

Adult CIRB - Late Phase Emphasis Meeting Agenda

October 5, 2023

I New Study - Initial Review

S1900J, A Phase II Study of Amivantamab-vmjw in Participants with MET Amplification-Positive Stage IV or Recurrent Non-Small Cell Lung Cancer (Lung-MAP Sub-Study) (Version Date 08/25/23)

II Amendment

A051701, Randomized Phase II/III Study of Venetoclax (ABT 199) Plus Chemoimmunotherapy for MYC/BCL2 Double-Expressing Lymphomas (Version Date 09/01/23)

III Continuing Review

A022104, The Janus Rectal Cancer Trial: A Randomized Phase II Trial Testing the Efficacy of Triplet versus Doublet Chemotherapy to Achieve Clinical Complete Response in Patients with Locally Advanced Rectal Cancer (Version Date 07/18/23)

IV 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 06/28/22)

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 04/26/22)

VI 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 08/18/23)

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 06/16/23)

VIII 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 07/14/23)

IX 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 03/17/23)

X Continuing Review

EA8185, Phase II Study of Bladder-Sparing Chemoradiation with Durvalumab in Clinical Stage III, Node Positive bladder Cancer (INSPIRE) (Version Date 05/26/23)

XI 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 05/09/23)

XII Continuing Review

NRG-GI005, Phase II/III Study of Circulating tumOr DNA as a Predictive BiomaRker in Adjuvant Chemotherapy in Patients with Stage IIA Colon Cancer (COBRA) (Version Date 04/07/21)

XIII 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)

XIV Continuing Review

S1608, Randomized Phase II Trial in Early Relapsing or Refractory Follicular Lymphoma (Version Date 10/06/22)

XV 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 06/10/22)

XVI 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 10/24/22)

XVII Continuing Review

S2011, Randomized Phase II Trial of Gemcitabine, Avelumab and Carboplatin vs. No Neoadjuvant Therapy Preceding Surgery for Cisplatin-Ineligible Muscle-Invasive Urothelial Carcinoma: SWOG GAP Trial (Version Date 03/09/23)

XVIII 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 05/23/23)

XIX 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 04/17/23)
