

Adult CIRB - Late Phase Emphasis Meeting Agenda

July 16, 2026

I New Study - Initial Review

A052401, A Randomized Phase 2/3 Study of the Bispecific Antibody (BsAb), Glofitamab, plus Chemoimmunotherapy in Newly Diagnosed and Relapsed Burkitt and High-Grade (Double Hit) B-cell Lymphomas with MYC and BCL2 Rearrangements (Version Date 06/05/26)

II New Study - Initial Review

EA8252, A Randomized Phase III Study of Adjuvant Pembrolizumab vs Active Surveillance after Nephrectomy in Patients with Non-Clear Cell Renal Cell Carcinoma (Version Date 05/28/26)

III Amendment

S2207, Randomized Phase II Study of the Addition of Targeted Therapeutic Agents to Tafasitamab-Based Therapy in Non-Transplant-Eligible Patients with Relapsed/Refractory Large B-Cell Lymphoma (Version Date 06/10/26)

IV 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 04/15/26)

V 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 02/25/26)

VI Continuing Review

EA4232, A Randomized Phase III Study to Evaluate Benefits of Autologous Stem Cell Transplant in Patients with Peripheral T Cell Lymphoma that Achieved a First Complete Remission (CR1) Following Induction Therapy (PTCL-STAT) (Version Date 04/25/25)

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

NRG-BN011, A Phase III Trial of Lomustine-Temozolomide Combination Therapy Versus Standard Temozolomide in Patients with Methylated MGMT Promoter Glioblastoma (Version Date 10/03/25)

IX 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)

X 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 02/05/26)

XI 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 01/30/26)
