

Adult CIRB - Early Phase Emphasis Meeting Agenda

December 6, 2022

I New Study - Initial Review

10479, A Phase I Dose Escalation-Expansion Trial of Sunitinib Malate plus Lutetium Lu 177 Dotatate (Lutathera) in Somatostatin Receptor Positive Pancreatic Neuroendocrine Tumors (Version Date 10/04/22)

II Amendment

10146, Randomized phase 2 clinical trial of nab-paclitaxel + durvalumab (MEDI4736) + tremelimumab + neoantigen vaccine vs. nab-paclitaxel + durvalumab (MEDI4736) + tremelimumab in patients with metastatic triple negative breast cancer (Version Date 10/26/22)

III Amendment

10268, Randomized Phase II Trial of Topotecan plus M6620 (VX-970, Berzosertib) vs. Topotecan alone in Patients with Relapsed Small-Cell Lung Cancer (Version Date 10/21/22)

IV Amendment

10291, A Phase 1b Study of Berzosertib in Combination with Radiation Therapy to Overcome Therapeutic Resistance in Chemotherapy Resistant Triple Negative and Estrogen and/or Progesterone Receptor Positive, HER2 Negative Breast Cancer (Version Date 09/16/22)

V Amendment

10346, Pilot Study of DS-8201a Pharmacodynamics in Patients with HER2-expressing Advanced Solid Tumors (Version Date 10/12/22)

VI Amendment

10417, Clinical Evaluation of ASTX727 in Combination with Venetoclax All-Oral Therapy vs. Standard of Care Cytarabine and Anthracycline Induction Chemotherapy for Younger FLT3WT Patients with ELN High-Risk Acute Myeloid Leukemia (Version Date 11/15/22)

VII Amendment

10450, A Phase 1b Trial of M3814 (Peposertib) in Combination with Lutetium 177 Dotatate for Well-Differentiated Somatostatin Receptor-Positive Gastroenteropancreatic Neuroendocrine Tumors (GEP-NETs) (Version Date 10/10/22)

VIII 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 10/10/22)

IX 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 03/16/22)

X 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 10/10/22)

XI Continuing Review

10183, A Pilot Study of Tazemetostat and Pembrolizumab (MK-3475) in Advanced Urothelial Carcinoma (Version Date 04/11/22)

XII Continuing Review

10496, A Phase 2 Study of Ipatasertib in Combination with Pembrolizumab for First Line Treatment of Recurrent or Metastatic Squamous Cell Cancer of the Head and Neck (Version Date 03/07/22)

XIII 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 06/27/22)
