, 30 then 20 mg/m2 to absence or presence of drug related adverse events. Arm B- MTX – 40 mg/m2 weekly with an option to escalate to 50mg/m2 and or to reduce to 40, 30 then 20 mg/m2 to absence or presence of drug related adverse events
   c. Contact: Debbie Kilpatrick at 215-955-0017 or deborah.kilpatrick@jefferson.edu

2. New Prostate Cancer Clinical Trial Announcement: STRIVE: A Multicenter, Phase 2, Randomized, Double-blind, Efficacy and Safety Study of Enzalutamide vs. Bicalutamide in Men with Prostate Cancer who have Failed Primary Androgen Deprivation Therapy
a. **Eligibility:** Ongoing androgen deprivation therapy for recurrent prostate cancer with a GnRH analogue at a stable dose within 4 weeks of randomization; Serum testosterone ≤ 50 ng/ml; Progressive disease defined as at least ONE of the following: PSA progression defined as a minimum of 2 rising PSA levels with at least one week in between and a PSA ≥ 5 ng/ml at Screening OR a PSADT of ≤ 10 months with Screening PSA ≥ 2 ng/ml, Soft tissue progression on CT or MRI or Bone disease progression based on bone scan.

b. **Treatment:** Subjects will be randomly assigned to receive Enzalutamide (Xtandi) or Bicalutamide (Casodex) in a 1:1 allocation ratio until disease progression.

c. **Contact:** Christine Hubert at 215-955-9954 or christine.hubert@jefferson.edu

3. **New Ovarian Cancer Clinical Trial Announcement:** A Randomized, Open-Label, Phase 2 Study of the IDO Inhibitor, INCB024360 versus Tamoxifen for Subjects with Biochemical-Recurrent-Only Epithelial Ovarian Cancer, Primary Peritoneal Carcinoma, or Fallopian Tube Cancer Following Complete Remission with First-Line Chemotherapy

a. **Eligibility:** Female subjects age 18 years or older who have had histologically confirmed FIGO Stage III or IV EOC, PPC, or FTC; The subject must have had a complete response to a single, prior first-line regimen which must have been a platinum-containing regimen, and subject is currently in clinical and radiological remission based on Response Evaluation Criteria in Solid Tumors (RECIST 1.1) criteria; Subjects who received maintenance paclitaxel or bevacizumab are eligible for enrollment provided they have discontinued therapy at least 4 weeks from randomization for prior taxane or at least 8 weeks from prior bevacizumab.

b. **Treatment:** This is a randomized, open-label, Phase 2 study of INCB024360 versus tamoxifen in women with histologically confirmed Federation of International Gynecologists and Obstetricians (FIGO) Stage III or IV epithelial ovarian cancer (EOC), primary peritoneal cancer (PPC), or fallopian tube carcinoma (FTC)

c. **Contact:** Cynthia Perez at 877-656-7120 or Cynthia.perez@jefferson.edu

**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:
ECOG 2108- Amend update pt materials
RTOG 0539- close to accrual
RTOG 1005- Update #3
ECOG 1305- addendum #10
ECOG 5508-QA amend/amend #3
RTOG 0839- Amendment #3
ECOG 1505- Update #4
RTOG 1106- Amendment #1
NSABP – FB6 Amendment #3
RTOG 0938- Amend change PI
ECOG 3108- Closed out
ECOG 1505- Update #5
CALGB 90203- QA amend
Please contact Rashada Dawson at 215-955-2135 or Rashada.Dawson@jeffersonhospital.org with any repository related questions.

**CTSU Update:**

**S1007, A Phase III Randomized Clinical Trial of Standard Adjuvant Endocrine Therapy +/- Chemotherapy in Patients with 1-3 Positive Nodes, Hormone Receptor-Positive and HER2-Negative Breast Cancer with Recurrence Score (RS) of 25 or Less**, will close the Quality of Life and Economic Sub-study as it will have reached its original accrual goal effective on November 15, 2012. SWOG plans to evaluate the number of eligible patients and the adequacy of follow-up, and may issue a study revision to allow for more accrual if there are too few evaluable patients.

**S0500, A Randomized Phase III Trial to Test the Strategy of Changing Therapy Versus Maintaining Therapy for Metastatic Breast Cancer Patients Who Have Elevated Circulating Tumor Cell Levels at First Follow-up Assessment**, released a memo that the Cellsave tubes with lot number 119609 expired on November 6, 2012.

Please contact Joshua Schoppe with any CTSU related issues.

**ECOG Update:**

Please note the **ECOG Coordinating Center is closed** Monday November 12, 2012 for Veteran’s Day. However a randomization staff member may be reached at 617-632-2022 during business hours to assist with ECOG patient registration.

**E3805, CHAARTED: ChemoHormonal Therapy versus Androgen Ablation Randomized Trial for Extensive Disease in Prostate Cancer**, will close to accrual effective November 21, 2012. This study will close to accrual as it has reached its accrual goal. Patients currently on study are to continue on
treatment and be followed per protocol. Biological samples are to be submitted per protocol. Forms should also continue to be submitted per the Forms Submission schedule.

**NSABP Update:**

**NSABP-39/RTOG 0413: A Randomized Phase III Study of Conventional Whole Breast Irradiation (WBI) Versus Partial Breast Irradiation (PBI) for Women with Stage 0, I, or II Breast Cancer:** If you have this trial open at your site, please read the email blast found at the link below.

https://members.nsabp.pitt.edu/B39_Email_Blast_1012.pdf

The NSABP has published instructions for the scheduling of protocol therapy during the holidays. Protocol specific instructions for all current trials are detailed in the document. This is a revised document dates 11/5/12. Please disregard the October 29, 2012, version of the memo.

https://members.nsabp.pitt.edu/Treatment_News.asp

The Fall 2012 Clinical Coordination Connection is focused on NSABP's P-5 protocol, with much useful information for sites conducting this trial.

**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 0933, A Phase II Trial of Hippocampal Avoidance During Whole Brain Radiotherapy for Brain Metastases,** will close to accrual at 5 PM EST Wednesday, November 7, because it has reached its target accrual.
The Fall 2012 edition of the **RTOG Newsletter** has been posted to the Web site. In this issue includes a NRG Oncology Update, a RTOG June Semiannual Meeting highlights, recently activated RTOG trials, mid-year site performance results, RTOG at ASTRO and more. Download your copy today at: [http://www.rtog.org/LinkClick.aspx?fileticket=moWX0e-4CBU%3d&tabid=360](http://www.rtog.org/LinkClick.aspx?fileticket=moWX0e-4CBU%3d&tabid=360)

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:**

**Upcoming Events:**
**Patient Navigator Meeting**, Jefferson Campus: November 9  
**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](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*