

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

**December 21, 2023**

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**I New Study - Initial Review**

**A062102**, Randomized Phase 2 Study of Iberdomide Maintenance Therapy Following Idecaptagene Vicleucel CAR-T in Multiple Myeloma Patients (Version Date 11/21/23)

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**II New Study - Initial Review**

**CCTG-CO32**, The NEO-RT Trial: A Phase 3 Randomized Trial of Neoadjuvant Chemotherapy, Excision and Observation versus ChemoRadioTherapy for Early Rectal Cancer (Version Date 11/16/23)

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**III New Study ReReview**

**EAF223**, Phase II Glioblastoma Accelerated Biomarkers Learning Environment Trial (GABLE) (Version Date 11/22/23)

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**IV Amendment**

**S2005**, A Phase II Randomized Study of Ibrutinib and Rituximab with or without Venetoclax in Previously Untreated Waldenström's Macroglobulinemia (WM)/Lymphoplasmacytic Lymphoma (LPL) (Version Date 10/27/23)

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**V Amendment**

**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 (Version Date 11/15/23)

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## **VI Continuing Review**

**A022001**, Phase II Randomized, Prospective Trial of Lutetium Lu 177 Dotatate PRRT Versus Capecitabine and Temozolomide in Well-Differentiated Pancreatic Neuroendocrine Tumors: The ComPareNET Trial (Version Date 10/12/23)

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## **VII Continuing Review**

**A031701**, A Phase II Study of Gemcitabine Plus Cisplatin Chemotherapy in Patients with Muscle-Invasive Bladder Cancer with Bladder Preservation for Those Patients Whose Tumors Harbor Deleterious DNA Damage Response (DDR) Gene Alterations (Version Date 01/13/21)

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## **VIII Continuing Review**

**NRG-HN005**, A Randomized Phase II/III Trial of De-intensified Radiation Therapy for Patients with Early-Stage, p16-Positive, Non-Smoking Associated Oropharyngeal Cancer (Version Date 08/21/23)

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## **IX Continuing Review**

**A051902**, A Randomized Phase II Study of CHO(E)P vs CC-486-CHO(E)P vs Duvelisib-CHO(E)P in Previously Untreated CD30 Negative Peripheral T-Cell Lymphomas (Version Date 11/28/22)

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## **X Continuing Review**

**E3A06**, Randomized Phase III Trial of Lenalidomide versus Observation Alone In Patients with Asymptomatic High-Risk Smoldering Multiple Myeloma (Version Date 09/26/19)

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## **XI Continuing Review**

**NRG-GI007**, Phase I Trial with Expansion Cohort of OBP-301 (Telomelysin) and Definitive Chemoradiation for Patients with Locally Advanced Esophageal And Gastroesophageal Cancer Who are Not Candidates for Surgery (Version

Date 07/10/23)

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## **XII Continuing Review**

**EA1211**, Interim FDG-PET/CT for PreDIcting REsponse of HER2+ Breast Cancer to Neoadjuvant Therapy: DIRECT trial (Version Date 01/04/23)

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## **XIII Continuing Review**

**NRG-BR007**, A Phase III Clinical Trial Evaluating De-Escalation of Breast Radiation for Conservative Treatment of Stage I, Hormone Sensitive, HER2-Negative, Oncotype Recurrence Score  $\leq 18$  Breast Cancer (Version Date 10/20/23)

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## **XIV Continuing Review**

**E1910**, A Phase III Randomized Trial of Blinatumomab for Newly Diagnosed BCR-ABL-negative B lineage Acute Lymphoblastic Leukemia in Adults (Version Date 01/20/23)

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