

Adult CIRB - Late Phase Emphasis Meeting Agenda

February 20, 2025

I New Study - Initial Review

A082303, MAXIM: Phase II Study of Mecbotamab-Vedotin, an Anti-AXL Antibody-Drug Conjugate as Treatment for Patients with Mesothelioma Upon Disease Progression After Platinum-Based and/or Immune Checkpoint Inhibitor-Based Systemic Therapy for Advanced Unresectable Disease (Version Date 01/09/25)

II Continuing Review

A082002, A Randomized Phase II/III Trial of Modern Immunotherapy Based Systemic Therapy with or without Radiation Therapy for PD-L1-Negative, Advanced Non-small Cell Lung Cancer (Version Date 09/30/24)

III Continuing Review

NRG-GY004, A Phase III Study Comparing Single-Agent Olaparib or the Combination of Cediranib and Olaparib to Standard Platinum-Based Chemotherapy in Women with Recurrent Platinum-Sensitive Ovarian, Fallopian Tube, or Primary Peritoneal Cancer (Version Date 07/27/23)

IV Continuing Review

EA4151, A Randomized Phase III Trial of Consolidation with Autologous Hematopoietic Cell Transplantation Followed by Maintenance Rituximab vs. Maintenance Rituximab Alone for Patients with Mantle Cell Lymphoma in Minimal Residual Disease-Negative First Complete Remission (Version Date 05/18/23)

V Continuing Review

NRG-GY024, Groningen International Study on Sentinel Nodes in Vulvar Cancer (GROINSS-V) III: A Prospective Phase II Treatment Trial (Version Date 10/19/23)

VI Continuing Review

EA6141, Randomized Phase II/III Study of Nivolumab plus Ipilimumab plus Sargramostim versus Nivolumab plus Ipilimumab in Patients with Unresectable Stage III or Stage IV Melanoma (Version Date 08/22/23)

VII Continuing Review

EA8211, Phase III Randomized Trial of Stereotactic Ablative Radiotherapy (SAbR) for Oligometastatic Advanced Renal Carcinoma (SOAR) (Version Date 10/29/24)

VIII Continuing Review

S2000, A Randomized Phase II Trial of Encorafenib + Binimetinib + Nivolumab vs Ipilimumab + Nivolumab in BRAF-V600 Mutant Melanoma with Symptomatic Brain Metastases (Version Date 05/22/24)

IX Continuing Review

MM10A-EA02, A Randomized Phase II Study of Venetoclax and HMA-Based Therapies for the Treatment of Older and Unfit Adults with Newly Diagnosed FLT3-Mutated Acute Myeloid Leukemia (AML): A MyeloMATCH Treatment Trial (Version Date 06/25/24)

X Continuing Review

EA2176, A Randomized Phase III Study of Immune Checkpoint Inhibition with Chemotherapy in Treatment-Naïve Metastatic Anal Cancer Patients (Version Date 08/15/23)
