

Adult CIRB - Early Phase Emphasis Meeting Agenda

July 5, 2023

I New Study - Initial Review

10596, A Phase 1b Study of Menin Inhibitor SNDX-5613 in Combination with Daunorubicin and Cytarabine in Newly Diagnosed Patients with Acute Myeloid Leukemia and NPM1 Mutated/FLT3 Wildtype or MLL/KMT2A Rearranged Disease (Version Date 05/05/23)

II New Study ReReview

EA2212, A Randomized Phase II Study of Perioperative Atezolizumab +/- Chemotherapy in Resectable MSI-H/dMMR Gastric and Gastroesophageal Junction (GEJ) Cancer (Version Date 06/20/23)

III Amendment

10346, Pilot Study of DS-8201a Pharmacodynamics in Patients with HER2-expressing Advanced Solid Tumors (Version Date 05/31/23)

IV Continuing Review

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

V Continuing Review

10500, Phase 1/Expansion Study of Tazemetostat Plus Belinostat for the Treatment of Relapsed or Refractory Lymphoma (Version Date 01/12/23)

VI Continuing Review

A071401, Phase II Trial of SMO/AKT/NF2/CDK Inhibitors in Progressive Meningiomas with SMO/AKT/NF2/CDK Pathway Mutations (Version Date 12/06/21)

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 \geq 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 \geq 65 Years of Age with Newly Diagnosed Philadelphia-Chromosome Positive (Ph+) ALL, Relapsed/Refractory 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 09/04/22)

IX Continuing Review

9825, A Phase 2 Study of Olaparib and Cediranib for the Treatment of Recurrent Ovarian Cancer (Version Date 08/30/21)

X Continuing Review

9924, A Phase I Trial of the Combination of Lenalidomide and Blinatumomab in Patients with Relapsed or Refractory Non-Hodgkins Lymphoma (NHL) (Version Date 03/23/21)