The Clinical Research E-News

Volume 4: ISSUE 3: May 18, 2012

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 Breast Cancer Clinical Trial Announcement:** Tolerability of the Combination of Lapatinib and Trastuzumab in Adults Age 60 or Older with Her2 Positive Metastatic Breast Cancer
   a. **Eligibility:** Metastatic Her 2/Neu positive breast cancer, female and male patients greater than 60 yrs old, ECOG PS less than 2 with an ejection fraction greater than 50%. Prior treatment allowed.
   b. **Treatment:** Lapatinib will be given as 1000mgs orally daily throughout the study period. Trastuzumab will be given in one of two schedules at the discretion of the treating physician.
   c. **Contact:** Melisa Mordenti at 215-955-8979 or Melisa.Mordenti@jefferson.edu

2. **New Hematologic Malignancies Clinical Trial Announcement:** A Two Step Approach to Allogeneic Hematopoietic Stem Cell Transplantation for High-Risk Hematologic Malignancies Using Two Related Donors
   a. **Eligibility:** The patient has a hematological malignancy which has shown resistance to standard therapy. The disease is not controlled at the time of HSCT. The patient must also meet organ function and performance criteria which are listed in the protocol and have 2 appropriate donors.
   b. **Treatment:** Transplant on the Jefferson 2 step approach, but instead of receiving T cells and stem cells from one donor, the patient will receive T cells and stem cells from 2 donors
   c. **Contact:** Ruth Kastalsky at 215-503-0448 or Ruth.Kastalsky@jefferson.edu
3. **New Urothelial Cancer Clinical Trial Announcement:** *A Randomized, Phase 2, Open-Label Study Evaluating DN24-02 As Adjuvant Therapy In Subjects With High Risk Her2+ Urothelial Carcinoma N10-1*

   a. **Eligibility:** High risk urothelial carcinoma based on local pathology report, defined as: Tumor stage ≥ pT2 or positive lymph nodes (N+) for subjects who received neoadjuvant chemotherapy or Tumor stage ≥ pT3 or N+ disease for subjects who have not received neoadjuvant chemotherapy. Radical surgical resection with lymph node dissection was performed within 12 weeks prior to randomization.

   b. **Treatment:** Subjects randomized to receive investigational treatment with DN24-02 will undergo a standard 1.5 to 2.0 blood volume leukapheresis, followed approximately 3 days later by an infusion of DN24-02. This process will be repeated at approximately 2-week intervals for a total of 3 infusions. Subjects randomized to the control arm will receive no investigational treatment and will be followed and treated per standard of care.

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

Pending Studies for Network Participation:

- **N107C/R1270**, *A Phase III Trial of Post-Surgical Stereotactic Radiosurgery Compared with Whole Brain Radiotherapy (WBRT) for Resected Metastatic Brain Disease*

- **NSABP B-49**, *A Phase III Clinical Trial Comparing the Combination of Docetaxel Plus Cyclophosphamide to Anthracycline-Based Chemotherapy Regimens for Women with Node-Positive or High-Risk Node-Negative, HER2-Negative Breast Cancer*

- **SWOG0931**, *EVEREST: EVErolimus for Renal Cancer Ensuing Surgical Therapy, A Phase III Study.*

- **RTOG1012**, *Phase II Randomized Trial of Prophylactic Manuka Honey for the Reduction of Chemoradiation Therapy Induced Esophagitis-Related Pain During the Treatment*
**RTOG1102**, *A Phase I Study of Induction Ganitumab (IND #113278) and Gemcitabine, Followed by Ganitumab, Capecitabine, and 3D-Conformal Radiation Therapy (3D-CRT) With Subsequent Maintenance Therapy for Locally Advanced Pancreatic Cancer.*

**RTOG1175/CALGB80803**, *Randomized Phase II Trial of PET Scan-Directed Combined Modality Therapy in Esophageal 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](mailto:Joshua.schoppe@jeffersonhospital.org).

**Regulatory Update:**
- RTOG 0436- Amendment #5
- ECOG 1305- Addendum #9
- PACCT-1- Addendum #6
- RTOG 0524-Amendment #8
- GOG 262- Revision #4
- GOG 252- Final Report
- RTOG 1010- Update #2
- ECOG 4402- Update #2
- SWOG 0600- Revision #7
- E2408- Admin changes to ICF
- NSABP P2-Closure 5/31/12
- RTOG 0929-Re-open
- CALGB 90802- Update #3
- E3805: Increase enrollment #
- RTOG 0920- Amendment #5
- ECOG 1508- Addendum #8
- ECOG 2809- Addendum#2
- ECOG 2804- Addendum #13
- ECOG 1609- Addendum #4
- CALGB 80405- Update #14
- ACOSOG Z1041- Update #7
- R0534-QOL closure
- RTOG 0839- Amendment #2
- RTOG 0614- Final Report
- JOG59-Risk added
- RTOG 1008-Amendment #3
- RTOG 0837-Amendment #6
- ECOG 2208- Addendum #4
- GOG 249- Revision#11
- ECOG 1208- Addendum #5
- CALGB 40502- closed to accrual

**IRB training reminder:** Researchers who are already certified, (certification is only required once now), only have to complete the Biomedical Research
Refresher every TWO years. The on-line training can be found at the Collaborative Institutional Training Initiative (CITI) webpage linked here: https://www.citiprogram.org/Default.asp?

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

CTSU Update:
Please note that the CTSU has added a "Rave" tab to their member's website: https://www.ctsu.org/RAVE/ As of April 1, 2012, all newly activated studies will be conducted exclusively in Medidata Rave, a web-based remote data entry system. This tab provides information on Medidata Rave, iMedidata, account activation and study invitation acceptance. Please check it out! If you have any questions about this please contact the CTSU help desk at ctsucontact@westat.com or 1-888-823-5923.

Revised CTEP Guidelines for Reporting of Pregnancy, Fetal Death and Death Neonatal can be viewed at the following link: https://members.nsabp.pitt.edu/Revised_Pregnancy_Report_031312.pdf

C90202, A Randomized Double-Blind, Placebo-Controlled Phase III Study of Early versus Standard Zoledronic Acid to Prevent Skeletal Related Events in Men with Prostate Cancer Metastatic to Bone, closed to patient accrual on April 4, 2012.

C70604, A Randomized, Phase III Study of Standard Dosing versus Longer Dosing Interval of Zoledronic Acid in Metastatic Cancer, closed to patient accrual on April 13, 2012.

Please contact Joshua Schoppe with any CTSU related issues.
ECOG Update:
ECOG-ACRIN, May 17, 2012 marks the official founding of the ECOG-ACRIN Cancer Research Group as its new constitution goes into effect. Group Co-Chairs Robert L. Comis, MD, and Mitchell L. Schnall, MD, PhD, issued a joint statement, saying, “Building the most attractive scientific program is the motivation for all our efforts. With this constitution as the framework, ECOG-ACRIN establishes for the public and private sectors one organizational structure capable of studying the entire cancer care pathway—prevention and screening, surveillance, early detection, staging, diagnosis, treatment, follow-up, and survivorship. We are driven by a genuine belief that together ECOG and ACRIN will contribute more to oncology than either organization could individually. For example, our core pathology and imaging scientists, and their associated laboratories and extensive IT infrastructures, make it entirely possible for the Group to integrate large data sets required for biomarker-driven science. Thus, future ECOG-ACRIN studies will be informed more by process than the classic definition of disease, to allow our patients throughout North America and the world the best, most advanced clinical research opportunities.”

E1505, Phase III Randomized Trial of Adjuvant Chemotherapy With or Without Bevacizumab for Patients with Completely Resected Stage IB (>4cm) – IIIA NSCLC and 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: In anticipation of an upcoming statistical analysis, the ECOG Coordinating Center is requesting that a priority be placed on submitting forms for the expected time intervals that are DUE or OVERDUE. Access the Expectancy Display application through the ECOG Web Application Portal at https://webapps.ecog.org to determine form expectancy status and the Reporting Assignment Tool for report period ranges for Disease and Vital Status Forms.
ECOG Performance Monitoring: The next data cut-off date of June 30, 2012 is approaching. Any data received on or before June 30, 2012 will be included in the upcoming Performance Monitoring. Data received after June 30, 2012 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:
Genentech has issued a letter to healthcare professionals and patients regarding the revoking of the approval of Avastin for treatment of metastatic breast cancer. The letter can be viewed at this link: https://members.nsabp.pitt.edu/Genentech_Outcome_Letter_031312.pdf

B-47: A Randomized Phase III Trial of Adjuvant Therapy Comparing Chemotherapy Alone (Six Cycles of Docetaxel Plus Cyclophosphamide or Four Cycles of Doxorubicin Plus Cyclophosphamide Followed by Weekly Paclitaxel) to Chemotherapy Plus Trastuzumab in Women with Node-Positive or High-Risk Node-Negative HER2-Low Invasive Breast Cancer: A training tool was posted on 4/13/2012, a web cast power point, to use as a site initiation visit. This is an excellent tool to utilize before you randomize a patient to B-47. https://members.nsabp.pitt.edu/B47_Special_Documents.asp

RTOG Update:
R0837, Randomized, Phase II, Double-Blind, Placebo-Controlled Trial of Conventional Chemoradiation and Adjuvant Temozolomide Plus Cediranib Versus Conventional Chemoradiation and Adjuvant Temozolomide Plus Placebo in Patients With Newly Diagnosed Glioblastoma,” closed to accrual at 5 PM EST Wednesday, May 9, because it has met its accrual goal.

R1115, 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, was activated on May 8, 2012. This study is the first phase III randomized trial to examine the combination of orteronel [TAK-700] with standard androgen deprivation therapy and concurrent radiation. If your site is interested please contact Joshua Schoppe.

The RTOG Semiannual Meeting will be held June 14 – 17, 2012 at the Loews Philadelphia Hotel in Philadelphia, PA. Hotel reservations must be made by May 25th to ensure availability. The RTOG website (http://www.rtog.org/AboutUs/RTOGMeetings/UpcomingMeetingInfo.aspx) will link you to the online registration portal and contains the meeting agenda, brochure (with hotel and travel information) and exhibitor information.

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/. This page contains links to the Remote Access Portal as well as the clinical trial document repository.
Upcoming Events:
RTOG Semiannual Meeting, Philadelphia, PA: June 14-17
CRA Quarterly Meeting, Jefferson Campus: June 20
GOG Semiannual Meeting, Boston, MA: July 26-29
CRA Quarterly Meeting, Jefferson Campus: September 19
ECOG-ACRIN Semiannual Meeting, Hollywood, FL: November 9-11

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