

Adult CIRB - Early Phase Emphasis Meeting Agenda

August 2, 2022

I 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 (Protocol Version Date 03/18/21)

II Continuing Review

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

III Continuing Review

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

IV Continuing Review

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

V Continuing Review

EA2142, Randomized Phase II Study of Platinum and Etoposide versus Temozolomide and Capecitabine in Patients with Advanced G3 Non-Small Cell Gastroenteropancreatic Neuroendocrine Tumors including Poorly Differentiated Neuroendocrine Carcinomas and Well-Differentiated Neuroendocrine Neoplasms (Protocol Version Date 01/23/20)

VI 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 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) (Protocol Version Date 08/16/21)

VII New Study - Initial Review

10517, An Open Label, Randomized Phase II Study Neoadjuvant Erdafitinib with or without Atezolizumab in Cisplatin-Ineligible Patients with Muscle Invasive Bladder Cancer (NERA) (Protocol Version Date 06/15/22)

VIII Amendment

10411, Phase 2 Study of Rogaratinib (BAY 1163877) in the Treatment of Patients with Sarcoma Harboring Alterations in Fibroblast Growth Factor Receptor (FGFR) 1-4 and SDH-deficient Gastrointestinal Stromal Tumor (GIST) (Protocol Version Date 06/30/22)

IX Amendment

10492, Phase 1/1b Study of AKT Inhibitor Ipatasertib with Chemoradiation for Locally Advanced Head and Neck Cancer (Protocol Version Date 05/26/22)

X Amendment

9892, Phase I Dose-Escalation Bioavailability Study of Oral Triapine in Combination with Concurrent Chemoradiation for Locally Advanced Cervical Cancer (LACC) and Vaginal Cancer (Protocol Version Date 06/29/22)
