

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

**Tuesday, February 6, 2018**

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**I Initial Review**

**10130**, A phase I study of single agent tazemetostat in subjects with advanced solid tumors and B-cell lymphomas with hepatic dysfunction (Protocol Version Date 12/12/17)

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**II Amendment Review**

**EA5162**, Phase II Study of AZD9291 (Osimertinib) in Advanced NSCLC Patients with Exon 20 Insertion Mutations in EGFR (Protocol Version Date 12/22/17)

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**III Continuing Review**

**9979**, Phase 1 and Pharmacology Study of Oral 5-iodo-2-pyrimidinone-2-deoxyribose (IPdR) as a Prodrug for IUdR-Mediated Tumor Radiosensitization in Brain Metastases (Protocol Version Date 10/23/17)

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**IV Amendment Review**

**9979**, Phase 1 and Pharmacology Study of Oral 5-iodo-2-pyrimidinone-2-deoxyribose (IPdR) as a Prodrug for IUdR-Mediated Tumor Radiosensitization in Brain Metastases (Protocol Version Date 12/12/17)

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**V Continuing Review**

**9922**, A Phase 2 Study of Ibrutinib (PCI-32765) in Refractory Distant Metastatic Cutaneous Melanoma: Correlation of Biomarkers with Response and Resistance (Protocol Version Date 11/06/17)

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**VI Continuing Review**

**10017**, A Randomized Phase 2 Trial of Atezolizumab (MPDL3280A), SGI-110 and CDX-1401 Vaccine in Recurrent Ovarian Cancer (Protocol Version Date 09/29/17)

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**VII Continuing Review**

**9775**, A Phase 2 Study of MLN0128 in Relapsed and/or Refractory Acute Lymphoblastic Leukemia (ALL) (Protocol Version Date 10/02/17)

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**VIII Continuing Review**

**S1318**, A Phase II Study of Blinatumomab (NSC-765986) and POMP (Prednisone, Vincristine, Methotrexate, 6-Mercaptopurine) for Patients  $\geq$  65 Years of Age with Newly Diagnosed Philadelphia-Chromosome Negative (Ph-) Acute Lymphoblastic Leukemia (ALL) and of Dasatinib (NSC-732517), Prednisone and Blinatumomab for Patients  $\geq$  65 Years Of Age with Newly Diagnosed Philadelphia-Chromosome Positive (Ph+) ALL, and Philadelphia-Chromosome-Like Signature (Ph-Like) ALL (Newly Diagnosed or Relapsed/Refractory) with Known or Presumed Activating Dastainib-Sensitive Mutations or Kinase Fusions (DSMKF) (Protocol Version Date 11/07/17)

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**IX**                      **Continuing Review**

**8329**, A Phase I/II Trial of ABT-888, an Inhibitor of Poly(ADP-ribose) Polymerase (PARP), and Topotecan (TPT) in Patients with Solid Tumors (Phase I) and Relapsed Ovarian Cancer or Primary Peritoneal Cancer (Phase II) After Prior Platinum Containing First-Line Chemotherapy (Protocol Version Date 03/24/17)

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**X**                        **Continuing Review**

**9948**, Phase 1 Dose Escalation and Randomized Phase 2 Trial of Carboplatin and Gemcitabine with or without VX-970 in First Recurrence Platinum-Sensitive Epithelial Ovarian, Peritoneal, and Fallopian Tube Cancer (Protocol Version Date 02/02/17)

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