

Adult CIRB - Late Phase Emphasis Meeting Agenda

April 4, 2024

I New Study - Initial Review

S2308, Randomized Phase III Study of Mosunetuzumab vs. Rituximab for Low Tumor Burden Follicular Lymphoma (Version Date 02/16/24)

II Amendment Prior to Activation

EA7222, A Randomized Phase III Trial of Doxorubicin + Pembrolizumab Versus Doxorubicin Alone for the Treatment of Undifferentiated Pleomorphic Sarcoma (UPS) and Related Poorly Differentiated Sarcomas (Version Date 02/16/24)

III Continuing Review

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

IV 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 02/07/24)

V Continuing Review

AMC-107, A Phase 2 Trial of Ixazomib for Kaposi Sarcoma (Version Date 09/22/22)

VI 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)

VII 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 08/21/23)

VIII 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)

IX Continuing Review

GOG-0262, A Phase III Trial of Every-3-Weeks Paclitaxel Versus Dose Dense Weekly Paclitaxel In Combination With Carboplatin With Or Without Concurrent and Consolidation Bevacizumab (NSC #704865, IND #113912) in the Treatment of Primary Stage II, III OR IV Epithelial Ovarian, Peritoneal or Fallopian Tube Cancer and ACRIN 6695: Perfusion CT Imaging To Evaluate Treatment Response in Patients Participating in GOG-0262 (Version Date 11/07/18)

X Continuing Review

S2200, A Phase II Randomized Trial of Cabozantinib (NSC #761968) with or without Atezolizumab (NSC #783608) in Patients with Advanced Papillary Renal Cell Carcinoma (PAPMET2) (Version Date 10/08/23)

XI Continuing Review

S2207, Randomized Phase II Study of the Addition of Targeted Therapeutic Agents to Tafasitamab-Based Therapy in Non-Transplant-Eligible Patients with Relapsed/Refractory Large B-Cell Lymphoma (Version Date 03/18/24)

XII Continuing Review

S2210, A Phase II Study of Neoadjuvant Carboplatin for Localized, High Risk Prostate Cancer with Germline BRCA1/2 Mutations (Version Date 06/07/23)

XIII Continuing Review

EA9152, A Phase Ib/II Study of Venetoclax (ABT-199) in Combination with Liposomal Vincristine or Vincristine Sulfate in Patients with Relapsed or Refractory T-cell or B-cell Acute Lymphoblastic Leukemia (Version Date 07/20/22)
