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

Featured Trials Actively Recruiting at the Kimmel Cancer Center at Jefferson:

1. Title: COMETI Phase 2: Characterization of Circulating Tumor Cells from Subjects with Metastatic Breast Cancer Using the CTC-Endocrine Therapy Index
   a. Eligibility: Subjects must have metastatic breast cancer. Subjects must have IHC-determined ER positive breast cancer according to institutional guidelines. Subjects must have HER2 negative breast cancer defined by CAP/ASCO criteria. Subjects must have currently progressive metastatic disease according to RECIST v1.1 criteria which may include objective criteria for progression based on physical findings and/or whole body anatomic (CT or MRI) and/or bone scintigraphic imaging, AND they have progressed on at least one previous line of ET for their metastatic disease (but are not currently progressing on fulvestrant), OR they show evidence of disease progression during or within 12 months of the end of adjuvant ET.
   b. Treatment: Subjects will have blood drawn for CTC-ETI calculation at baseline (within 30 days prior to the initiation of ET) and then subsequently 1, 2, 3 and up 12 months after the initiation of therapy, or at the time of disease progression, or discontinuation of treatment, whichever occurs first. Only subjects with a successful baseline CTC-ETI calculation will remain on study and have subsequent serial blood draws performed.
   c. Contact: Cynthia Perez at 215-955-9626 or Cynthia.Perez@jefferson.edu

2. Title: A Phase II Study of Azacitidine and Sirolimus for the Treatment of High Risk Myelodysplastic Syndrome or Acute Myeloid Leukemia Refractory to or Not Eligible for Intensive Chemotherapy
   a. Eligibility: Patients must have a diagnosis of one of the following: MDS as defined by >10% bone marrow blasts or high risk cytogenetic categories. AML Relapsed, refractory, or unable to tolerate conventional chemotherapy. Patients must have a life expectancy of at least 4 weeks. Patients must have completed any radiotherapy four weeks prior to study entry, 0-2 weeks for local palliative XRT (small port). Patients must have recovered from the toxic effects of any prior chemotherapy to < Grade 2)
Patients must not be receiving any chemotherapy agents (except Hydroxyurea) - Intrathecal ARA-C and intrathecal methotrexate are permissible (as they are not systemic and only isolated to the central nervous system).

b. **Treatment:** Azacitidine and Sirolimus will be given to patient meeting inclusions and exclusion criteria, and will be stratified according to disease at entrance to study, i.e. myelodysplastic syndrome and acute myelogenous leukemia.

c. **Contact:** Jennifer Cloud at 877-656-2891 or Jennifer.Cloud@jefferson.edu

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Now Open for Network Participation

**RTOG0913**, Phase I/II Trial of Concurrent RAD001 (Everolimus) with Temozolomide/Radiation Followed by Adjuvant RAD001/Temozolomide in Newly Diagnosed Glioblastoma

**SWOG1216**, A Phase III Randomized Trial Comparing Androgen Deprivation Therapy + TAK-700 with Androgen Deprivation Therapy + Bicalutamide in Patients with Newly Diagnosed Metastatic Hormone Sensitive Prostate Cancer

Pending Studies for Network Participation:

**ECOG1412**, Randomized Phase II Open Label Study of Lenalidomide R-CHOP (R2CHOP) vs RCHOP (Rituximab, Cyclophosphamide, Doxorubicin, Vincristine and Prednisone) in Patients with Newly Diagnosed Diffuse Large B Cell Lymphoma

**ECOG2211**: A Randomized Phase II Study of Temozolomide or Temozolomide and Capecitabine in Patients with Advanced Pancreatic Neuroendocrine Tumors

**GOG-263**: Randomized Phase III Clinical Trial of Adjuvant Radiation Versus Chemoradiation in Intermediate Risk, Stage I/IIA Cervical Cancer Treated with Initial Radical Hysterectomy and Pelvic Lymphadenectomy
NSABP-50-I/ GBG77 (KATHERINE) Trial: A Randomized, Multicenter, Open-Label Phase III Study to Evaluate the Efficacy and Safety of Trastuzumab Emtansine versus Trastuzumab as Adjuvant Therapy for Patients with HER-2Positive Primary Breast Cancer Who Have Residual Tumor Present Pathologically in the Breast or Axillary Lymph Nodes Following Preoperative Therapy

NSABP B-51, A Randomized Phase III Clinical Trial Evaluating Post Mastectomy Chestwall and Regional Nodal XRT and Post Lumpectomy Regional Nodal XRT in Patients with Positive Axillary Nodes Before Neoadjuvant Chemotherapy who Convert to Pathologically Negative Axillary Nodes After Neoadjuvant Chemotherapy

RTOG1216, Randomized Phase II/III Trial of Surgery and Postoperative Radiation Delivered with Concurrent Cisplatin versus Docetaxel versus Docetaxel and Cetuximab for High-Risk Squamous Cell Cancer of the Head and Neck

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

Please contact Rashada Dawson at 215-955-2135 or Rashada.Dawson@jeffersonhospital.org if your site is interested in participating in any of these trials.

Regulatory Update:
S1216, new approval ltr
S0819- amend #13
R1270- amend #4

FB-6- final report
R1021- closed to accrual
R0631- amend #6
Please contact Rashada Dawson for any clinical trial document repository questions or concerns.

**CTSU Update:**

NIH CTEN has made the decision to end the current endorsement program through the CTSU as of August 1, 2013. Please note, qualified, adult, U.S. based full member sites will continue to be able to participate in trials posted to the CTSU website that are not classified as limited participation. Sites that are members of the lead protocol organization must credit the lead protocol organization until further notice. The credited group will be responsible for payment to the enrolling site. CTSU has created or amended policies as a result of this change. The policies are located under the Education and Resources tab > CTSU Operational Information > Policy Guidelines on the CTSU website.

**TAILORx/PACCT-1:** Effective August 12th 2013, the RDC option for this study will no longer be available and your site will need to submit data using paper CRFs. Instructions for submitting data via paper will be provided prior to August 12th. Please contact the CTSU Help Desk, CTSUContact@westat.com, with questions regarding this transition or accompanying activity.

Please contact Joshua Schoppe at 215-955-0448 or at Joshua.schoppe@jeffersonhospital.org with any CTSU related issues.
ECOG Update:
Upcoming Performance Monitoring: The next Performance Monitoring data cut-off date of September 30, 2013 is approaching. Any data received on or before September 30, 2013 will be included in the upcoming Performance Monitoring. Data received after September 30, 2013 will be considered late. It is important to remember that data timeliness will be evaluated by assessing two components: the rate of CRF submission 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.

Effective July 17, 2013, all patients treated on E4402, Randomized Phase III Trial Comparing Two Different Rituximab Dosing Regimens for Patients with Low Tumor Burden Indolent non-Hodgkin's Lymphoma, will be considered off treatment and will be followed according to the long-term follow-up schedule. As a result of the recommendations, the follow-up schedule for E4402 has been relaxed, and the following case report forms have been revised. [http://www.ecog.org/forms/e4402_allforms.pdf](http://www.ecog.org/forms/e4402_allforms.pdf)

PACT1 EL112LAB Sample Submission Clarification: On the PACCT-1 Trial’s sub study EL112LAB, North American Breast Cancer Groups Biospecimen Bank for Determinants of Late Relapse in Operable Breast Cancer, please follow the blood collection and submission schedule, upon registration to Step 3 and at relapse, outlined in the patient consent and Appendix XII. Section 7.4 is incorrect. The indication of yearly blood draws will be removed in the next amendment to the protocol. Questions may be directed to LateRelapse@jimmy.harvard.edu

Please contact Joshua Schoppe with any ECOG related issues.
NSABP Update:
P-5: Statin Polyp Prevention Trial in Patients with Resected Colon Cancer:
As of June 19th, 367 patients (or 21%) of the required 1,740 sample size, have
been enrolled to the P-5 trial. The trial opened to accrual in March of 2010 and
this accrual rate is substantially BELOW our initial projections. AstraZeneca
has kindly agreed to supply 5 years of both Crestor® and placebo for all
patients entered into the P-5 trial on or before December 31, 2013. As a result
of this decision, accrual MUST be completed before the end of this year. Over
500 IRB's have approved this trial and accrual could be completed if each of
these sites enters 2 patients over the next 6 months. That is not an easy task
and will require screening large numbers of patients. However, the trial
remains scientifically and clinically important. Toxicity to date has been low,
balanced in the two groups, and does not include unexpected toxicities.

Please contact Vicki Squire with any NSABP related issues at 215-503-5641 or
Vicki.squire@jeffersonhospital.org

RTOG Update:
RTOG 1016, Phase III Trial of Radiotherapy Plus Cetuximab versus
Chemoradiotherapy in HPV-Associated Oropharynx Cancer, will close to
patient accrual on Friday, August 2 at 5 p.m. Eastern because the study has met
its original accrual objective. The study team is reviewing data in support of a
proposal to amend the study to increase the sample size by several hundred
patients. We are hopeful that the study will reopen to accrual approximately 6
months from now, pending approval by the RTOG Data Monitoring
Committee, the NCI, and our corporate partner (Bristol-Myer Squibb).

RTOG 1306, A Randomized Phase II Study of Individualized Combined
Modality Therapy for Stage III Non-Small Cell Lung Cancer (NSCLC), has
been granted pre-activation status. This status is used to permit the release of
the Cancer Therapy Evaluation Program (CTEP)-approved protocol to our
member sites for submission to their local IRBs. Please contact Rashada Dawson if your site is interested in participating in any of these trials.

Please contact Joshua Schoppe with any RTOG related issues.

**Jefferson Oncology Group (JOG) Update:**
Save the date for the Annual Investigators Meeting on October 10\(^{th}\) at Sheraton in Valley Forge.

**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:**
- **CRA Quarterly Meeting**, Jefferson Campus: September 11, 2013
- **JOG Annual Meeting**, Sheraton Valley Forge, PA, October 10, 2013
- **ECOG-ACRIN Meeting**, Fort Lauderdale, FL: November 15-17, 2013
- **CRA Quarterly Meeting**, Jefferson Campus: December 18, 2013
- **NRG Meeting**, San Diego, CA, February 6-9, 2014

*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