

Adult CIRB - Late Phase Emphasis Meeting Agenda

November 18, 2021

I Continuing Review

EA5163, INSIGNA: A Randomized, Phase III Study of Firstline Immunotherapy alone or in Combination with Chemotherapy in Induction/Maintenance or Postprogression in Advanced Nonsquamous Non-Small Cell Lung Cancer (NSCLC) with Immunobiomarker SIGNature-driven Analysis (Protocol Version Date 10/25/21)

II Continuing Review

EA5182, Randomized Phase III Study of Combination Osimertinib (AZD9291) and Bevacizumab versus Osimertinib (AZD9291) Alone as First-Line Treatment for Patients with Metastatic EGFR-Mutant Non-Small Cell Lung Cancer (NSCLC) (Protocol Version Date 04/14/21)

III Continuing Review

EA8185, Phase II Study of Bladder-Sparing Chemoradiation with Durvalumab in Clinical Stage III, Node Positive bladder Cancer (INSPIRE) (Protocol Version Date 07/15/21)

IV Continuing Review

NRG-GI005, Phase II/III Study of Circulating tumor DNA as a Predictive Biomarker in Adjuvant Chemotherapy in Patients with Stage IIA Colon Cancer (COBRA) (Protocol Version Date 04/07/21)

V New Study - Initial Review

EA8134, InPACT- International Penile Advanced Cancer Trial (International Rare Cancers Initiative Study) (Protocol Version Date 05/24/21 US Protocol Version Date 09/27/21)

VI New Study - Initial Review

NRG-GY025, A Randomized Phase II Trial of Nivolumab and Ipilimumab Compared to Nivolumab Monotherapy in Patients with Deficient Mismatch Repair System Recurrent Endometrial Carcinoma (Protocol Version Date 10/13/21)

VII New Study - Initial Review

S2015, Melanoma Margins Trial (MelMarT): A Phase III, Multi-Centre, Multi-National Randomised Control Trial Investigating 1cm v 2cm Wide Excision Margins for Primary Cutaneous Melanoma (Protocol Version Date 09/01/21 US Protocol Version Date 10/06/21)
