Adult CIRB - Early Phase Emphasis Meeting Agenda

September 6, 2022

I Continuing Review

10030, A phase 1 study of blinatumomab in combination with checkpoint inhibitor(s) of PD-1 (nivolumab) or both PD-1 (nivolumab) and CTLA-4 (ipilimumab) in patients with poor-risk, relapsed or refractory CD19+ precursor B-lymphoblastic leukemia  (Protocol Version Date 01/28/21)

II Continuing Review

10042, A Phase II trial of AZD9291 (osimertinib) with or without bevacizumab in patients with EGFR mutation positive NSCLC and brain metastases (Protocol Version Date 12/11/20)

III Continuing Review

10056, A Phase 2 Study of Talamogene Laherparepvec (T-VEC) and Radiation in Localized Soft Tissue Sarcoma  (Protocol Version Date 05/25/22)

IV Continuing Review

10214, Immune Checkpoint Blockade for Kidney Transplant Recipients with Selected Unresectable or Metastatic Cancers  (Protocol Version Date 01/28/21)

V Continuing Review

10285, Phase 1/2 Study of an EZH2 inhibitor (tazemetostat) in combination with dual BRAF/MEK inhibition in patients with BRAF-mutated metastatic melanoma who progressed on prior BRAF/MEK inhibitor therapy  (Protocol Version Date 03/18/22)

VI Continuing Review

10355, A phase I study of DS-8201a in combination with olaparib in HER2-expressing malignancies  (Protocol Version Date 04/13/22)

VII Continuing Review
10371, A Pharmacodynamics-Driven Trial of Talazoparib, an Oral PARP Inhibitor, in Patients With Advanced Solid Tumors and Aberrations in Genes Involved in DNA Damage Response (Protocol Version Date 06/01/22)

VIII New Study - Initial Review

10528, A Phase 1 Study of the Polymerase Theta (POLθ) Inhibitor Novobiocin in BRCA-mutant and Other DNA Damage Repair-Deficient Solid Tumors (Protocol Version Date 07/25/22)

IX New Study - Initial Review

EAY191, Molecular Analysis for Combination Therapy Choice (ComboMATCH) (Protocol Version Date 08/01/22)

X New Study - Initial Review

EAY191-N4, Molecular Analysis for Combination Therapy Choice (ComboMATCH) EAY191-N4: A Randomized Trial of Selumetinib and Olaparib or Selumetinib Alone in Patients with Recurrent or Persistent RAS Pathway Mutant Ovarian and Endometrial Cancers A ComboMATCH Treatment Trial (Protocol Version Date 08/02/22)