NCCTG Data Monitoring Committee Adverse Events Report
Meeting Date: September 26, 2006

Committee Membership: Voting: C. Blanke, H. Burris, L. Gaspar, K. Huppler Hullsiek, R. Marks, P. McAllister, V. Stearns

Non-Voting: B. Friedlin, J. Kelaghan, M. Mooney, D. Sargent

On 9/26/06, the NCCTG Data Monitoring Committee met and reviewed the following phase-III trials. For each trial a complete report including accrual, baseline characteristics, toxicity, and blinded efficacy data was presented to and discussed by the NCCTG EDMC. The official action item for each trial is presented below, along with a notation of any specific issues raised or discussed regarding toxicity, if applicable.

BREAST

#N9831 (Adjuvant AC + Paclitaxel +/- Trastuzumab in HER-2 Overexpressing Node-Positive Breast Cancer):

- *Action*: A formal interim analysis of the comparison of arm A to arm B was reviewed. The committee voted unanimously to continue follow-up and monitoring per protocol. The committee reviewed the current adverse event data and no issues were identified.

CANCER CONTROL

#N01C8 (Osteoporosis Prevention in Prostate Cancer Patients Receiving Androgen Ablation Therapy: A Phase III Randomized, Placebo-Controlled, Double-Blind Study)

- *Action*: The committee voted unanimously to a) continue follow-up and monitoring per protocol, and b) request study team to provide a plan to obtain further baseline and 1 year bone mineral density measurements. The committee reviewed the current adverse event data and no issues were identified.

#N00CB (A Phase III Randomized, Double-Blind, Placebo-Controlled Trial of Gabapentin in the Management of Hot Flashes in Men)

- *Action*: The committee voted unanimously to continue per protocol. The committee reviewed the current adverse event data and no issues were identified.

#N02C1 (A Randomized Controlled Trial of Risedronate for Prevention of Bone Loss in Women Undergoing Chemotherapy for Primary Breast Cancer).

- *Action*: The committee voted unanimously to a) continue per protocol, b) to deny the study team request to release study data. The team may request data release at a future point where the data maturity is greater. The committee reviewed the current adverse event data and no issues were identified.

#N03CA (The Use of American Ginseng (panax quinquefolius) to Improve Cancer-Related Fatigue: A Randomized, Double-Blind, Dose-Finding, Placebo-Controlled Study)

- *Action*: The committee voted unanimously to allow release of data to the study team per NCCTG policy of 95% data completion for the primary endpoint, but to continue DMC montoring. The committee reviewed the current adverse event data and no issues were identified.

***#N03CC* (A Randomized, Controlled, Open-Label Trial of Empiric Prophylactic vs. Delayed Use of Zoledronic Acid for Prevention of Bone Loss in Postmenopausal Women with Breast Cancer Initiating Therapy with Letrozole After Tamoxifen)**

- *Action*: The committee voted unanimously to a) continue per protocol, and b) to deny the study team request to release study data. The team may request data release at a future point where the data maturity is greater. The committee reviewed the current adverse event data and no issues were identified.

GI

***#N0147* (A Randomized Phase III Trial of Irinotecan (CPT-11) and/or Oxaliplatin (OXAL) Plus 5-Fluorouracil (5-FU)/Leucovorin (CF) after Curative Resection for Patients for Patients with Stage III Colon Cancer)**

- *Action*: The committee voted unanimously to a) continue study per protocol, and b) request the study team propose a formal adverse event stopping rule for review by the DMC. The current adverse event data were reviewed.

Studies Approved Without Further Discussion

For all of the trials listed here the DMC reviewed the current toxicity and efficacy data, and no issues requiring intervention were identified.

Study	Disease Site	Status
N00C9 – The Use of Ginkgo Biloba for the Prevention of Chemotherapy-Related Cognitive Dysfunction	Cancer Control	Open
N01C5 – The Use of Valeriana Officinalis (Valerian) in Improving Sleep in Patients Who are Undergoing Adjuvant Treatment for Cancer: A Phase III Randomized, Placebo-Controlled, Double-Blind Study	Cancer Control	Open
N02C4 – Phase III Double-Blind, Placebo-Controlled Randomized Comparison of Creatinine for Cancer-Associated Weight Loss	Cancer Control	Open
N04C7 – A Phase III Randomized, Placebo-Controlled, Double-Blind Study of Intravenous Calcium/Magnesium to Prevent Oxaliplatin-Induced Sensory Neurotoxicity	Cancer Control	Open
N05C5 – A Phase III Randomized, Placebo-Controlled, Double-Blind Trial to Determine the Effectiveness of a Urea/Lactic Acid-Based Topical Keratolytic Agent and Vitamin B-6 for Prevention of Capecitabine-Induced Hand and Foot Syndrome	Cancer Control	Open

Notes: 1. Further information on accrual or adverse events for any of these trials is available by contacting the NCCTG Operations Office.

2. Additional information regarding the NCCTG DMC policy is available by contacting the NCCTG Operations Office.

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