

Adult CIRB - Late Phase Emphasis Meeting Agenda

August 1, 2024

I New Study - Initial Review

EA8231, A Phase III Randomized Trial of Pembrolizumab in Combination with Sacituzumab Govitecan vs Sacituzumab Govitecan Alone in Anti-PD(L)1-Resistant Advanced Urothelial Cancer (Version Date 05/10/24)

II New Study - Initial Review

NRG-HN014, Randomized Phase III Trial of Neoadjuvant Immunotherapy with Response Adapted Treatment versus Standard of Care Treatment for Resectable Stage III/IV Cutaneous Squamous Cell Carcinoma (Version Date 06/28/24)

III Amendment

EA8191, Phase III Study of Local or Systemic Therapy INTensification DIrected by PET in Prostate CANcer Patients with Post-ProstaTEctomy Biochemical Recurrence (INDICATE) (Version Date 07/09/24)

IV Continuing Review

A021901, Randomized Phase II Trial of Lutetium Lu 177 Dotatate versus Everolimus in Somatostatin Receptor Positive Bronchial Neuroendocrine Tumors (Version Date 01/31/24)

V Continuing Review

AMC-108, Multicenter Phase II Study of Pomalidomide Monotherapy in Kaposi Sarcoma (Version Date 07/25/23)

VI Continuing Review

S1416, Phase II Randomized Placebo-Controlled Trial of Cisplatin with or without ABT-888 (Veliparib) in Metastatic Triple-Negative Breast Cancer and/or BRCA Mutation-Associated Breast Cancer with or Without Brain Metastases (Version Date 05/29/24)

VII Continuing Review

MYELOMATCH, Master Screening and Reassessment Protocol (MSRP) for Tier Advancement in the NCI MyeloMATCH Clinical Trials (Version Date 06/12/24)
