



**CANCER AND LEUKEMIA GROUP B  
GROUP CHAIR'S OFFICE**

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**MONICA M. BERTAGNOLLI, MD**  
GROUP CHAIR

**MEMORANDUM**

Date: August 15, 2010

To: CALGB Principal Investigators and Lead CRAs

From: Monica M. Bertagnolli, MD, Group Chair

Re: CALGB Data and Safety Monitoring Board (DSMB) Report

The CALGB Data and Safety Monitoring Board (DSMB) met on June 25, 2010. Attached please find a listing of each study reviewed, the DSMB recommendation, and the action taken in response to the recommendation.

These statements may be submitted to your IRB per local IRB guidelines.

Questions may be directed to Michael Kelly, MA, Acting Director of Protocol Operations ([mkelly1@uchicago.edu](mailto:mkelly1@uchicago.edu); 773-702-8812).

## Cancer Control and Health Outcomes

70305 The CALGB Data and Safety Monitoring Board (DSMB) reviewed CALGB 70305, A randomized study of lymphedema in women treated for breast cancer, during a meeting on June 25, 2010. The DSMB recommended continued accrual and monitoring.

Action: Recommendation accepted.

70604 The CALGB Data and Safety Monitoring Board (DSMB) reviewed CALGB 70604, A randomized phase III study of standard dosing versus longer dosing interval of zoledronic acid in metastatic cancer, during a meeting on June 25, 2010. The DSMB recommended continued accrual and monitoring.

Action: Recommendation accepted.

## Oncology Nursing Committee

170601 The CALGB Data and Safety Monitoring Board (DSMB) reviewed CALGB 170601, A phase III double blind study of oral duloxetine for treatment of pain associated with chemotherapy induced peripheral neuropathy, during a meeting on June 25, 2010. The DSMB recommended continued accrual and monitoring.

Action: Recommendation accepted.

## Surgery Committee

140503 The CALGB Data and Safety Monitoring Board (DSMB) reviewed CALGB 140503, A randomized phase III trial of lobectomy versus sublobar resection for small ( $\leq 2$  cm) peripheral non-small cell lung cancer, during a meeting on June 25, 2010. The DSMB recommended continued accrual and monitoring.

Action: Recommendation accepted.

## GI Committee

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80101 The CALGB Data and Safety Monitoring Board (DSMB) reviewed CALGB 80101, Phase III intergroup trial of adjuvant chemoradiation after resection of gastric or gastroesophageal adenocarcinoma, during a meeting on June 25, 2010. The DSMB recommended continued monitoring.

Action: Recommendation accepted.

80405 The CALGB Data and Safety Monitoring Board (DSMB) reviewed CALGB 80405, A phase III trial of irinotecan/5FU/leucovorin or oxaliplatin/5FU/leucovorin with bevacizumab or cetuximab (C225) or with the combination of bevacizumab and cetuximab for patients with untreated

metastatic adenocarcinoma of the colon and rectum, during a meeting on June 25, 2010. The DSMB recommended continued accrual and monitoring.

Action: Recommendation accepted.

## **Leukemia Committee**

10603 The CALGB Data and Safety Monitoring Board (DSMB) reviewed CALGB 10603, A phase III randomized double blind study of induction (daunorubicin/cytarabine) and consolidation (high dose cytarabine) chemotherapy + midostaurin (PKC 412; IND# 101261) or placebo in newly diagnosed patients < 60 years of age with FLT3 mutated acute myeloid leukemia, during a meeting on June 25, 2010. The DSMB recommended continued accrual and monitoring.

Action: Recommendation accepted.

## **Transplant Committee**

100103 The CALGB Data and Safety Monitoring Board (DSMB) reviewed CALGB 100103, A phase II study of allogeneic transplant for older patients with AML in first morphologic complete remission using a non-myeloablative preparation regimen, during a meeting on June 25, 2010. The DSMB recommended continued monitoring and accrual.

Action: Recommendation accepted.

## **Respiratory Committee**

30610 The CALGB Data and Safety Monitoring Board (DSMB) reviewed CALGB 30610, Phase III comparison of thoracic radiotherapy regimens in patients with limited small cell lung cancer also receiving etoposide and cisplatin, during a meeting on June 25, 2010. The DSMB recommended continued accrual and monitoring.

Action: Recommendation accepted.

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~~30607 The CALGB Data and Safety Monitoring Board (DSMB) reviewed CALGB 30607, Randomized phase III double blind placebo controlled trial of sunitinib as maintenance therapy in non-progressing patients following an initial 4 cycles of platinum based combination chemotherapy in advanced, stage IIIB/IV non-small cell lung cancer, during a meeting on June 25, 2010. The DSMB recommended continued accrual and monitoring.~~

~~Action: Recommendation accepted.~~

30506 The CALGB Data and Safety Monitoring Board (DSMB) reviewed CALGB 30506, A randomized phase III trial of adjuvant therapy in early stage NSCLC

evaluating the potential utility of a genomic prognostic model to identify patients as candidates for adjuvant therapy, during a meeting on June 25, 2010. The DSMB recommended that a conference call between the DSMB and the study team be set up within the next 2 weeks to discuss the status of the study and potential remedies for the current accrual rate. Note: subsequent to this DSMB review the study was temporarily suspended to accrual due to the unavailability of the lung metagene profiling.

Action: Recommendation accepted.

## GU Committee

90202 The CALGB Data and Safety Monitoring Board (DSMB) reviewed CALGB 90202, 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, during a meeting on June 25, 2010. The DSMB recommended continued accrual and monitoring.

Action: Recommendation accepted.

90203 The CALGB Data and Safety Monitoring Board (DSMB) reviewed CALGB 90203, A randomized phase III trial of neo-adjuvant docetaxel and androgen deprivation prior to radical prostatectomy versus immediate radical prostatectomy in patients with high risk clinically localized prostate cancer, during a meeting on June 25, 2010. The DSMB recommended continued accrual and monitoring.

Action: Recommendation accepted.

90601 The CALGB Data and Safety Monitoring Board (DSMB) reviewed CALGB 90601, A randomized, double blinded phase III study comparing gemcitabine cisplatin and bevacizumab to gemcitabine, cisplatin, and placebo in patients with advanced transitional cell carcinoma; Intergroup C90601, during a meeting on June 25, 2010. The DSMB recommended continued accrual and monitoring.

Action: Recommendation accepted.

## Lymphoma Committee

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50303 The CALGB Data and Safety Monitoring Board (DSMB) reviewed CALGB 50303, Phase III randomized study of R-CHOP v. dose adjusted EPOCH-R with molecular profiling in untreated *de novo* diffuse large B-cell lymphoma, during a meeting on June 25, 2010. The DSMB recommended continued accrual and monitoring.

Action: Recommendation accepted.

## Breast Committee

40101 The CALGB Data and Safety Monitoring Board (DSMB) reviewed CALGB 40101, Cyclophosphamide and doxorubicin (4 vs. 6 cycles) versus paclitaxel (4 vs. 6 cycles) as adjuvant therapy for women with node negative breast cancer: a 2x2 factorial phase III randomized study now modified as Cyclophosphamide and doxorubicin (CA x4) versus paclitaxel (4 cycles) as adjuvant therapy for breast cancer in women with 0-3 positive axillary lymph nodes, during a meeting on June 25, 2010. The DSMB recommended closure of 40101 due to insufficient accrual.

Action: Recommendation accepted.

40302 The CALGB Data and Safety Monitoring Board (DSMB) reviewed CALGB 40302, Endocrine therapy with or without inhibition of EGF and HER2 growth factor receptors: a randomized, double-blind, placebo-controlled, phase III trial of Fulvestrant with or without lapatinib for post menopausal women with hormone receptor positive advanced breast cancer, during a meeting on June 25, 2010. The DSMB recommended closure of this trial as a protocol specified futility boundary has been crossed indicating little or no difference between the treatment arms.

Action: Recommendation accepted.

40502 The CALGB Data and Safety Monitoring Board (DSMB) reviewed CALGB 40502, A Randomized Phase III trial of weekly paclitaxel compared to weekly nanoparticle albumin bound paclitaxel or ixabepilone combined with bevacizumab as first line therapy for locally recurrent or metastatic breast cancer, during a meeting on June 25, 2010. The DSMB recommended continued accrual and monitoring.

Action: Recommendation accepted.

40503 The CALGB Data and Safety Monitoring Board (DSMB) reviewed CALGB 40503, Endocrine therapy in combination with anti-VEGF therapy: A randomized double-blind, placebo-controlled phase III trial of endocrine therapy alone or endocrine therapy plus bevacizumab for women with hormone receptor positive advanced breast cancer, during a meeting on June 25, 2010. The DSMB recommended continued accrual and monitoring to the phase III letrozole portion of the trial. A majority of the voting DSMB members recommended that DSMB need not formally monitor the randomized phase II tamoxifen portion of the study.

Action: Recommendation accepted.

40601 The CALGB Data and Safety Monitoring Board (DSMB) reviewed CALGB 40601, Randomized phase III trial of paclitaxel combined with trastuzumab, lapatinib, or both as neoadjuvant treatment of HER-2 positive primary breast cancer, during a meeting on June 25, 2010. The DSMB recommended continued accrual and monitoring.

Action: Recommendation accepted.

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