

Adult CIRB - Early Phase Emphasis Meeting Agenda

February 18, 2020

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 01/13/20)

II Continuing Review

10075, A Phase 1B Study of KRT-232 (AMG-232) in Combination with Decitabine in Acute Myeloid Leukemia (Protocol Version Date 09/23/19)

III Continuing Review

10076, A Phase 1 Dose-Escalation And Exploratory Dose Expansion Study Of AMG 232 In Combination With Carfilzomib, Lenalidomide, And Dexamethasone In Relapsed And/Or Refractory Myeloma (Protocol Version Date 09/23/19)

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 MEDI4736 (Durvalumab) in Patients with Advanced Solid Tumors (Protocol Version Date 08/15/19)



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VI Continuing Review

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)

VII New Study - Initial Review

10327, A Phase 1 Trial of MLN0128 (sapanisertib) and CB-839 HCl (telaglenastat) in Advanced NSCLC Patients (Protocol Version Date 01/10/20)
