Adult CIRB – Early Phase Emphasis
Meeting Agenda

Tuesday, March 21, 2017
10:00 am – 2:00 pm (Eastern)

I **Initial Review**

10026, A Phase 1 Study of Ipilimumab in Combination with Decitabine in Relapsed or Refractory Myelodysplastic Syndrome/Acute Myeloid Leukemia (Protocol Version Date 01/31/17)

II **Initial 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 01/17/17)

III **Initial Review**

10056, A Phase 2 Study of Talimogene Laherparepvec (T-VEC) and Radiation in Localized Soft Tissue Sarcoma (Protocol Version Date 02/07/17)

IV **Amendment Review**

A091304, A Phase I /Randomized Phase II Study of MLN0128 (TAK-228) vs. Pazopanib In Patients With Locally Advanced/Unresectable And/Or Metastatic Sarcoma (Protocol Version Date 02/15/17)

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 09/16/16)

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**

Primary Reviewer: John Sarantopoulos, M.D.
9947, A Randomized Phase 2 Trial of Cisplatin/Gemcitabine with or without VX-970 in Metastatic Urothelial Carcinoma (Protocol Version Date 09/28/16)

IX **Reports of Expedited Reviews between 2/01/17 - 2/28/17**

- Early Phase Emphasis CIRB Local Context Subcommittee Report
- Expedited Reviews and Study Acknowledgements
- Study Activation Acknowledgements
- Amendment Activation Acknowledgements