

Adult CIRB - Early Phase Emphasis Meeting Agenda

July 20, 2021

I Amendment Prior to Activation

10440, A Phase 1/1a Study of Venetoclax, MLN9708 (ixazomib citrate) and Dexamethasone for Relapsed/Refractory Light Chain Amyloidosis (Protocol Version Date 06/23/21)

II Continuing Review

10005, A Phase 2 Study of Anti-PD-L1 Antibody (Atezolizumab) in Alveolar Soft Part Sarcoma (Protocol Version Date 05/17/21)

III 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 05/14/21)

IV Continuing Review

10104, A Randomized Phase 2 Study of Cabozantinib in Combination with Nivolumab in Advanced, Recurrent Metastatic Endometrial Cancer (Protocol Version Date 01/29/21)

V Continuing Review

10181, A Phase 2 Study of Savolitinib in Subjects with MET Amplified Metastatic Colorectal Cancer (Protocol Version Date 12/03/20)

VI 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 02/08/21)

VII Continuing Review

10302, Phase II Trial of Radium-223 Dichloride in Combination with Paclitaxel in Patients with Bone Metastatic Breast Cancer (Protocol Version Date 05/13/21)

VIII 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)

IX Continuing Review

10387, Pilot Trial of Nivolumab plus Cabozantinib for Advanced Solid Tumors in Patients with HIV Infection (Protocol Version Date 06/01/21)

X Continuing Review

9892, Phase I Dose-Escalation Bioavailability Study of Oral Triapine in Combination with Concurrent Chemoradiation for Locally Advanced Cervical Cancer (LACC) and Vaginal Cancer (Protocol Version Date 03/17/21)

XI Continuing Review

9938, Phase I clinical trial of M6620 in combination with the topoisomerase I inhibitor irinotecan in patients with advanced solid tumors (Protocol Version Date 02/05/21)

XII New Study - Initial Review

10483, Phase Ib trial of Erdafitinib combined with Enfortumab Vedotin following platinum and PD1/L1 inhibitors for metastatic urothelial carcinoma with FGFR2/3 genetic alterations (Protocol Version Date 05/26/21)
