Adult CIRB - Early Phase Emphasis Meeting Agenda

December 3, 2019

I Amendment Prior to Activation

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 10/30/19)

II Continuing Review

10200, A Phase Ib/II Study of the Histone Methyltransferase Inhibitor Pinometostat in Combination with Azacitidine in Patients with 11q23-Rearranged Acute Myeloid Leukemia (Protocol Version Date 10/25/19)

III Continuing Review

10214, Immune Checkpoint Blockade for Kidney Transplant Recipients with Selected Unresectable or Metastatic cancers (Protocol Version Date 10/09/19)

IV Continuing Review

9947, A Randomized Phase 2 Trial of Cisplatin/Gemcitabine with or without M6620 (VX-970) in Metastatic Urothelial Carcinoma (Protocol Version Date 06/04/19)

V New Study - Initial Review

10366, A Phase 1/2 Study of M3814 in Combination with Hypofractionated Radiotherapy for the Treatment of Locally Advanced Pancreatic Adenocarcinoma (Protocol Version Date 10/23/19)