

Adult CIRB - Early Phase Emphasis Meeting Agenda

May 6, 2025

I Amendment

10620, A Phase 1b Trial of Teclistamab in Combination with Iberdomide for Relapsed/Refractory Multiple Myeloma (Version Date 03/05/25)

II Amendment

10499, Phase Ib/II Study of ZEN003694 and Entinostat in Advanced and Refractory Solid Tumors (Version Date 03/07/25)

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

10500, Phase 1/Expansion Study of Tazemetostat Plus Belinostat for the Treatment of Relapsed or Refractory Lymphoma (Version Date 02/03/25)

V Continuing Review

10170, A Phase 2 Study of AZD1775 in SETD2-Deficient Advanced Solid Tumor Malignancies (Version Date 08/24/20)

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

10355, A phase I study of DS-8201a in combination with olaparib in HER2-expressing malignancies (Version Date 11/18/24)

VIII 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 02/06/25)

IX 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)

X Continuing Review

10505, A Phase 1 and Randomized Phase 2 Trial of Selinexor and Temozolomide in Recurrent Glioblastoma (Version Date 01/24/25)

XI Continuing Review

10590, NORM: Nodular Lymphocyte-predominant Hodgkin Lymphoma Patients Treated in a Randomized Phase 2 Trial with Either Rituximab or Mosunetuzumab (Version Date 10/03/24)

XII Continuing Review

10629, A Phase I Dose Finding and Phase II Randomized Trial of Iadademstat Combined with Immune Checkpoint Inhibition Maintenance After Initial Chemoimmunotherapy in Patients with Extensive-Stage Small Cell Lung Cancer (Version Date 02/26/25)
