

Adult CIRB - Early Phase Emphasis Meeting Agenda

January 21, 2020

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 08/21/19)

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 08/16/19)

III Continuing Review

10195, A Phase 2 Study of Copanlisib (BAY 80-6946) in Combination with Fulvestrant in Patients with Metastatic Breast Cancer Progressing After Aromatase Inhibitor Plus CDK 4/6 Inhibitor (Protocol Version Date 12/19/19)

IV Continuing Review

10204, A Phase 1b Study of Nivolumab in Patients with Autoimmune Disorders and Advanced Malignancies (AIM-NIVO) (Protocol Version Date 03/25/19)

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 (Protocol Version Date 08/19/19)

VI Continuing Review

10249, MLN9708 (Ixazomib) and MLN4924 (Pevonedistat) in Relapsed/Refractory Multiple Myeloma Patients: A Phase 1b Trial (Protocol Version Date 11/11/19)

VII Continuing Review

9676, A Phase 1 Trial of MK-3475 Plus Ziv-Aflibercept in Patients with Advanced Solid Tumors (Protocol Version Date 01/02/20)

VIII Continuing Review

9844, A Phase 1 Study Evaluating Safety, Tolerability, and Preliminary Antitumor Activity of Entinostat and Nivolumab with or without Ipilimumab in Advanced Solid Tumors (Protocol Version Date 05/09/19)

IX New Study - Initial Review

10335, A Phase 1 Study of Lenalidomide in Combination with EPOCH Chemotherapy for HTLV-Associated Adult T-Cell Leukemia-Lymphoma (ATLL) (Protocol Version Date 12/04/19)

X Amendment

9910, A phase 1 trial of MLN0128 (TAK-228) in combination with osimertinib (AZD9291) in advanced EGFR mutation positive non-small cell lung cancer (NSCLC) after progression on a previous EGFR tyrosine kinase inhibitor (Protocol Version Date 11/21/19)
