

Adult CIRB - Late Phase Emphasis Meeting Agenda

January 18, 2024

I New Study - Initial Review

S2303, Randomized Phase II/III Trial of 2nd Line Nivolumab + Paclitaxel + Ramucirumab versus Paclitaxel + Ramucirumab in Patients with PD-L1 CPS \geq 1 Advanced Gastric and Esophageal Adenocarcinoma (PARAMMUNE) (Version Date 11/10/23)

II Continuing Review

A031902, CASPAR - A Phase III Trial of Enzalutamide and Rucaparib as a Novel Therapy in First-Line Metastatic Castration-Resistant Prostate Cancer (Version Date 12/10/21)

III Continuing Review

A042001, A Randomized Phase II Study Comparing Inotuzumab Plus Chemotherapy versus Standard Chemotherapy in Older Adults with Philadelphia-Chromosome-Negative B-cell Acute Lymphoblastic Leukemia (Version Date 04/05/22)

IV Continuing Review

A091902, A Multicenter Phase II Trial of Paclitaxel with and without Nivolumab in Taxane Naive, and Nivolumab and Cabozantinib in Taxane Pretreated Subjects with Angiosarcoma (Version Date 10/10/23)

V Continuing Review

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 04/18/23)
