

Adult CIRB - Early Phase Emphasis Meeting Agenda

January 19, 2021

I Continuing Review

10057, A Phase II Study of Talimogene laherparepvec Followed by Talimogene laherparepvec + Nivolumab in Refractory T Cell and NK Cell Lymphomas, Cutaneous Squamous Cell Carcinoma, Merkel Cell Carcinoma, and Other Rare Skin Tumors (Protocol Version Date 09/04/20)

II Continuing Review

10075, A Phase 1B Study of KRT-232 (AMG-232) in Combination with Decitabine in Acute Myeloid Leukemia (Protocol Version Date 02/03/20)

III Continuing Review

10076, A Phase 1 Dose-Escalation and Exploratory Dose Expansion Study of KRT-232 (AMG 232) in Combination with Carfilzomib, Lenalidomide, and Dexamethasone in Relapsed and/or Refractory Myeloma. (Protocol Version Date 08/04/20)

IV Continuing Review

10147, A Phase II randomized study of topotecan/carboplatin with or without veliparib in advanced myeloproliferative disorders and chronic myelomonocytic leukemia (CMML). (Protocol Version Date 10/24/19)

V Continuing Review

10217, A Phase 1b Biomarker-Driven Combination Trial of Copanlisib, Olaparib, and Durvalumab (MEDI4736) in Patients with Advanced Solid Tumors (Protocol Version Date 10/22/20)

VI Continuing Review

10327, A Phase 1 Trial of MLN0128 (sapanisertib) and CB-839 HCl (telaglenastat) in Advanced NSCLC Patients (Protocol Version Date 07/06/20)

VII Continuing Review

10388, A Phase I Trial of Triapine and Lutetium Lu 177 Dotatate in Combination for Well-Differentiated Somatostatin Receptor-Positive Gastroenteropancreatic Neuroendocrine Tumors (GEP-NETs) (Protocol Version Date 10/14/20)

VIII Amendment

10191, A Phase 2 Study of M6620 in Combination with Carboplatin compared with Docetaxel in Combination with Carboplatin in Metastatic Castration-Resistant Prostate Cancer (Protocol Version Date 12/14/20)
