

Adult CIRB - Late Phase Emphasis Meeting Agenda

May 2, 2024

I Amendment

S2000, A Randomized Phase II Trial of Encorafenib + Binimetinib + Nivolumab vs Ipilimumab + Nivolumab in BRAF-V600 Mutant Melanoma with Symptomatic Brain Metastases (Version Date 03/19/24)

II Continuing Review

S2104, Randomized Phase II Trial of Postoperative Adjuvant Capecitabine and Temozolomide versus Observation in High-Risk Pancreatic Neuroendocrine Tumors (Version Date 08/18/23)

III Continuing Review

S2212, Shorter Anthracycline-Free Chemo Immunotherapy Adapted to Pathological Response in Early Triple Negative Breast Cancer (SCARLET), A Randomized Phase III Study (Version Date 06/20/23)

IV Continuing Review

A031801, A Phase II Randomized Trial of Radium-223 Dichloride and Cabozantinib in Patients with Advanced Renal Cell Carcinoma with Bone Metastasis (RadiCaL) (Version Date 02/15/22)

V Continuing Review

A052101, A Randomized Phase 3 Trial of Continuous vs Intermittent Maintenance Therapy with Zanubrutinib as Upfront Treatment in Older Patients with Mantle Cell Lymphoma (INTERCON) (Version Date 11/21/23)



VI Continuing Review

EA1183, FDG PET to Assess Therapeutic Response in Patients with Bonedominant Metastatic Breast Cancer, FEATURE (Version Date 10/21/22)

VII Continuing Review

EA2183, A Phase III Study of Consolidative Radiotherapy in Patients with Oligometastatic HER2 Negative Esophageal and Gastric Adenocarcinoma (EGA) (Version Date 03/28/24)

VIII Continuing Review

NRG-BR004, A Randomized, Double-Blind, Phase III Trial of Taxane/Trastuzumab/Pertuzumab with Atezolizumab or Placebo in First-Line HER2-Positive Metastatic Breast Cancer (Version Date 08/15/22)

IX Continuing Review

NRG-GI008, Colon Adjuvant Chemotherapy Based on Evaluation of Residual Disease (CIRCULATE-NORTH AMERICA) (Version Date 09/25/23)