Adult CIRB - Early Phase Emphasis Meeting Agenda

October 1, 2024

I   New Study - Initial Review

10667, Pilot Study of Pidnarulex Pharmacodynamics in Patients with Advanced Solid Tumors (Version Date 09/03/24)

II   Continuing Review ReReview

10347, A phase I study with an expansion cohort of duvelisib and nivolumab in mycosis fungoides (MF) and Sézary syndrome (SS) (Version Date 08/22/23)

III   Continuing Review

10020, A Phase II Open-Label, Randomized Study of PARP Inhibition (olaparib) Either Alone or in Combination with Anti-PD-L1 Therapy (atezolizumab; MPDL3280A) in Homologous DNA Repair (HDR) Deficient, Locally Advanced or Metastatic Non-HER2-positive Breast Cancer (Version Date 12/07/23)

IV   Continuing Review

10144, A Phase II Study of Olaparib (AZD2281) in Patients with Metastatic/Advanced Urothelial Carcinoma and other genitourinary tumors with DNA-Repair Defects (Version Date 02/28/24)

V   Continuing Review

10166, A Phase 2 Study of Atezolizumab and Cobimetinib in PD-1/PD-L1 Inhibitor Resistant or Refractory Non-Small Cell Lung Cancer (Version Date 02/14/24)

VI   Continuing Review

10346, Pilot Study of DS-8201a Pharmacodynamics in Patients with HER2-expressing Advanced Solid Tumors (Version Date 07/15/24)

VII   Continuing Review

10538, Venetoclax In Combination with ASTX727, an All-ORal TherapY for Chronic Myelomonocytic Leukemia and Other MDS/MPN with Excess Blasts (VICTORY-MDS/MPN): a Randomized, Phase 2 trial (Version Date 04/25/24)

VIII   Continuing Review

10612, A Randomized Phase 2 Study of Daratumumab-Selinexor-Velcade-Dexamethasone (Dara-SVD) for High-Risk Newly Diagnosed Multiple Myeloma (Version Date 06/06/24)

IX   Continuing Review

10250, A Phase II Study of the PARP Inhibitor Olaparib in Combination with the DNA Damaging Agent Temozolomide for the Treatment of Advanced Uterine Leiomyosarcoma (Version Date 07/12/23)

X   Continuing Review

10440, A Phase 1/1a Study of Venetoclax, MLN9708 (ixazomib citrate) and Dexamethasone for Relapsed/Refractory Light Chain Amyloidosis (Version Date 09/21/23)