

Adult CIRB - Late Phase Emphasis Meeting Agenda

April 3, 2025

I. Initial Review

A092204, A Phase II Study of Cabozantinib in Combination with Cemiplimab (REGN2810) (Cabo-Cemiplimab (REGN2810)) versus Cabozantinib Alone in Adolescents and Adults with Advanced Adrenocortical Cancer (Version Date 02/21/25)

II. Initial Review

EA2234, A Randomized Phase II/III Trial of Intraperitoneal Paclitaxel Plus Systemic Treatment vs Systemic Treatment Alone in Gastric Carcinomatosis – STOPGAP II (Version Date 02/14/25)

III. Initial Review

EA6244, A Randomized Phase III Study of Management of Treatment Naive Primary Melanoma in Elderly Patients (Version Date 02/24/25)

IV. Amendment

A071701, Genomically-Guided Treatment Trial in Brain Metastases (Version Date 12/20/24)



V. 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 11/07/24)

VI. Continuing Review

EA2183, A Phase III Study of Consolidative Radiotherapy in Patients with Oligometastatic HER2 Negative Esophageal and Gastric Adenocarcinoma (EGA) (Version Date 10/17/24)

VII. Continuing Review

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

VIII. Continuing Review

S2104, Randomized Phase II Trial of Postoperative Adjuvant Capecitabine and Temozolomide versus Observation in High-Risk Pancreatic Neuroendocrine Tumors (Version Date 07/08/24)

IX. 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 10/24/24)



X. Continuing Review

S2308, Randomized Phase III Study of Mosunetuzumab vs. Rituximab for Low Tumor Burden Follicular Lymphoma (Version Date 10/17/24)