

Adult CIRB - Early Phase Emphasis Meeting Agenda

September 1, 2020

I Continuing Review

10100, A Randomized, Phase 2 Trial to Evaluate the Safety and Efficacy of Eribulin Mesylate in Combination with Atezolizumab Compared to Atezolizumab Alone in Subjects with Locally Advanced or Metastatic Transitional Cell Urothelial Cancer Where Cisplatin-Based Treatment is Not an Option (Protocol Version Date 06/29/20)

II Continuing Review

10104, A Randomized Phase 2 Study of Cabozantinib in Combination with Nivolumab in Advanced, Recurrent Metastatic Endometrial Cancer. (Protocol Version Date 10/23/19)

III Continuing Review

10302, Phase II Trial of Radium-223 Dichloride in Combination with Paclitaxel in Patients with Bone Metastatic Breast Cancer (Protocol Version Date 06/23/20)

IV Continuing Review

10315, A Phase 2 Study of XL184 (Cabozantinib) in Combination with Nivolumab and Ipilimumab for the Treatment of Poorly Differentiated Neuroendocrine Carcinomas (Protocol Version Date 10/18/19)

V Continuing Review

9837, Phase I Study of TRC102 in Combination with Cisplatin and Pemetrexed in Patients with Advanced Solid Tumors / Phase II Study of TRC102 with Pemetrexed in Patients Refractory to Pemetrexed and Cisplatin or Carboplatin (Protocol Version Date 03/07/19)

VI New Study - Initial Review

NRG-HN008, Phase I Trial with Expansion Cohort of DNA-PK Inhibition and IMRT in Cisplatin-Ineligible Patients with Stage 3-4 Local-Regionally Advanced Head and Neck Squamous Cell Carcinoma (HNSCC) (Protocol Version Date 08/06/20)
