

Adult CIRB - Late Phase Emphasis Meeting Agenda June 3, 2021

I Continuing Review

A091404, A Phase II Study of Enzalutamide (NSC# 766085) for Patients with Androgen Receptor Positive Salivary Cancers (Protocol Version Date 09/10/19)

II Continuing Review

EA6174, STAMP: Surgically Treated Adjuvant Merkel cell Carcinoma with Pembrolizumab, a Phase III Trial (Protocol Version Date 08/24/20)

III Continuing Review

EA8183, A Phase III Double Blinded Study of Early Intervention after RADICAl ProstaTEctomy with Androgen Deprivation Therapy with Darolutamide vs. Placebo in Men at Highest Risk of Prostate Cancer Metastasis by Genomic Stratification (ERADICATE) (Protocol Version Date 10/13/20)

IV Continuing Review

NRG-HN007, An Open-Label, Phase III Study of Platinum-Gemcitabine with or without Nivolumab in the First-Line Treatment of Recurrent or Metastatic Nasopharyngeal Carcinoma (Protocol Version Date 02/16/21)

V Continuing Review

S1500, A Randomized, Phase II Efficacy Assessment of Multiple MET Kinase Inhibitors (Cabozantinib [NSC #761968], Crizotinib [NSC #749005], Savolitinib [NSC #785348], and Sunitinib [NSC #736511]) in Metastatic Papillary Renal Carcinoma (PAPMET) (Protocol Version Date 09/15/20)



VI Amendment

E4412, A Phase I Study with an Expansion Cohort/Randomized Phase II Study of the Combinations of Ipilimumab, Nivolumab and Brentuximab Vedotin in Patients with Relapsed/Refractory Hodgkin Lymphoma (Protocol Version Date 04/21/21)