

Adult CIRB - Early Phase Emphasis Meeting Agenda

June 6, 2023

I New Study - Initial Review

EA2212, A Randomized Phase II Study of Perioperative Atezolizumab +/- Chemotherapy in Resectable MSI-H/dMMR Gastric and Gastroesophageal Junction (GEJ) Cancer (Version Date 03/13/23)

II New Study - Initial Review

10559, A Phase 2 Study of Erdafitinib in Patients with Recurrent or Progressive IDH-Wild Type Glioma with an FGFR-TACC Gene Fusion (Version Date 04/10/23)

III New Study ReReview

10556, Randomized Phase 2 Study of Cabozantinib, Ipilimumab, and Nivolumab in Patients with Soft Tissue Sarcoma (Version Date 05/19/23)

IV Amendment

NRG-LU004, Phase I Trial of Radiotherapy Combined With Durvalumab Alone Plus Either Monalizumab or Oleclumab in PD-L1 High Locally Advanced Non-Small Cell Lung Cancer (NSCLC) (ARCHON-1) (Version Date 04/19/23)

V Continuing Review

10184, Birinapant and Intensity Modulated Re-Irradiation Therapy (IMRRT) for Locoregionally Recurrent Head and Neck Squamous Cell Carcinoma (HNSCC) (Version Date 12/15/22)

VI Continuing Review

10276, A Phase I/II Study of M3814 and Avelumab in Combination with Hypofractionated Radiation in Patients with Advanced/Metastatic Solid Tumors and Hepatobiliary Malignancies (Version Date 08/26/22)

VII Continuing Review

10433, Phase I/Ib trial evaluating the safety and efficacy of BET inhibitor, ZEN003694 with PD-1 inhibitor, nivolumab with or without CTLA-4 inhibitor, ipilimumab in solid tumors (Version Date 04/11/23)

VIII Continuing Review

10324, A Phase I/Ib Dose Escalation Study of Pegylated Liposomal Doxorubicin (PLD) With Pepsertib (M3814) in Platinum-Resistant or Ineligible Ovarian and Related Cancers with Planned Expansions in High Grade Serous (HGSOC) and Low Grade Serous Ovarian Cancer (LGSOC) (Version Date 05/02/23)

IX Continuing Review

10384, A Phase 1b/2 Study of Hu5F9-G4 (magrolimab) in Combination with Mogamulizumab in Relapsed/Refractory Treated T- cell Lymphoma (Version Date 08/09/22)