

Adult CIRB - Late Phase Emphasis Meeting Agenda

September 1, 2022

I Continuing Review

A031803, Phase II Trial of Intravesical Gemcitabine and MK-3475 (pembrolizumab) in the Treatment of Patients with BCG-Unresponsive Non-Muscle Invasive Bladder Cancer (Protocol Version Date 05/11/22)

II Continuing Review

A031901, Duration of Immune Checkpoint Therapy in Locally Advanced or Metastatic Urothelial Carcinoma: A Randomized Phase 3 Non-Inferiority Trial (IMAGINE) (Protocol Version Date 04/27/22)

III 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)

IV 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)

V 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)

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 11/05/20)

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 05/17/21)

IX Continuing Review

NRG-GY014, A Phase II Study of Tazemetostat (EPZ-6438) (IND # 138671) in Recurrent or Persistent Endometrioid or Clear Cell Carcinoma of the Ovary, and Recurrent or Persistent Endometrioid Endometrial Adenocarcinoma (Protocol Version Date 04/06/22)

X 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 01/07/22)

XI 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)

XII 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)

XIII Continuing Review

S1806, Phase III Randomized Trial of Concurrent Chemoradiotherapy with or without Atezolizumab in Localized Muscle Invasive Bladder Cancer (Protocol Version Date 06/30/22)

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 03/30/22)

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 06/10/22)

XVI Amendment ReReview

NRG-LU005, Limited Stage Small Cell Lung Cancer (LS-SCLC): A Phase III Randomized Study of Chemoradiation Versus Chemoradiation Plus Atezolizumab (Protocol Version Date 08/03/22)

XVII Amendment

EA9152, A Phase Ib/II Study of Venetoclax (ABT-199) in Combination with Liposomal Vincristine in Patients with Relapsed or Refractory T-cell or B-cell Acute Lymphoblastic Leukemia (Protocol Version Date 07/20/22)
