

Adult CIRB - Late Phase Emphasis Meeting Agenda

August 17, 2023

I New Study - Initial Review

A032103, MODERN: An Integrated Phase 2/3 and Phase 3 Trial of MRD-Based Optimization of ADjuvant ThERapy in URothelial CaNcer (Version Date 03/21/23)

II Continuing Review

A021901, Randomized Phase II Trial of Lutetium Lu 177 Dotatate versus Everolimus in Somatostatin Receptor Positive Bronchial Neuroendocrine Tumors (Version Date 05/06/22)

III Continuing Review

AMC-108, Multicenter Phase II Study of Pomalidomide Monotherapy in Kaposi Sarcoma (Version Date 08/05/22)

IV Continuing Review

NRG-GU011, A Phase II Double-Blinded, Placebo Controlled Trial of Prostate Oligometastatic Radiotherapy with or without Androgen Deprivation Therapy in Oligometastatic Prostate Cancer (NRG PROMETHEAN) (Version Date 03/23/23)

V Continuing Review

EA9171, BLAST MRD CML 1 Trial: BLockade of PD-1 Added to Standard Therapy to Target Measurable Residual Disease (MRD) in Chronic Myeloid Leukemia (CML)- A Phase II Study of Adding the Anti-PD-1 Pembrolizumab to Tyrosine Kinase Inhibitors in Patients with CML and Persistently Detectable MRD (Version Date 02/10/23)
