DATE: 2012-May-04

TO:  SC.20 Principal Investigators
    SC.20 Principal Clinical Research Associates
    Centre Ethics Representatives
    Centre Representatives

FROM: Carolyn Wilson, Study Coordinator

TRIAL: SC.20: A Phase III International Randomized Trial of Single versus Multiple Fractions for Re-Irradiation of Painful Bone Metastases, and
       SC.20U: A Study of the Effect of Re-Irradiation for Bone Pain on Urinary Markers of Osteoclast Activity (a companion study to SC.20)

** NOTICE OF TRIAL ACCRUAL CLOSURE **

I am writing to inform you that the NCIC CTG SC.20 trial will be officially closed to further accrual no later than 6:00 p.m. EDT on May 31, 2012, or when the 850th patient is randomized, whichever occurs first. Please continue to enter patients up until that time, but no later. Currently, 845 patients have been randomized. Further randomization will not be possible after the 850th patient is entered. If the accrual target is reached prior to the date specified, sites will be notified.

Reason for Trial Closure

To allow sufficient time for data cleaning and abstract submission in early 2013, the trial committee requested that the Data Safety Monitoring Committee (DSMC) allow the study to close to accrual on May 31, 2012, even if all 850 patients in the target sample size had not been accrued. At the time of request submission, it was anticipated that more than 840 patients would be randomized to the trial by the closure date requested. This request was reviewed by the DSMC at their meeting on April 27, 2012 and approved. Formal minutes from the DSMC meeting are forthcoming.

Future Treatment and Follow-up

Please continue to treat and follow patients and submit patient documentation as per the schedule outlined in the protocol.

Patient Records

Please note that although this trial is closed to accrual, trial documents must still be retained. NCIC CTG will continue to notify participating centres when trial related records no longer need to be retained in accordance with all applicable regulations.

Ethics and Regulatory Documentation

We advise you to notify your Research Ethics Board that this study is now closed to new accrual. Centres must continue to notify NCIC CTG of serious adverse events in accordance with the protocol.
Annual re-approval:

Annual re-approval is required at your centre while the study is ongoing. Annual re-approval must continue while patients are undergoing protocol mandated treatment/interventions, being followed, and while data is being collected. It is the responsibility of the centre and the local REB to ensure that the level of review received is in accordance with local policy.

Trial Modifications:
Centres are required to process any trial modifications that may be distributed by NCIC CTG. If the centre/REB feels the modification is not applicable to their institution, the centre must immediately notify NCIC CTG.

We anticipate that trial results will be released in 2013. Publications of trials in which NCIC CTG patients participate will be made available at the following link: https://scooby.ctg.queensu.ca/publications/displaying_publications.php

We sincerely thank you for all your hard work on both SC.20 and SC.20U and look forward to your continued participation on other NCIC CTG trials.

Sincerely yours,

Carolyn Wilson, M.Sc.
Study Coordinator

Ralph M. Meyer, MD, FRCP(C)
Physician Coordinator
Edith and Carla Eisenhauer Chair in Clinical Cancer Research
Director, NCIC Clinical Trials Group
Professor, Departments of Oncology, Medicine and Community Health and Epidemiology
Queen’s University

cc: Bingshu Chen, Senior Biostatistician
Ethics Clinical Research Associates
NCIC CTG Ethics Research Associates
Participating Intergroup Study Chairs
Participating Intergroup Data Managers and Registrars