



Adult CIRB – Late Phase Emphasis Meeting Agenda

Thursday, April 20, 2017
9:00 am – 12:55 pm (Eastern)

I Initial Review

A041501, A Phase III Trial to Evaluate the Efficacy of the Addition of Inotuzumab Ozogamicin (A Conjugated Anti-CD22 Monoclonal Antibody) to Frontline Therapy in Young Adults (Ages 18-39 Years) with Newly Diagnosed Precursor B-Cell ALL (Protocol Version Date 03/15/17)

II Initial Review

S1613, A Randomized Phase II Study of Trastuzumab and Pertuzumab (TP) Compared to Cetuximab and Irinotecan (CETIRI) in Advanced/Metastatic Colorectal Cancer (MCRC) with HER-2 Amplification (Protocol Version Date 03/10/17)

III Initial Review

NRG-BN005, A Phase II Randomized Trial of Proton vs. Photon Therapy (IMRT) for Cognitive Preservation in Patients with IDH Mutant, Low to Intermediate Grade Gliomas (Protocol Version Date 03/09/17)

IV Continuing Review

ANZGOG-0902-GOG-0274, A Phase III Trial of Adjuvant Chemotherapy Following Chemoradiation as Primary Treatment for Locally Advanced Cervical Cancer Compared to Chemoradiation Alone: THE OUTBACK TRIAL (ANZGOG 0902/GOG-0274/RTOG 1174) (Protocol Version Date 05/09/16 Study Chair Handbook Date 06/24/16)

V Continuing Review

NCIC-MA.32, A Phase III Randomized Trial of Metformin Versus Placebo on Recurrence and Survival in Early Stage Breast Cancer (Protocol Version Date 02/04/16)

VI Continuing Review

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 Lymphomas (Protocol Version Date 10/26/15)

VII Continuing Review

E2905, 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 03/10/17)

VIII 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 07/11/16)

IX Continuing Review

E4402, Randomized Phase III Trial Comparing Two Different Rituximab Dosing Regimens for Patients with Low Tumor Burden Indolent Non-Hodgkin's Lymphoma (Protocol Version Date 04/23/14 Update Date 03/11/15)

X Continuing Review

S1507, A Phase II Trial of Trametinib with Docetaxel in Patients with Kras Mutation Positive Non-Small Cell Lung Cancer (NSCLC) and Progressive Disease Following One or Two Prior Systemic Therapies (Protocol Version Date 01/04/17)

XI Continuing Review

S1416, Phase II Randomized Placebo-Controlled Trial of Cisplatin with or without ABT-888 (Veliparib) in Metastatic Triple-Negative Breast Cancer and/or BRCA Mutation-Associated Breast Cancer (Protocol Version Date 06/14/16)

XII Reports of Expedited Reviews March 2017

- Late Phase Emphasis CIRB Local Context Subcommittee Report
 - Expedited Reviews and Study Acknowledgements
 - Study Activation Acknowledgements
 - Amendment Activation Acknowledgements
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