

Adult CIRB - Early Phase Emphasis Meeting Agenda

November 1, 2022

I Amendment

10366, A Phase 1/2 Study of M3814 (peposertib) in Combination with Hypofractionated Radiotherapy for the Treatment of Locally Advanced Pancreatic Adenocarcinoma (Version Date 08/23/22)

II Continuing Review

10216, A Phase Ib Study of Osimertinib (AZD9291) and Telaglenastat (CB-839) HCl in Patients with EGFR Mutant Non-Small Cell Lung Cancer (Version Date 04/05/22)

III 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 (Version Date 02/12/21)

IV Continuing Review

10075, A Phase 1B Study of KRT-232 (AMG-232) in Combination with Decitabine in Acute Myeloid Leukemia (Version Date 11/10/21)

V Continuing Review

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

VI Continuing Review

10061, A Phase 1 Study of Pembrolizumab (MK-3475) in Combination with Recombinant Interleukin-12 in Patients with Solid Tumors (Version Date 07/26/2022)

VII Memos

9673, PART A: A Multi-Institutional Phase 2 Study of Nivolumab in Refractory Metastatic Squamous Cell Carcinoma of the Anal Canal PART B: A Multi-Institutional Phase 2 Study of Nivolumab or Nivolumab in Combination with Ipilimumab in Refractory Metastatic Squamous Cell Carcinoma of the Anal Canal (Version Date 03/18/21)
