

Adult CIRB – Early Phase Emphasis Meeting Agenda

Tuesday, April 3, 2018 10:00 am – 1:10 pm (Eastern)

I. Initial Review

10144, A Phase II Study of Olaparib (AZD2281) in Patients with Metastatic/Advanced Urothelial Carcinoma with DNA-Repair Defects (Protocol Version Date 01/23/18)

II. Initial Review

10145, Phase IB Combination Study of Copanlisib And Nivolumab In Advanced Solid Tumors and Lymphomas (Protocol Version Date 01/26/18)

III. Study Chair Response to Initial Review

10147, A Phase II randomized study of topotecan/carboplatin with or without veliparib in advanced myeloproliferative disorders and chronic myelomonocytic leukemia (CMML). (Protocol Version Date 02/26/18)

IV. Continuing Review

9876, Phase 1b Study of HSP90 Inhibitor, AT13387 in Combination with Paclitaxel in Patients with Advanced, Triple Negative Breast Cancer. (Protocol Version Date 03/19/18)

V. Continuing Review

9950, A Phase I Study of VX-970 in Combination with Cisplatin and XRT in Patients with Locally Advanced HPV (-) Head and Neck Squamous Cell Carcinoma (Protocol Version Date 01/26/18)

VI. Continuing Review

10061, A Phase 1 Study of MK-3475 (Pembrolizumab) in Combination with Recombinant Interleukin-12 in Patients with Solid Tumors (Protocol Version Date 01/09/18)

VII. Continuing Review

NRG-GY002, A Phase II Evaluation of Nivolumab, a Fully Human Antibody against PD-1, in the Treatment of Persistent or Recurrent Cervical Cancer (Protocol Version Date 01/31/17)