

Adult CIRB - Late Phase Emphasis Meeting Agenda

January 19, 2023

I Continuing Review

A031701, A Phase II Study of Gemcitabine Plus Cisplatin Chemotherapy in Patients with Muscle-Invasive Bladder Cancer with Bladder Preservation for Those Patients Whose Tumors Harbor Deleterious DNA Damage Response (DDR) Gene Alterations (Version Date 01/13/21)

II Continuing Review

A051902, A Randomized Phase II Study of CHO(E)P vs CC-486-CHO(E)P vs Duvelisib-CHO(E)P in Previously Untreated CD30 Negative Peripheral T-Cell Lymphomas (Version Date 07/02/21)

III Continuing Review

A081105, Randomized Study of Erlotinib Vs Observation in Patients with Completely Resected Epidermal Growth Factor Receptor (EGFR) Mutant Non-Small Cell Lung Cancer (NSCLC) (Version Date 01/20/21)

IV Continuing Review

E3A06, Randomized Phase III Trial of Lenalidomide versus Observation Alone In Patients with Asymptomatic High-Risk Smoldering Multiple Myeloma (Version Date 09/26/19)

VI Continuing Review

NRG-BR007, A Phase III Clinical Trial Evaluating De-Escalation of Breast Radiation for Conservative Treatment of Stage I, Hormone Sensitive, HER2-Negative, Oncotype Recurrence Score ≤18 Breast Cancer (Version Date 03/05/21)