

Adult CIRB - Late Phase Emphasis Meeting Agenda

May 15, 2025

I New Study - Initial Review

MM3TCT-A03, A Two Cohort, Randomized, Double-Blind, Placebo-Controlled, Phase II Multi-Center Signal-Finding Study of Venetoclax Combined with Reduced-Intensity Conditioning Followed by Allogeneic Hematopoietic Cell Transplantation then Venetoclax Maintenance in Adult Patients with Acute Myeloid Leukemia in First Complete Remission: A MyeloMATCH Sub-Study (Version Date 03/20/25)

II New Study - Initial Review

S2433, Randomized Phase III Study of Second-Line Chemotherapy with or without Panitumumab for KRAS Wild Type, Locally Advanced or Metastatic Pancreatic Adenocarcinoma (Version Date 04/04/25)

III Continuing Review

S2209, A Phase III Randomized Trial for Newly Diagnosed Multiple Myeloma (NDMM) Patients Considered Frail or in a Subset of “Intermediate Fit” Comparing Upfront Three-Drug Induction Regimens Followed by Double- or Single-Agent Maintenance (Version Date 02/22/24)

IV Continuing Review

A031803, Phase II Trial of Intravesical Gemcitabine and MK-3475 (pembrolizumab) in the Treatment of Patients with BCG-Unresponsive Non-Muscle Invasive Bladder Cancer (Version Date 04/23/25)

V Continuing Review

A092104, A Randomized Phase 2/3 Study of Olaparib plus Temozolomide versus Investigator's Choice for the Treatment of Patients with Advanced Uterine Leiomyosarcoma after Progression on Prior Chemotherapy (Version Date 06/28/24)

VI Continuing Review

A092105, Randomized Phase 2 Study of Nivolumab and Ipilimumab with or without Cabozantinib in Patients with Advanced Nasopharyngeal Carcinoma that have Progressed after Platinum Treatment and Immunotherapy (Version Date 11/07/24)

VII Continuing Review

CALGB-100104, A Phase III Randomized, Double-Blind Study of Maintenance Therapy with CC-5013 (NSC #703813, IND#70116) or Placebo Following Autologous Stem Cell Transplantation for Multiple Myeloma (Version Date 09/27/19)

VIII Continuing Review

CCTG MA.39, Tailor RT: A Randomized Trial of Regional Radiotherapy in Biomarker Low Risk Node Positive and T3N0 Breast Cancer (Version Date 09/19/22)

IX Continuing Review

EA8212, A Randomized Phase III Trial of Intravesical BCG veRsus Intravesical Docetaxel and GEmcitabine Treatment in BCG Naïve High Grade Non-Muscle Invasive Bladder Cancer (BRIDGE) (Version Date 10/28/24)

X Continuing Review

NRG-BN012, A Randomized Phase III Trial of Pre-Operative Compared to Post-Operative Stereotactic Radiosurgery in Patients with Resectable Brain Metastases (Version Date 01/20/23)

XI Continuing Review

NRG-GI006, Phase III Randomized Trial of Proton Beam Therapy (PBT) versus Intensity Modulated Photon Radiotherapy (IMRT) for the Treatment of Esophageal Cancer (Version Date 11/05/20)

XII Continuing Review

NRG-GU013, The Phase III "High Five Trial" Five Fraction Radiation for High-Risk Prostate Cancer (Version Date 07/07/23)
