

Adult CIRB - Early Phase Emphasis Meeting Agenda

June 4, 2024

I Continuing Review

10483, Phase Ib trial of Erdafitinib combined with Enfortumab Vedotin following platinum and PD1/L1 inhibitors for metastatic urothelial carcinoma with FGFR2/3 genetic alterations (Version Date 02/07/24)

II Continuing Review

10500, Phase 1/Expansion Study of Tazemetostat Plus Belinostat for the Treatment of Relapsed or Refractory Lymphoma (Version Date 01/17/24)

III Continuing Review

A071401, Phase II Trial of SMO/AKT/NF2/CDK Inhibitors in Progressive Meningiomas with SMO/AKT/NF2/CDK Pathway Mutations (Version Date 08/03/23)

IV Continuing Review

EA2212, A Randomized Phase II Study of Perioperative Atezolizumab +/- Chemotherapy in Resectable MSI-H/dMMR Gastric and Gastroesophageal Junction (GEJ) Cancer (Version Date 12/08/23)

V Continuing Review

10590, NORM: Nodular Lymphocyte-predominant Hodgkin Lymphoma Patients Treated in a Randomized Phase 2 Trial with Either Rituximab or Mosunetuzumab (Version Date 02/19/24)

VI Continuing Review

9825, A Phase 2 Study of Olaparib and Cediranib for the Treatment of Recurrent Ovarian Cancer (Version Date 07/18/23)

VII Continuing Review

9673, PART A: A Multi-Institutional Phase 2 Study of Nivolumab in Refractory Metastatic Squamous Cell Carcinoma of the Anal Canal PART B: A Multi-Institutional Phase 2 Study of Nivolumab or Nivolumab in Combination with Ipilimumab in Refractory Metastatic Squamous Cell Carcinoma of the Anal Canal (Version Date 11/14/22)

VIII Continuing Review

S1318, A Phase II Study of Blinatumomab (NSC-765986) and POMP (Prednisone, Vincristine, Methotrexate 6-Mercaptopurine) for Patients ≥ 65 Years of Age with Newly Diagnosed Philadelphia-Chromosome Negative (Ph-) Acute Lymphoblastic Leukemia (ALL) and of Dasatinib (NSC-732517), Prednisone and Blinatumomab for Patients ≥ 65 Years of Age with Newly Diagnosed Philadelphia-Chromosome Positive (Ph+) ALL and Philadelphia- Chromosome-Like Signature (Ph-like) ALL (Newly Diagnosed or Relapsed/Refractory) With Known or Presumed Activating Dasatinib-Sensitive Mutations or Kinase Fusions (DSMKF) (Version Date 08/16/23)
