

Adult CIRB - Early Phase Emphasis Meeting Agenda

December 15, 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 09/08/20)

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 08/24/20)



FOR THE NATIONAL CANCER INSTITUTE

VI Continuing Review

10249, MLN9708 (Ixazomib) and MLN4924 (Pevonedistat) in Relapsed/Refractory Multiple Myeloma Patients: A Phase 1b Trial (Protocol Version Date 09/06/20)

VII Continuing Review

10300, BLockade of PD-1 Added to Standard Therapy to target Measurable Residual Disease in Acute Myeloid Leukemia 1 (BLAST MRD AML-1): A Randomized Phase 2 Study of the Anti-PD-1 Antibody Pembrolizumab in Combination with Conventional Intensive Chemotherapy as Frontline Therapy in Patients with Acute Myeloid Leukemia (Protocol Version Date 07/22/20)

VIII Continuing Review

10329, Phase I Sequential Trial of Agents Against DNA Repair (STAR) (Protocol Version Date 10/05/20)

IX Continuing 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 05/13/20)

X Continuing Review

10367, A Phase 1b Study with Expansion Cohort of Escalating Doses of KRT-232 (AMG 232) Administered in Combination with Standard Induction Chemotherapy (Cytarabine and Idarubicin) in Newly Diagnosed Acute Myelogenous Leukemia (AML) (Protocol Version Date 04/07/20)

XI 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)



FOR THE NATIONAL CANCER INSTITUTE

XII 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 09/01/20)

XIII New Study ReReview

10403, Phase 1 Trial of Gemcitabine Combined with the BAY 1895344 ATR Inhibitor with Expansion Cohorts in Advanced Pancreatic and Ovarian Cancer (Protocol Version Date 11/30/20)

XIV New Study - Initial Review

10347, A phase I study with an expansion cohort of duvelisib and nivolumab in mycosis fungoides (MF) and Sézary syndrome (SS) (Protocol Version Date 10/30/20)

XV Amendment

10301, A Phase I and Randomized Phase II Trial of Radium-223 dichloride, M3814, & Avelumab in Advanced Metastatic Castrate-Resistant Prostate Cancer (mCRPC) (Protocol Version Date 10/26/20)
