

Adult CIRB - Late Phase Emphasis Meeting Agenda

May 4, 2023

I Amendment

NRG-BN009, Phase III Trial of Salvage Stereotactic Radiosurgery (SRS) or SRS + Hippocampal-Avoidant Whole Brain Radiotherapy (HA-WBRT) for First or Second Distant Brain Relapse after Upfront SRS with Brain Metastasis Velocity ≥ 4 Brain Metastases/Year (Version Date 04/06/23)

II Continuing Review

10231, NCORP Tissue Procurement Protocol: An NCI Cancer Moonshot Study (Version Date 09/20/19)

III Continuing Review

A041703, A Phase II Study of Inotuzumab Ozogamicin Followed by Blinatumomab for Ph-Negative CD22-Positive B-Lineage Acute Lymphoblastic Leukemia in Newly Diagnosed Older Adults or Adults with Relapsed or Refractory Disease (Version Date 11/02/21)

IV Continuing Review

E1A11, Randomized Phase III Trial of Bortezomib, LENalidomide and Dexamethasone (VRd) Versus Carfilzomib, Lenalidomide and Dexamethasone (CRd) Followed by Limited or Indefinite DURATION Lenalidomide Maintenance in Patients with Newly Diagnosed Symptomatic Multiple Myeloma (ENDURANCE) (Version Date 10/21/20)

V Continuing Review

E4412, A Phase I Study with an Expansion Cohort/Randomized Phase II Study of the Combinations of Ipilimumab, Nivolumab and Brentuximab Vedotin in Patients with Relapsed/Refractory Hodgkin Lymphoma (Version Date 02/02/23)

VI Continuing Review

EA4181, A Randomized 3-Arm Phase II Study Comparing 1.) Bendamustine, Rituximab and High Dose Cytarabine (BR/CR) 2.) Bendamustine, Rituximab, High Dose Cytarabine and Acalabrutinib (BR/CR-A), and 3.) Bendamustine, Rituximab and Acalabrutinib (BR-A) in Patients ≤ 70 years old with Untreated Mantle Cell Lymphoma (Version Date 11/07/22)

VII Continuing Review

S1815, A Phase III Randomized Trial of Gemcitabine, Cisplatin, and Nab-Paclitaxel versus Gemcitabine and Cisplatin in Newly Diagnosed, Advanced Biliary Tract Cancers (Version Date 06/13/21)
