

Adult CIRB - Early Phase Emphasis Meeting Agenda

October 5, 2021

I Continuing Review

10021, A Phase 2 Study of MEDI4736(durvalumab) and Tremelimumab Alone or in Combination with High or Low-Dose Radiation in Metastatic Colorectal and NSCLC (Protocol Version Date 08/30/19)

II Continuing Review

10030, A phase 1 study of blinatumomab in combination with checkpoint inhibitor(s) of PD-1 (nivolumab) or both PD-1 (nivolumab) and CTLA-4 (ipilimumab) in patients with poor-risk, relapsed or refractory CD19+ precursor B-lymphoblastic leukemia (Protocol Version Date 01/28/21)

III Continuing Review

10056, A Phase 2 Study of Talimogene Laherparepvec (T-VEC) and Radiation in Localized Soft Tissue Sarcoma (Protocol Version Date 04/22/21)

IV Continuing Review

10107, Phase 1 Safety Run-In and Phase 2 Randomized Clinical Trial of Anetumab Ravtansine and Pembrolizumab (MK-3475) Compared to Pembrolizumab Alone for Mesothelin-Positive Malignant Pleural Mesothelioma (Protocol Version Date 05/03/21)

V Continuing Review

10214, Immune Checkpoint Blockade for Kidney Transplant Recipients with Selected Unresectable or Metastatic cancers (Protocol Version Date 01/28/21)

VI Continuing Review

10285, Phase 1/2 Study of an EZH2 inhibitor (tazemetostat) in combination with dual BRAF/MEK inhibition in patients with BRAF-mutated metastatic melanoma who progressed on prior BRAF/MEK inhibitor therapy (Protocol Version Date 02/15/21)

VII Continuing Review

10329, Phase I Sequential Trial of Agents Against DNA Repair (STAR) (Protocol Version Date 08/26/21)

VIII Continuing Review

10355, A phase I study of DS-8201a in combination with olaparib in HER2-expressing malignancies (Protocol Version Date 09/09/21)

IX Continuing Review

10371, A Pharmacodynamics-Driven Trial of Talazoparib, an Oral PARP Inhibitor, in Patients With Advanced Solid Tumors and Aberrations in Genes Involved in DNA Damage Response (Protocol Version Date 06/03/21)

X New Study - Initial Review

10499, Phase Ib/II study of ZEN003694 and entinostat in advanced and refractory solid tumors and lymphomas (Protocol Version Date 08/18/21)

XI Amendment

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 (Protocol Version Date 09/07/21)

XII Amendment

10287, A randomized Phase I/II trial of fulvestrant and abemaciclib in combination with copanlisib (FAC) versus fulvestrant and abemaciclib alone (FA) for endocrine-resistant, hormone receptor positive, HER2 negative metastatic breast cancer (FAC vs FA) (Protocol Version Date 08/13/21)

XIII Amendment

10389, A Phase I Trial Combining WEE1 Inhibitor Adavosertib (AZD1775) with Radiation Therapy for Metastatic or Inoperable and Ineligible for Definitive Chemoradiation Esophageal and Gastroesophageal Junction Cancer (Protocol Version Date 08/30/21)