

Adult CIRB - Early Phase Emphasis Meeting Agenda

July 19, 2022

I Continuing Review

10126, A Pilot Phase I Study of Atezolizumab (MPDL3280A) in Combination with Immunogenic Chemotherapy (Gemcitabine-Oxaliplatin) and Rituximab for Transformed Diffuse Large B-Cell Lymphoma (Protocol Version Date 05/14/21)

II Continuing Review

10170, A Phase 2 Study of AZD1775 in SETD2-Deficient Advanced Solid Tumor Malignancies (Protocol Version Date 08/24/20)

III Continuing Review

10324, A Phase I/Ib Dose Escalation Study of Pegylated Liposomal Doxorubicin (PLD) With Peposertib (M3814) in Platinum-Resistant or Ineligible Ovarian and Related Cancers with Planned Expansions in High Grade Serous (HGSO) and Low Grade Serous Ovarian Cancer (LGSO) (Protocol Version Date 04/21/22)

IV Continuing Review

10384, A Phase 1b/2 Study of Hu5F9-G4 (magrolimab) in Combination with Mogamulizumab in Relapsed/Refractory Treated T- cell Lymphoma (Protocol Version Date 01/24/22)

V 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 (Protocol Version Date 02/04/22)

VI Continuing Review

10466, A Phase 2 Study of Bevacizumab, Erlotinib and Atezolizumab in Subjects with Advanced Hereditary Leiomyomatosis and Renal Cell Cancer (HLRCC) Associated or Sporadic Papillary Renal Cell Cancer (Protocol Version Date 08/06/21)

VII Continuing Review

10476, A Randomized Phase 2 Study of Combination Atezolizumab and CDX-1127 (Varlilumab) With or Without Addition of Cobimetinib in Previously Treated Unresectable Biliary Tract Cancers (Protocol Version Date 04/26/22)

VIII Continuing Review

ABTC-1801, Phase I/II Study of Pamiparib (BGB-290) with Temozolomide in Recurrent Gliomas with IDH1/2 Mutations (Protocol Version Date 07/29/20)

IX New Study - Initial Review

10487, A Phase II study of Lutetium Lu 177 dotatate in metastatic prostate cancer with neuroendocrine differentiation (Protocol Version Date 05/17/22)

X New Study - Initial Review

10500, Phase 1/Expansion Study of Tazemetostat Plus Belinostat for the Treatment of Relapsed or Refractory Lymphoma (Protocol Version Date 05/25/22)

XI New Study - Initial Review

10505, A Phase 1/2 Trial of Selinexor and Temozolomide in Recurrent Glioblastoma (Protocol Version Date 05/18/22)

XII Amendment

10422, A Phase 1/1b Dose Escalation Study of Abemaciclib and Olaparib for Recurrent Platinum-Resistant Ovarian Cancer (Protocol Version Date 06/15/22)
