



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

**Tuesday, March 7, 2017  
10:00 am – 1:20 pm (Eastern)**

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**I Initial Review**

**10017**, A Randomized Phase 2 Trial of Atezolizumab (MPDL3280A), SGI-110 and CDX-1401 Vaccine in Recurrent Ovarian Cancer (Protocol Version Date 01/23/17)

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**II Initial Review – Legacy Study**

**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 01/13/17)

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**III Initial Review- Study Chair Response**

**10013**, Randomized Phase 2 Study of Neoadjuvant Chemotherapy, Carboplatin and Paclitaxel, with or without Atezolizumab in Triple Negative Breast Cancer (TNBC) (Protocol Version Date 02/15/17)

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**IV Continuing Review**

**9775**, A Phase 2 Study of MLN0128 (TAK-228) in Relapsed and/or Refractory Acute Lymphoblastic Leukemia (ALL) (Protocol Version Date 09/09/16)

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**V Continuing Review**

**9948**, A 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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**VI Continuing Review**

**9922**, A Phase 2 Study of Ibrutinib (PCI-32765) in Refractory Distant Metastatic Cutaneous Melanoma: 12/12/16)

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**VII 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 01/19/17)

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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 12/09/16)

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