

Adult CIRB - Late Phase Emphasis Meeting Agenda

August 21, 2025

I New Study - Initial Review

NRG-GI012, Phase III Randomized Trial of IO-Based Systemic Treatment +/- Liver SBRT in Hepatocellular Cancer with Macrovascular Invasion (HELIO-RT) (Version Date 07/23/25)

II Amendment

A041703, A Phase II Study of Inotuzumab Ozogamicin Followed by Blinatumomab for Ph-Negative CD22-Positive B-Lineage Acute Lymphoblastic Leukemia in Newly Diagnosed Older Adults or Adults with Relapsed or Refractory Disease (Version Date 07/09/25)

III Continuing Review

A022104, The Janus Rectal Cancer Trial: A Randomized Phase II/III Trial Testing the Efficacy of Triplet Versus Doublet Chemotherapy Regarding Clinical Complete Response and Disease-Free Survival in Patients with Locally Advanced Rectal Cancer (Version Date 01/21/25)

IV Continuing Review

A022106, Phase II/III Second-Line NABPLAGEM vs. Nab-Paclitaxel/Gemcitabine in BRCA1/2 or PALB2 Mutant Metastatic Pancreatic Ductal Adenocarcinoma (PLATINUM) (Version Date 09/28/23)

V Continuing Review

A032001, MAIN-CAV: Phase III Randomized Trial of Maintenance Cabozantinib and Avelumab vs Maintenance Avelumab After First-Line Platinum-Based Chemotherapy in Patients with Metastatic Urothelial Cancer (Version

Date 08/01/25)

VI Continuing Review

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 07/17/25)

VII Continuing Review

EA5163, INSIGNA: A Randomized, Phase III Study of Firstline Immunotherapy alone or in Combination with Chemotherapy in Induction/Maintenance or Postprogression in Advanced Nonsquamous Non-Small Cell Lung Cancer (NSCLC) with Immunobiomarker SIGNature-driven Analysis (Version Date 04/24/25)

VIII Continuing Review

EA9213, A Phase II Study of Daratumumab-Hyaluronidase for Chemotherapy-Relapsed/Refractory Minimal Residual Disease (MRD) in T Cell Acute Lymphoblastic Leukemia/Lymphoma (T-ALL/T-LBL) (Version Date 06/05/25)

IX Continuing Review

NRG-BN011, A Phase III Trial of Lomustine-Temozolomide Combination Therapy Versus Standard Temozolomide in Patients with Methylated MGMT Promoter Glioblastoma (Version Date 08/14/24)

X Continuing Review

NRG-GY028, A Phase IB and Randomized Phase II Trial of Megestrol Acetate with or without Ipatasertib in Recurrent or Metastatic Endometrioid Endometrial Cancer (Version Date 01/03/25)

XI Continuing Review

S1403, A Randomized Phase II Trial of Afatinib Plus Cetuximab Versus Afatinib Alone in Treatment-Naive Patients with Advanced, EGFR Mutation Positive Non-Small Cell Lung Cancer (NSCLC) (BI 1200.124) (Version Date 09/26/22)

XII Continuing Review

S1933, A Pilot Study of Hypofractionated Radiotherapy Followed by Atezolizumab Consolidation in Stage II or III NSCLC Patients with Borderline Performance Status (Version Date 03/03/25)

XIII Continuing Review

NRG-HN011, A Randomized Phase II Study of Nivolumab Versus Nivolumab and BMS-986016 (Relatlimab) as Maintenance Treatment After First-Line Treatment with Platinum-Gemcitabine-Nivolumab for Patients with Epstein-Barr Virus-Associated Recurrent/Metastatic Nasopharyngeal Carcinoma (REMAIN) (Version Date 08/04/25)

XIV Continuing Review

EA3161, A Phase III Randomized Study of Maintenance Nivolumab versus Observation in Patients with Locally Advanced, Intermediate Risk HPV Positive OPSCC (Version Date 07/30/25)
