

Adult CIRB - Late Phase Emphasis Meeting Agenda

August 7, 2025

I Amendment

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

II 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 04/24/25)

III Amendment

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 06/05/25)

III 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)

IV 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)

V 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)

VI Continuing Review

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

VII 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)

VIII 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 05/23/25)

IX Continuing Review

S1905, A Phase I/II Study of AKR1C3-Activated Prodrug OBI-3424 (OBI-3424) in Patients with Relapsed/Refractory T-Cell Acute Lymphoblastic Leukemia (T-ALL)/T-Cell Lymphoblastic Lymphoma (T-LBL) (Version Date 02/11/25)

X 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)

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 02/21/25)

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

S1608, Randomized Phase II Trial in Early Relapsing or Refractory Follicular Lymphoma (Version Date 02/28/25)
