

Adult CIRB – Early Phase Emphasis Meeting Agenda

Tuesday, March 20, 2018 10:00 am – 11:20 pm (Eastern)

I. Amendment Review

10061, A Phase 1 Study of Pembrolizumab (MK-3475) in Combination with Recombinant Interleukin-12 in Patients with Solid Tumors (Protocol Version Date 01/09/18)

II. Amendment Review – Study Chair Response Table

9979, Phase 1 and Pharmacology Study of Oral 5-iodo-2-pyrimidinone-2-deoxyribose (IPdR) as a Prodrug for IUdR-Mediated Tumor Radiosensitization in Brain Metastases (Protocol Version Date 02/26/18)

III. Continuing Review

9676, A Phase 1 Trial of MK-3475 Plus Ziv-Aflibercept in Patients with Advanced Solid Tumors (Protocol Version Date 11/22/17)

IV. 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 01/17/18)

V. 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 08/24/17)