

Adult CIRB - Early Phase Emphasis Meeting Agenda

December 21, 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 02/12/21)

II Continuing Review

10075, A Phase 1B Study of KRT-232 (AMG-232) in Combination with Decitabine in Acute Myeloid Leukemia (Protocol Version Date 10/07/21)

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 02/23/21)

IV 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 09/25/21)

V Continuing Review

10327, A Phase 1 Trial of MLN0128 (sapanisertib) and Telaglenastat (CB-839) HCl in Advanced NSCLC Patients (Protocol Version Date 09/27/21)

VI Continuing Review

10358, Phase 1/1B study of DS-8201a in combination with ATR Inhibition (AZD6738) in advanced solid tumors with HER2 expression (DASH Trial) (Protocol Version Date 08/24/21)

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 07/06/21)

VIII New Study - Initial Review

10237, A Phase 1 Study of MLN7243(TAK-243) for Either Relapsed/Refractory Acute Myeloid Leukemia or Myelodysplastic Syndrome/Chronic Myelomonocytic Leukemia Refractory to Hypomethylating Agents (Protocol Version Date 11/16/21)

IX Amendment

10410, A Phase 1 Study of IPdR in Combination with Capecitabine and Radiotherapy in Rectal Cancer (Protocol Version Date 11/01/21)

X Amendment

EAY131, Molecular Analysis for Therapy Choice (MATCH) (Protocol Version Date 11/03/21)
