

Adult CIRB - Late Phase Emphasis Meeting Agenda

April 17, 2025

I New Study - Initial Review

MM1YA-A04, Phase II Study of Cytarabine + Daunorubicin (7 + 3) + Gemtuzumab Ozogamicin vs Cytarabine + Daunorubicin (7 + 3) + Venetoclax for the Treatment of Newly Diagnosed Core Binding Factor Acute Myeloid Leukemia (CBF-AML) in Younger Adults: A MyeloMATCH Substudy (Version Date 03/17/25)

II Continuing Review

E2905, Randomized Phase III Trial Comparing the Frequency of Major Erythroid Response (MER) to Treatment with Lenalidomide (Revlimid®) Alone and in Combination with Epoetin Alfa (Procrit®) in Subjects with Low- or Intermediate-1 Risk MDS and Symptomatic Anemia (Version Date 08/12/22)

III Continuing Review

EAA181, Effective Quadruplet Utilization After Treatment Evaluation (EQUATE): A Randomized Phase III Trial for Newly Diagnosed Multiple Myeloma Not Intended for Early Autologous Transplantation (Version Date 10/24/23)

IV Continuing Review

A052101, A Randomized Phase 3 Trial of Continuous vs Intermittent Maintenance Therapy with Zanubrutinib as Upfront Treatment in Older Patients with Mantle Cell Lymphoma (INTERCON) (Version Date 09/24/24)

V Continuing Review

A092001, Phase 2 Randomized Trial of Neoadjuvant or Palliative Chemotherapy with or Without Immunotherapy for Peritoneal Mesothelioma (Version Date 03/14/25)

VI Continuing Review

EA3231, A Randomized Phase III Study of BRAF-Targeted Therapy vs Cabozantinib in RAI-Refractory Differentiated Thyroid Cancer with BRAF V600Em (Version Date 11/07/24)
