

Adult CIRB - Late Phase Emphasis Meeting Agenda

July 3, 2025

I Amendment

A041501, A Phase III Trial to Evaluate the Efficacy of the Addition of Inotuzumab Ozogamicin (A Conjugated Anti-CD22 Monoclonal Antibody) to Frontline Therapy in Young Adults (Ages 18-39 Years) with Newly Diagnosed Precursor B-Cell ALL (Version Date 04/24/25)

II New Study - Initial Review

NRG-GU015, The Phase III Adaptive Radiation and Chemotherapy for Muscle Invasive Bladder Cancer Trial (ARCHER) (Version Date 05/28/25)

III New Study - Initial Review

SN2426, A Randomized Phase II Study of Amivantamab (JNJ-61186372) and hyaluronidase (rHuPH20) versus Cetuximab in Immunocompromised Participants with Recurrent Inoperable or Metastatic Cutaneous Squamous Cell Carcinoma (Version Date 06/03/25)

IV Continuing Review

NRG-BN013, Phase III Trial of Single Fraction Stereotactic Radiosurgery (SRS) versus Fractionated SRS (FSRS) for Intact Brain Metastases (Version Date 04/18/25)

V Continuing Review

NRG-BR009, A Phase III Adjuvant Trial Evaluating the Addition of Adjuvant Chemotherapy to Ovarian Function Suppression plus Endocrine Therapy in Premenopausal Patients with pN0-1, ER Positive/HER2-Negative Breast Cancer and an Oncotype Recurrence Score ≤ 25 (OFSET) (Version Date 07/27/23)

VI Continuing Review

A021901, Randomized Phase II Trial of Lutetium Lu 177 Dotatate versus Everolimus in Somatostatin Receptor Positive Bronchial Neuroendocrine Tumors (Version Date 02/05/25)

VII Continuing Review

AMC-108, Multicenter Phase II Study of Pomalidomide Monotherapy in Kaposi Sarcoma (Version Date 10/22/24)

VIII Continuing Review

MYELOMATCH, Master Screening and Reassessment Protocol (MSRP) for Tier Advancement in the NCI MyeloMATCH Clinical Trials (Version Date 03/21/25)

IX Continuing Review

S2206, Phase III Trial of Neoadjuvant Durvalumab (NSC 778709) plus Chemotherapy versus Chemotherapy Alone for Adults with MammaPrint High 2 Risk (MP2) Hormone Receptor (HR) Positive/Human Epidermal Growth Factor Receptor (HER2) Negative Stage II-III Breast Cancer (Version Date 03/26/25)
