

**Adult CIRB – Early Phase Emphasis
Meeting Agenda**

**Tuesday, February 20, 2018
10:00 am – 12:40 pm (Eastern)**

I Initial Review

10106, A phase I and randomized phase II study of KW-0761 (Mogamulizumab) and MK-3475 (Pembrolizumab) in relapsed and refractory lymphomas (Protocol Version Date 12/12/17)

II Initial Review – Study Chair Response

7977, A Phase I Dose-Escalation Study of Oral ABT-888 (NSC #737664) Plus Intravenous Irinotecan (CPT-11, NSC#616348) Administered in Patients with Advanced Solid Tumors (Protocol Version Date 01/08/18)

III Amendment Review

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 (Protocol Version Date 12/19/17)

IV Continuing Review

10026, A Phase 1 Study of Ipilimumab in Combination with Decitabine in Relapsed or Refractory Myelodysplastic Syndrome/Acute Myeloid Leukemia (Protocol Version Date 11/22/17)

V Continuing Review

10042, A Phase II trial of AZD9291 (osimertinib) with or without bevacizumab in patients with EGFR mutation positive NSCLC and brain metastases (Protocol Version Date 12/06/17)

VI Continuing Review

A091202, A Phase II Study of the Peroxisome Proliferator-Activated Receptor Gamma Agonist, Efatutazone in Patients with Previously Treated, Unresectable Myxoid Liposarcoma (Protocol Version Date 05/31/17)

VII Continuing Review

9653, Phase II Trial of Gemcitabine-Eribulin (GE) in Cisplatin Ineligible Patients with Advanced or Unresectable Urothelial Carcinoma of the Bladder (Protocol Version Date 05/02/16)

VIII **Continuing Review**

9947, A Randomized Phase 2 Trial of Cisplatin/Gemcitabine with or without VX-970 in Metastatic Urothelial Carcinoma (Protocol Version Date 02/28/17)
