

Adult CIRB - Early Phase Emphasis Meeting Agenda

September 5, 2023

I New Study - Initial Review

10601, A Phase 1 Study of Mosunetuzumab with Polatuzumab Vedotin and Lenalidomide (M+Pola+Len) in Relapsed/Refractory (R/R) Diffuse Large B-Cell Lymphoma (DLBCL) (Version Date 07/14/23)

II Amendment

10292, DURVA+ : Evaluation of the Safety and Pharmacodynamics of Anti-PD-L1 Antibody Durvalumab in Combination with Chemotherapy in Patients with Advanced Solid Tumors (Version Date 08/01/23)

III Amendment

10492, Phase 1/1b Study of AKT Inhibitor Ipatasertib with Chemoradiation for Locally Advanced Head and Neck Cancer (Version Date 08/01/23)

IV Continuing Review

10204, A Phase 1b Study of Nivolumab in Patients with Autoimmune Disorders and Advanced Malignancies (AIM-NIVO) (Version Date 10/10/22)

V Continuing Review

10208, A Phase I study of Anetumab Ravnansine in Combination with either Anti-PD-1 Antibody, or Anti-CTLA4 and Anti-PD-1 Antibodies or Anti-PD-1 Antibody and Gemcitabine in Mesothelin-Positive Advanced Pancreatic Adenocarcinoma (Version Date 12/01/22)

VI Continuing Review

10403, Phase 1 Trial of Gemcitabine Combined with the Elimusertib (BAY 1895344) ATR Inhibitor with Expansion Cohorts in Advanced Pancreatic and Ovarian Cancer (Version Date 04/21/23)

VII Continuing Review

10335, A Phase 1 Study of Lenalidomide in Combination with EPOCH Chemotherapy for HTLV-Associated Adult T-Cell Leukemia-Lymphoma (ATLL) (Version Date 02/08/21)

VIII Continuing Review

10449, A Phase 1 Study of ZEN003694 in Combination with Binimetinib in Solid Tumors with RAS Pathway Alterations and Triple Negative Breast Cancer (Version Date 06/01/23)

IX Continuing Review

10129, A Phase 2 Study of the PARP Inhibitor Olaparib (AZD2281) in IDH1 and IDH2 mutant Advanced Solid Tumors (Version Date 07/20/23)

X Continuing Review

EAY191, Molecular Analysis for Combination Therapy Choice (ComboMATCH) (Version Date 03/03/23)

XI Continuing Review

10422, A Phase 1/1b Dose Escalation Study of Abemaciclib and Olaparib for Recurrent Platinum-Resistant Ovarian Cancer (Version Date 07/19/23)
