

Adult CIRB - Late Phase Emphasis Meeting Agenda

February 16, 2023

I 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)

II 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 03/16/22)

III 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 10/28/22)

IV Continuing Review

S1802, Phase III Randomized Trial of Standard Systemic Therapy (SST) versus Standard Systemic Therapy Plus Definitive Treatment (Surgery or Radiation) of the Primary Tumor in Metastatic Prostate Cancer (Version Date 11/18/21)