

Adult CIRB - Early Phase Emphasis Meeting Agenda

June 21, 2022

I Continuing Review

10005, A Phase 2 Study of Anti-PD-L1 Antibody (Atezolizumab) in Alveolar Soft Part Sarcoma (Protocol Version Date 05/18/22)

II 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 12/21/21)

III Continuing Review

10301, A Phase I and Randomized Phase II Trial of Radium-223 dichloride, M3814, & Avelumab in Advanced Metastatic Castrate-Resistant Prostate Cancer (mCRPC) (Protocol Version Date 12/21/21)

IV Continuing Review

10302, Phase II Trial of Radium-223 Dichloride in Combination with Paclitaxel in Patients with Bone Metastatic Breast Cancer (Protocol Version Date 05/02/22)

V 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 02/22/21)

VI Continuing Review

10387, Pilot Trial of Nivolumab plus Cabozantinib for Advanced Solid Tumors in Patients with HIV Infection (Protocol Version Date 04/14/22)



VII Continuing Review

9938, Phase I clinical trial of M6620 (VX-970, berzosertib) in combination with the topoisomerase I inhibitor irinotecan in patients with advanced solid tumors (Protocol Version Date 11/18/21)

VIII Amendment

10204, A Phase 1b Study of Nivolumab in Patients with Autoimmune Disorders and Advanced Malignancies (AIM-NIVO) (Protocol Version Date 04/29/22)

IX Amendment

10301, A Phase I and Randomized Phase II Trial of Radium-223 dichloride, M3814, & Avelumab in Advanced Metastatic Castrate-Resistant Prostate Cancer (mCRPC) (Protocol Version Date 05/12/22)