NCCTG Data Monitoring Committee Adverse Events Report
Meeting Date: April 11, 2006

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

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

On 4/11/06, 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*: The DMC voted unanimously (7-0) to provide the study chair with quarterly updates regarding the expected time of interim analysis for each of the two comparisons of interest, but not the actual number of events overall or by arm. The adverse event data were reviewed and no issues of concern were noted.

CANCER CONTROL

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

- *Action*: The DMC voted unanimously (7-0) to release data to study team, but to continue study monitoring. The adverse event data were reviewed and no issues of concern were noted.

#N01C9 (Docetaxol and Infliximab/Placebo in Non-Small Cell Lung Cancer Patients)

- *Action*: The DMC voted unanimously (7-0) to terminate DMC monitoring and release data to the study team. The adverse event data were reviewed and no issues of concern were noted.

#N01C4 (Phase III Double-Blind, Placebo-Controlled Randomized Comparison of Zinc Sulfate Versus Placebo for the Prevention of Altered Taste in Patients with Head and Neck Cancer During Radiation)

- *Action*: The DMC voted unanimously (7-0) to release data to study team and terminate DMC monitoring. The adverse event data were reviewed and no issues of concern were noted.

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

- *Action*: The DMC voted unanimously (7-0) to continue per protocol. The study team is strongly encouraged to allow the trial to complete its full accrual of 220 patients. The adverse event data were reviewed and no issues of concern were noted.

#N01CB (The Efficacy of Lidocaine Patch in the Management of Postsurgical Neuropathic Pain in

Patients with Cancer: A Phase III Double-Blind, Crossover Study)

- *Action*: The DMC voted unanimously (7-0) to recommend study closure due to slow accrual, release data to study team, and terminate DMC monitoring. The adverse event data were reviewed and no issues of concern were noted.

#N00C9 The Use of Ginkgo Biloba for the Prevention of Chemotherapy-Related Cognitive Dysfunction

- *Action*: The DMC reviewed the current toxicity and efficacy data, and no issues requiring intervention were identified.

#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

- *Action*: The DMC reviewed the current toxicity and efficacy data, and no issues requiring intervention were identified.

#N02C1 – A Randomized Controlled Trial of Risedronate for Prevention of Bone Loss In Women Undergoing Chemotherapy for Primary Breast Cancer

- *Action*: The DMC reviewed the current toxicity and efficacy data, and no issues requiring intervention were identified.

#N02C4 – Phase III Double-Blind, Placebo-Controlled Randomized Comparison of Creatine for Cancer-Associated Weight Loss

- *Action*: The DMC reviewed the current toxicity and efficacy data, and no issues requiring intervention 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 DMC reviewed the current toxicity and efficacy data, and no issues requiring intervention 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 DMC reviewed the current toxicity and efficacy data, and no issues requiring intervention 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 DMC voted unanimously (7-0) to continue accrual per protocol. The adverse event data were reviewed and no issues of concern were noted.

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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