

Adult CIRB - Late Phase Emphasis Meeting Agenda

October 7, 2021

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 01/26/21)

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 and T3N0 Breast Cancer (Protocol Version Date 03/23/21)

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)

V 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)

VI 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 11/05/20)

VII 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 05/17/21)

VIII 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)

IX 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 02/15/21)

X 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 06/10/21)

XI 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 08/11/21)

XII 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 10/22/20)

XIII Continuing Review

S1806, Phase III Randomized Trial of Concurrent Chemoradiotherapy with or without Atezolizumab in Localized Muscle Invasive Bladder Cancer (Protocol Version Date 07/07/21)

XIV Continuing Review

S1937, A Phase III Randomized Trial of Eribulin (NSC #707389) with or without Gemcitabine versus Standard of Care (Physician's Choice) for Treatment of Metastatic Urothelial Carcinoma Refractory to, or Ineligible for, Anti PD1/PDL1 Therapy (Protocol Version Date 03/11/21)

XV Continuing Review

S2007, A Phase II Trial of Sacituzumab Govitecan (IMMU-132) (NSC #820016) for Patients with HER2-Negative Breast Cancer and Brain Metastases (Protocol Version Date 10/30/20)

XVI New Study - Initial Review

EA3202, A Phase II/III Trial of Chemotherapy + Cetuximab vs Chemotherapy + Bevacizumab vs Atezolizumab + Bevacizumab Following Progression on Immune Checkpoint Inhibition in Recurrent/Metastatic Head and Neck Cancers (Protocol Version Date 09/02/21)

XVII New Study - Initial Review

S1800D, A Phase II/III Study of N-803 (ALT-803) Plus Pembrolizumab Versus Standard of Care in Participants with Stage IV or Recurrent Non-Small Cell Lung Cancer Previously Treated with Anti-PD-1 or Anti-PD-L1 Therapy (Lung-MAP Non-Match Sub-Study) (Protocol Version Date 09/02/21)

XVIII New Study - Initial Review

S2012, Randomized Phase II/III Trial of First Line Platinum/Etoposide with or without Atezolizumab (NSC #783608) in Patients with Poorly Differentiated Extrapulmonary Small Cell Neuroendocrine Carcinomas (NEC) (Protocol Version Date 08/23/21)

XIX Memos

S1602, A Phase III Randomized Trial to Evaluate the Influence of BCG Strain Differences and T Cell Priming with Intradermal BCG Before Intravesical Therapy for BCG-Naïve High-Grade Non-Muscle Invasive Bladder Cancer (Protocol Version Date 07/22/19)

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