

Adult CIRB - Late Phase Emphasis Meeting Agenda

July 2, 2026

I New Study - Initial Review

EA8251, A Randomized Phase II/III Trial Evaluating Bipolar Androgen Therapy Followed by Darolutamide vs Standard of Care in Patients with Metastatic Castration Resistant Prostate Cancer (Version Date 06/03/26)

II New Study - Initial Review

EA2251, A Phase II/III Randomized Study of Ivonescimab with Gemcitabine and Cisplatin versus Standard of Care Chemoimmunotherapy in Advanced Biliary Tract Cancer (Version Date 05/22/26)

III Amendment

A062102, Randomized Phase 2 Study of Iberdomide Maintenance Therapy Following Idecabtagene Vicleucel CAR-T in Multiple Myeloma Patients (Version Date 05/21/26)

IV Continuing Review

A032102, PREcision DIagnostics in Prostate Cancer Treatment (PREDICT) (Version Date 03/21/25)

V Continuing Review

CTIU2317-A082304-S2402, Perioperative versus Adjuvant Systemic Therapy in Patients with Resectable Non-Small Cell Lung Cancer - PROSPECT LUNG (Version Date 10/29/24)

VI Continuing Review

E1912, A Randomized Phase III Study of Ibrutinib (PCI- 32765)-based Therapy vs Standard Fludarabine, Cyclophosphamide, and Rituximab (FCR) Chemoimmunotherapy in Untreated Younger Patients with Chronic Lymphocytic Leukemia (CLL) (Version Date 08/21/25)

VII Continuing Review

EA3191, A Phase II Randomized Trial of Adjuvant Therapy with Pembrolizumab after Resection of Recurrent/Second Primary Head and Neck Squamous Cell Carcinoma with High Risk Features (Version Date 04/18/25)

VIII Continuing Review

EA5182, Randomized Phase III Study of Combination Osimertinib (AZD9291) and Bevacizumab versus Osimertinib (AZD9291) Alone as First-Line Treatment for Patients with Metastatic EGFR-Mutant Non-Small Cell Lung Cancer (NSCLC) (Version Date 10/03/24)

IX Continuing Review

EA7222, A Randomized Phase III Trial of Doxorubicin + Pembrolizumab Versus Doxorubicin Alone for the Treatment of Dedifferentiated Liposarcoma (DDLPS), Undifferentiated Pleomorphic Sarcoma (UPS) and Related Poorly Differentiated Sarcomas (Version Date 03/17/26)

X Continuing Review

NRG-GY037, A Phase III Study of Induction Pembrolizumab and Chemotherapy Followed by Chemoradiation and Pembrolizumab vs Chemoradiation and Pembrolizumab Both Followed by Pembrolizumab for High Risk Locally Advanced Cervical Cancer (Version Date 08/13/25)

XI Continuing Review

S1925, Randomized, Phase III Study of Early Intervention with Venetoclax and Obinutuzumab versus Delayed Therapy with Venetoclax and Obinutuzumab in Newly Diagnosed Asymptomatic High-Risk Patients with Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma (CLL/SLL): EVOLVE CLL/SLL Study (Version Date 03/27/26)

XII Continuing Review

S1929, Phase II Randomized Study of Maintenance Atezolizumab Versus Atezolizumab in Combination with Talazoparib in Patients with SLFN11 Positive Extensive Stage Small Cell Lung Cancer (ES-SCLC) (Version Date 03/03/25)

XIII 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 12/16/25)

XIV Continuing Review

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 06/18/25)

XV Continuing Review

S2427, Single Arm Phase II Study of Bladder Preservation with Immunoradiotherapy After a Clinically Meaningful Response to Neoadjuvant Therapy in Patients with Muscle Invasive Bladder Cancer (BRIGHT) (Version Date 12/01/25)
