

Adult CIRB - Late Phase Emphasis Meeting Agenda

November 5, 2020

I Continuing Review

A011502, A Randomized Phase III Double Blinded Placebo-Controlled Trial of Aspirin as Adjuvant Therapy for HER2 Negative Breast Cancer: The ABC Trial (Protocol Version Date 11/27/18)

II Continuing Review

CALGB-100104, A Phase III Randomized, Double-Blind Study of Maintenance Therapy with CC-5013 (NSC #703813, IND#70116) or Placebo Following Autologous Stem Cell Transplantation for Multiple Myeloma (Protocol Version Date 09/27/19)

III Continuing Review

CCTG MA.39, Tailor RT: A Randomized Trial of Regional Radiotherapy in Biomarker Low Risk Node Positive Breast Cancer (Protocol Version Date 04/04/18)

IV 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 11/07/19)



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V Continuing Review

E5508, Randomized Phase III Study of Maintenance Therapy with Bevacizumab, Pemetrexed, or a Combination of Bevacizumab and Pemetrexed Following Carboplatin, Paclitaxel and Bevacizumab for Advanced Non-Squamous NSCLC (Protocol Version Date 10/12/18)

VI Continuing Review

NRG-BR005, A Phase II Trial Assessing the Accuracy of Tumor Bed Biopsies in Predicting Pathologic Response in Patients with Clinical/Radiologic Complete Response after Neoadjuvant Chemotherapy in Order to Explore the Feasibility of Breast Conserving Treatment without Surgery (Protocol Version Date 10/08/19)

VII Continuing Review

NRG-GI006, Phase III Randomized Trial of Proton Beam Therapy (PBT) versus Intensity Modulated Photon Radiotherapy (IMRT) for the Treatment of Esophageal Cancer (Protocol Version Date 12/19/18)

VIII Continuing Review

NRG-GY009, A Randomized, Phase II/III Study of Pegylated Liposomal Doxorubicin and CTEP-Supplied Atezolizumab (IND #134427) versus Pegylated Liposomal Doxorubicin, CTEP-Supplied Bevacizumab and CTEP-Supplied Atezolizumab versus Pegylated Liposomal Doxorubicin and CTEP-Supplied Bevacizumab in Platinum Resistant Ovarian Cancer (Protocol Version Date 06/29/20)

IX Continuing Review

NRG-GY014, A Phase II Study of Tazemetostat (EPZ-6438) in Recurrent or Persistent Endometrioid or Clear Cell Carcinoma of the Ovary, and Recurrent or Persistent Endometrioid Endometrial Adenocarcinoma (Protocol Version Date 07/07/20)

X Continuing Review

NSABP-B-51, A Randomized Phase III Clinical Trial Evaluating Post-Mastectomy Chestwall and Regional Nodal XRT and Post-Lumpectomy Regional Nodal XRT in Patients with Positive



Axillary Nodes Before Neoadjuvant Chemotherapy Who Convert to Pathologically Negative Axillary Nodes After Neoadjuvant Chemotherapy (Protocol Version Date 03/18/20)

XI Continuing 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 09/17/19)

XII Continuing Review

S1616, A Phase II Randomized Study of Nivolumab (NSC-748726) with Ipilimumab (NSC-732442) or Ipilimumab Alone in Advanced Melanoma Patients Refractory to an Anti-PD1 or Anti-PD-L1 Agent (Protocol Version Date 11/08/19)

XIII Continuing Review

S1701, A Randomized Phase II Trial of Carboplatin-Paclitaxel with or without Ramucirumab in Patients with Unresectable Locally Advanced, Recurrent, or Metastatic Thymic Carcinoma (Protocol Version Date 05/29/20)

XIV Continuing Review

S1712, A Randomized Phase II Study of Ruxolitinib (NSC-752295) in Combination with BCR-ABL Tyrosine Kinase Inhibitors in Chronic Myeloid Leukemia (CML) Patients with Molecular Evidence of Disease (Protocol Version Date 01/07/20)

XV Continuing Review

S1803, Phase III Study of Daratumumab/rHuPH20 (NSC-810307) + Lenalidomide or Lenalidomide as Post-Autologous Stem Cell Transplant Maintenance Therapy in Patients with Multiple Myeloma (MM) using Minimal Residual Disease to Direct Therapy Duration (DRAMMATIC STUDY) (Protocol Version Date 01/21/20)



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XVI New Study - Initial Review

A031901, Duration of Immune Checkpoint Therapy in Locally Advanced or Metastatic Urothelial Carcinoma: A Randomized Phase 3 Non-Inferiority Trial (Protocol Version Date 10/07/20)

XVII New Study - Initial Review

S1900E, A Phase II Study of AMG 510 in Participants with Previously Treated Stage IV or Recurrent KRAS G12C Mutated Non-Squamous Non-Small Cell Lung Cancer (ECOG-ACRIN LungMAP Sub-Study) (Protocol Version Date 09/29/20)

XVIII Amendment

A031702, A Phase II Study of Ipilimumab, Cabozantinib, and Nivolumab in Rare Genitourinary Cancers (ICONIC) (Protocol Version Date 09/23/20)

XIX Amendment

EA1131, A Randomized Phase III Post-Operative Trial of Platinum Based Chemotherapy Vs. Capecitabine in Patients with Residual Triple-Negative Breast Cancer following Neoadjuvant Chemotherapy (Protocol Version Date 08/20/20)

XX Amendment

EA2174, A Phase II/III Study of Peri-operative Nivolumab and Ipilimumab in Patients with Locoregional Esophageal and Gastroesophageal Junction Adenocarcinoma (Protocol Version Date 09/17/20)
