

Adult CIRB - Early Phase Emphasis Meeting Agenda

November 2, 2021

I Continuing Review

10058, A Phase I Study of talimogene laheparepvec (TALIMOGENE LAHERPAREPVEC) with Neoadjuvant Chemotherapy and Radiation in Adenocarcinoma of the Rectum (Protocol Version Date 06/14/21)

II Continuing Review

10129, A Phase 2 Study of the PARP Inhibitor Olaparib (AZD2281) in IDH1 and IDH2 mutant Advanced Solid Tumors (Protocol Version Date 09/08/21)

III Continuing Review

10204, A Phase 1b Study of Nivolumab in Patients with Autoimmune Disorders and Advanced Malignancies (AIM-NIVO) (Protocol Version Date 03/09/21)

IV Continuing Review

10399, A Phase 1 Study of Entinostat in Combination with Atezolizumab / Carboplatin / Etoposide in Previously Untreated Extensive-Stage Small Cell Lung Cancer (Protocol Version Date 08/17/21)

V Continuing Review

9676, A Phase 1 Trial of MK-3475 Plus Ziv-Aflibercept in Patients with Advanced Solid Tumors (Protocol Version Date 03/04/20)

VI New Study - Initial Review

10449, A Phase 1 Study of ZEN003694 in Combination with Binimetinib in Solid Tumors with RAS Pathway Alterations and Triple Negative Breast Cancer (Protocol Version Date 09/22/21)



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VII Amendment

10450, A Phase 1b Trial of M3814 (Peponsertib) in Combination with Lutetium 177 Dotatate for Well-Differentiated Somatostatin Receptor-Positive Gastroenteropancreatic Neuroendocrine Tumors (GEP-NETs) (Protocol Version Date 09/08/21)

VIII Amendment

9938, Phase I clinical trial of M6620 in combination with the topoisomerase I inhibitor irinotecan in patients with advanced solid tumors (Protocol Version Date 09/09/21)

IX Amendment

ABTC-1701, Pilot Surgical PK Study of Bemcentinib in Recurrent Glioblastoma Patients (Protocol Version Date 10/07/21)
