

**Adult CIRB - Late Phase Emphasis Meeting Agenda**

**July 20, 2023**

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**I Amendment**

**NRG-GI008**, Colon Adjuvant Chemotherapy Based on Evaluation of Residual Disease (CIRCULATE-US) (Version Date 06/14/23)

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**II Amendment**

**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) (Version Date 05/18/23)

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**III Amendment**

**S2114**, A Randomized Phase II Trial of Consolidation Therapy Following CD19 CAR T-Cell Treatment for Relapsed/Refractory Large B-Cell Lymphoma or Grade IIIB Follicular Lymphoma (Version Date 05/23/23)

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**IV 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 (Version Date 03/21/23)

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**V Continuing Review**

**ABTC-1604**, Phase 0/I Study of AMG 232 (KRT 232) Concentrations in Brain Tissue in Patients with Recurrent Glioblastoma and of AMG 232 (KRT 232) in Combination with Radiation in Patients with Newly Diagnosed Glioblastoma and Unmethylated MGMT Promoters (Version Date 12/19/22)

## **VI 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 (Version Date 09/27/19)

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## **VII Continuing Review**

**CCTG MA.39**, Tailor RT: A Randomized Trial of Regional Radiotherapy in Biomarker Low Risk Node Positive and T3N0 Breast Cancer (Version Date 09/19/22)

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## **VIII Continuing 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 (Version Date 05/23/23)

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## **IX 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 (Version Date 11/05/20)

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## **X 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 (Version Date 01/11/23)

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## **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 (Version Date 01/07/22)

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## **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 (Version Date 11/11/22)

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## **XIII 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 (Version Date 09/23/22)

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## **XIV Continuing Review**

**S1806**, Phase III Randomized Trial of Concurrent Chemoradiotherapy with or without Atezolizumab in Localized Muscle Invasive Bladder Cancer (Version Date 11/11/22)

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## **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 (Version Date 10/10/22)

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## **XVI 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 (Version Date 03/30/22)

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