

Adult Central IRB Meeting Agenda

Thursday, February 18, 2010

I General Business

- The next meeting is scheduled for March 4, 2010
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II Minutes

- February 4, 2010
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III Report from the AE Subcommittee

- Adverse Event Report
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IV Continuing Review

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 (GW572016) For Postmenopausal Women With Hormone Receptor Positive Advanced Breast Cancer (Protocol Version Date 08/21/09)

V Continuing Review

CALGB 90206, A Randomized Phase III Trial of Interferon Alfa-2B or Interferon Alfa-2B Plus Bevacizumab in Patients with Advanced Renal Carcinoma (Protocol Version Date 11/19/09)

VI Continuing Review

NSABP B-36, A Clinical Trial of Adjuvant Therapy Comparing Six Cycles of 5-Fluorouracil, Epirubicin and Cyclophosphamide (FEC) to Four Cycles of Adriamycin and Cyclophosphamide (AC) in Patients with Node-Negative Breast Cancer (Protocol Version Date 04/20/07)

VII Continuing Review

NSABP B-38, A Phase III Adjuvant Trial Comparing Three Chemotherapy Regimens in Women with Node-Positive Breast Cancer: Docetaxel/Doxorubicin/Cyclophosphamide (TAC); Dose-Dense (DD) Doxorubicin/Cyclophosphamide Followed by DD Paclitaxel (DD AC?P); DD Doxorubicin/ Cyclophosphamide Followed by DD Paclitaxel Plus Gemcitabine (DD AC?PG) (Protocol Version Date 04/17/07)

VIII Continuing Review

ECOG 2905, Randomized Phase III Trial Comparing the Frequency of Major Erythroid Response (MER) to Treatment with Lenalidomide (Revlimid®) Alone and in Combination with Epoetin Alfa (Procrit®) in Subjects with Low- or Intermediate-1 Risk MDS and Symptomatic Anemia (Protocol Version Date 12/03/09)

IX Continuing Review

GOG 0213, A Phase III Randomized Controlled Clinical Trial of Carboplatin and Paclitaxel alone or in Combination with Bevacizumab (NSC #704865, IND #7921) followed by Bevacizumab and Secondary Cytoreductive Surgery in Platinum-Sensitive, Recurrent Ovarian, Peritoneal Primary and Fallopian Tube Cancer (Protocol Version Date 03/06/09)

X Continuing Review

ECOG E4A03, A Randomized Phase III Study of CC-5013 Plus Dexamethasone Versus CC-5013 Plus Low Dose Dexamethasone in Multiple Myeloma with Thalidomide Plus Dexamethasone Salvage Therapy for Non-Responders (Protocol Version Date 12/01/09)

XI Unanticipated Problem Determination – Ibandronate Shortage

SWOG S0307, Phase III Trial of Bisphosphonates as Adjuvant Therapy for Primary Breast Cancer

XII Continuing Review

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 (Protocol Version Date 05/22/09)

XIII Amendment Review

CALGB 30506 Update 1, A Randomized Phase III Trial of Adjuvant Therapy in Early Stage Non-Small Cell Lung Cancer Evaluating the Potential Utility of a Genomic Prognostic Model to Identify Patients as Candidates for Adjuvant Chemotherapy (Protocol Version Date 01/11/10)

XIV Continuing Review

RTOG 0920, A Phase III Study of Postoperative Radiation Therapy (Imrt) +/- Cetuximab for Locally-Advanced Resected Head and Neck Cancer (Protocol Version Date 10/12/09)
