

Adult CIRB - Late Phase Emphasis Meeting Agenda

November 6, 2025

I 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 12/12/24)

II Continuing Review

A022101, A Pragmatic Randomized Phase III Trial Evaluating Total Ablative Therapy for Patients with Limited Metastatic Colorectal Cancer: Evaluating Radiation, Ablation, and Surgery (ERASur) (Version Date 02/01/25)

III 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)

IV 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 05/27/25)

V Continuing Review

A062101, A Phase I/II Study of the Safety, Tolerability and Efficacy of Belantamab Mafodotin (GSK2857916) in Combination with Iberdomide (CC-220)/Dexamethasone versus Belantamab Mafodotin (GSK2857916)/Dexamethasone in Relapsed Refractory Multiple Myeloma (Version Date 07/08/24)

VI Continuing Review

CCTG-NE1, NET RETREAT: A Phase II Study of 177 Lutetium-DOTATATE Retreatment vs. Everolimus or Sunitinib or Cabozantinib in Metastatic/Unresectable Gastroenteropancreatic Neuroendocrine Tumours (Version Date 08/01/25)

VII Continuing Review

CCTG-PR24, Androgen Suppression Combined with Elective Nodal Irradiation and Dose Escalated Prostate Treatment: A Non-Inferiority, Phase III Randomized Controlled Trial of Stereotactic Body Radiation Therapy versus Brachytherapy Boost in Patients with Unfavourable Risk Localized Prostate Cancer (ASCENDE SBRT) (Version Date 06/27/25)

VIII 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)

IX Continuing Review

EA2182, A Randomized Phase II Study of De-Intensified ChemoRadiation for Early-Stage Anal Squamous Cell Carcinoma (DECREASE) (Version Date 09/19/23)

X Continuing Review

EA1211, Interim FDG-PET/CT for PreDIcting REsponse of HER2+ Breast Cancer to Neoadjuvant Therapy: DIRECT trial (Version Date 07/07/25)

XI Continuing Review

EA8191, Phase III Study of Local or Systemic Therapy INtensification DIrected by PET in Prostate CANcer Patients with Post-ProstaTEctomy Biochemical Recurrence (INDICATE) (Version Date 02/10/25)

XII 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 ≤ 18 Breast Cancer (Version Date 10/20/23)

XIII Continuing Review

NRG-BR008, Phase III Randomized Trial of Radiotherapy Optimization for Low-Risk HER2-Positive Breast Cancer (HERO) (Version Date 11/25/24)

XIV Continuing Review

NRG-GY026, A Phase II/III Study of Paclitaxel/Carboplatin Alone or Combined with Either Trastuzumab and Hyaluronidase-oysk (HERCEPTIN HYLECTA) or Pertuzumab Trastuzumab and Hyaluronidase-zzfx (PHESGO) in HER2 Positive, Stage I-IV Endometrial Serous Carcinoma or Carcinosarcoma (Version Date 10/16/25)

XV Continuing Review

EA3211, Phase III Randomized Trial of Immunotherapy with or without Consolidative Radiotherapy for Oligometastatic Head and Neck Squamous Cell Carcinoma (Version Date 09/23/25)

XVI Continuing Review

S1802, Phase III Randomized Trial of Standard Systemic Therapy (SST) versus Standard Systemic Therapy Plus Definitive Treatment (Surgery or Radiation) of the Primary Tumor in Metastatic Prostate Cancer (Version Date 06/07/24)

XVII Continuing Review

S1931, Phase III Trial Of Immunotherapy-Based Combination Therapy With Or Without Cytoreductive Nephrectomy For Metastatic Renal Cell Carcinoma (Probe Trial) (Version Date 07/22/25)



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XVIII Continuing Review

MM10A-S03, Randomized Phase II Trial of ASTX727 and Venetoclax Compared with ASTX727, Venetoclax, and Enasidenib for Newly Diagnosed Older Adults with IDH2 Mutant Acute Myeloid Leukemia: A MyeloMATCH Substudy (Version Date 02/28/25)
