The Clinical Research E-News

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New Activations at TJU: NSABP FRP’s FC-4, “A Randomized Phase II Clinical Trial Investigating Irinotecan Plus Cetuximab With or Without Anti-Insulin-Like Growth Factor-I Receptor Monoclonal Antibody (IMC-A12) for the Treatment of Patients with Metastatic K-RAS Wild-Type Carcinoma of the Colon or Rectum that has Progressed on Oxaliplatin and Bevacizumab Given as First-Line Therapy (NSABP PROTOCOL FC-4/CP13-0708).”

Regulatory Update: The following studies have had recent consent form changes posted on the repository website:

N0147MARVEL (N0723)
RTOG 0625E4805
ECOG PR 11RTOG 0415
GOG 219ECOG 5103

If any of these studies pertain to your site please visit the repository at: http://www.kimmelcancercenter.org/kcc/JKCCN/file-repository/. Please contact Rolma Mancinow at rolma.mancinow@jeffersonhospital.org or 215-955-7954 with any repository related questions.

Regulatory Corner: Please be aware that if you are trying to register a patient for a CIRB study through the CTSU, the approval date on the registration form refers to the date of CIRB approval NOT the date of Jefferson’s IRB approval. If you use the date of Jefferson's IRB approval, your registration form will be rejected by the CTSU. Please contact Rolma Mancinow with any Regulatory issues.
Quality Assurance Update: The informed consent form for CALGB 30610/RTOG 0538, "A Phase III Comparison of Thoracic Radiotherapy Regimens in Patients with Limited Small Cell Lung Cancer also Receiving Cisplatin and Etoposide," was recently revised and has been posted on the JKCCN repository (approved 5-28-09). One change was made in the "What is the purpose of this study?" section, lines 55-56, on page 2. The word "not" was added to the following sentence: "You are being asked to take part in this study because you have small cell lung cancer that has not been found outside the chest." Re-consenting is not necessary because of this change, but please take note of this small, but important revision. Please contact Kelly Shipman with any QA related issues at Kelly.shipman@jeffersonhospital.org or 215-955-2135.

CTSU Update: N0723, MARVEL: “Marker Validation of Erlotinib in Lung Cancer- A Phase III Biomarker Validation Study of Second-line Therapy in Patients with Advanced Non-Small Cell Lung Cancer (NSCLC) Randomized to Pemetrexed Versus Erlotinib,” the NCI has issued an Action Letter updating the comprehensive adverse events and potential risks (CAEPR) that describes modifications of the risk information associated with Erlotinib dated June 5, 2009. Accrual of new patients is suspended until the TJUH IRB has reviewed and approved this amendment. Patients currently on study may continue on study provided they are informed of the new risks identified as part of the CAEPR. This information must be communicated to patients and documented in the source for all patients already enrolled on study without waiting for IRB review/approval since this information is being provided in order to eliminate immediate hazard to them. Patients are considered “on-study” if they have signed consent as of the date of the Action Letter. The N0723 Erlotinib Action Letter is available on the CTSU protocol web pages (http://members.ctsu.org).
**S0307:** “*Phase III Trial of Bisphosphonates as Adjuvant Therapy for Primary Breast Cancer,*” as of Monday June 1, 2009 a temporary clodronate shortage exists. UVI, Inc., drug distributor for the S0307 trial, has confirmed that they are experiencing another temporary shortage of clodronate tablets. The clodronate tablets continue to be manufactured by Bayer Schering Pharma; however, a new shipment is not expected to be released until next week. While it is anticipated that this shortage will only last approximately 1-2 weeks, please contact UVI, Inc. at 800/370-2508 before registering a patient to check on available clodronate supplies and to adjust registration plans and/or treatment start dates accordingly.

If you have a CTSU related question please contact Joshua Schoppe at Joshua.schoppe@jeffersonhospital.org or 215-955-0448

**ECOG Update:** Upcoming Performance Monitoring: The next Performance Monitoring data cut-off date of June 30, 2009 is approaching. Any data received on or before June 30, 2009 will be included in the upcoming Performance Monitoring. *Data received after June 30, 2009* will be considered late. It is important to remember that data timeliness will be evaluated by assessing two components: The rate of CRFs submitted during active treatment 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.

**E2805:** “*ASSURE: Adjuvant Sorafenib or Sunitinib for Unfavorable Renal Carcinoma,*” has been activated by ECOG effective May 22, 2009. Accrual of new patients will not be accepted until the TJUH IRB has completed their review and approved Addendum #6. This is in process and a follow up email will be sent when new accrual can begin.

**Reminder:** SPRING ECOG MEETING: JUNE 14-16, 2009.
Please also register if you haven't already done so: 
https://www.regonline.com/ECOG_Spring2009

If you have an ECOG related question please contact Joshua Schoppe

**NSABP Update: Featured Trial, NSABP 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. Please keep this hormonal continuation trial in mind as you work with your oncologists. Since this trial is not for newly diagnosed patients, your surgeons and medical oncologists may need an occasional reminder to screen for women who are near to completion of their 5 years of hormonal therapy. Accrual so far is at 68% (2616 out of 3840). It is open at 6 JKCCN affiliates, but there was only one accrual to the trial among those sites in May. Considering that the work involved in this trial is relatively simple, it would be worthwhile to renew interest in the trial. Please put this on the agenda for your next meeting with your oncologist.

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

**RTOG Update: RTOG 0320,** "A Phase III Trial Comparing Whole Brain Radiation and Stereotactic Radiosurgery Alone Versus With Temozolomide or Erlotinib in Patients with Non-Small Cell Lung Cancer and 1-3 Brain Metastases," was recently suspended to enrollment by RTOG, due to the addition of newly identified risk information for erlotinib. The Jefferson IRB will soon be reviewing the new amendment that is associated with this risk profile change (Amendment #7), and this trial should be open enrollment again in the near future. A description of this amendment can be found on the
RTOG website at: http://www.rtog.org/members/protocols/0320/summary_changes.html. You will be notified by email when accrual may resume.

Reminder: RTOG Meeting:
Registration and attendee information for the upcoming RTOG Semiannual Meeting has been posted on the RTOG website. The meeting will be held June 25-28, 2009, at the Chicago Marriott Downtown Magnificent Mile. Information about the meeting can be found at http://www.rtog.org/meeting/main.html. Please take advantage of the opportunity to complete your meeting registration in advance via the website.

If you have an RTOG related question please contact Kelly Shipman.

Jefferson Oncology Group (JOG) Update:

Sponsors of JOG trials are more frequently requesting that we poll for interest well in advance of the trial's activation. This is due to the trend toward selecting sites outside the United States; fewer US sites are selected and are determined early in the process toward activation. Please note that we will strive to give you as much information regarding time lines as we can so that you can project ahead with regard to competing trials.

JOG 52: Wyeth 3144A2-3004-WW, A Randomized Double Blind Placebo-Controlled Trial of Neratinib (HKI-272) After Trastuzumab in Women With Early-Stage HER-2/neu Overexpressed/Amplified Breast Cancer. This is a study of an experimental drug (neratinib) versus a combination of drugs (lapatinib and capecitabine) in women who have erbB-2 (HER-2) positive metastatic or locally advanced breast cancer. The goal of this study is to compare the two regimens in shrinking tumors and to extend the lives of women with erbB2 (HER-2) positive breast cancer. The study will also
compare the safety of the two regimens and compare quality of life of patients on the two regimens. More information can be found at clinicaltrials.gov.

**JOG 053:** *Randomized, Multicenter, Double-Blind, Phase 3 Trial of Drug D versus Placebo in Patients with Newly Diagnosed or Relapsed Advanced (stage IIIB-IV) Primary Adenocarcinoma of the Lung Treated with Docetaxel or Paclitaxel Plus Cisplatin.* This is for first line treatment of all lung cancers, including bronchialveolar, adding Drug D versus placebo to the above regimens. Expected activation is the fall of 2009, but the sponsor needs to determine US sites now. If you are interested please contact us and we will email you a blinded study synopsis.

If your site is interested, please contact Joshua Schoppe or Vicki Squire by June 11, 2009.

*Reminder: JKCCN CRA Meeting: The next CRA meeting will be held at TJU on Wednesday, June 24, 2009: 9am-1pm.*

Reminder: Still Time to Register, Joint HCC Symposium, KCC at Jefferson, FCCC and Abramson Cancer Center at the University of Pennsylvania: Drs. Brian Carr, Professor of Medicine at Jefferson Medical College, Minhuyen Nguyen, Director of Clinical Gastroenterology at Fox Chase Cancer Center, and Weijing Sun, Associate Professor of Medicine at the Abramson Cancer Center at the University of Pennsylvania, would like to invite you to attend the:

**Philadelphia Hepatoma Symposium**  
Wednesday, June 10, 2009 at 5:00pm - 8:45 pm.  
**Table 31 Restaurant**  
**1701 John F. Kennedy Boulevard, Phila., PA 19103**  
Cocktails, Dinner and free parking will be provided.
An agenda and early registration is available at www.kimmelcancercenter.org/HCC

*The Clinical Research E-News Archive* is now located on the Kimmel Cancer Center webpage under the JKCCN Member Area:

http://www.kimmelcancercenter.org/kcc/JKCCN/jcn_enewsletter.html

*Please provide feedback and any suggestions to Joshua Schoppe at 215-955-0448 or email at Joshua.schoppe@jeffersonhospital.org*