

Adult CIRB - Early Phase Emphasis Meeting Agenda

January 18, 2022

I Continuing Review ReReview

10334, BLockade of PD-1 Added to Standard Therapy to target Measurable Residual Disease in Acute Myeloid Leukemia 2 (BLAST MRD AML-2): A randomized Phase 2 Study of the Venetoclax, Azacitidine, and Pembrolizumab (VAP) Versus Venetoclax and Azacitidine as First Line Therapy in Older Patients with Acute Myeloid Leukemia (AML) who are Ineligible or who Refuse Intensive Chemotherapy (Protocol Version Date 10/11/21)

II Continuing Review

10089, A Randomized Phase 2 Study of CDX-1127 (Varlilumab) in Combination with Nivolumab in Patients with Relapsed or Refractory Aggressive B-cell Lymphomas (Protocol Version Date 02/17/21)

III Continuing Review

10096, A Phase 1/2 Study of Combination Olaparib and Radium-223 in Men with Metastatic Castration-Resistant Prostate Cancer with Bone Metastases (COMRADE) (Protocol Version Date 08/26/21)

IV Continuing Review

10268, Randomized Phase II Trial of Topotecan plus M6620 (VX-970, Berzosertib) vs. Topotecan alone in Patients with Relapsed Small-Cell Lung Cancer (Protocol Version Date 05/19/21)

V Continuing Review

10292, DURVA+ : Evaluation of the Safety and Pharmacodynamics of Anti-PD-L1 Antibody Durvalumab in Combination with Chemotherapy in Patients with Advanced Solid Tumors (Protocol Version Date 07/14/21)

VI Continuing Review

10313, A phase IB and randomized open-label phase II study of Berzosertib (M6620, VX-970) in combination with carboplatin/gemcitabine/pembrolizumab in patients with chemotherapy-

naïve advanced non-small cell lung cancer of squamous cell histology (Protocol Version Date 10/20/21)

VII Continuing Review

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) (Protocol Version Date 09/08/21)

VIII Continuing Review

A011203, A Randomized Phase II Trial of Tamoxifen Versus Z-Endoxifen HCL in Postmenopausal Women with Metastatic, Estrogen Receptor Positive, HER2 Negative Breast Cancer (Protocol Version Date 04/24/18)

IX New Study - Initial Review

10445, Phase I Dose Escalation and Expansion Study of Tazemetostat in Combination with Topotecan and Pembrolizumab in Recurrent Small Cell Lung Cancer (Protocol Version Date 11/15/21)

X New Study - Initial Review

10480, Phase Ib/II Study of EPA-based EphA2 Targeted Therapy for Patients with Metastatic Triple-Negative Inflammatory Breast Cancer (Protocol Version Date 12/14/21)

XI Amendment

10367, A Phase 1b Study with Expansion Cohort of Escalating Doses of KRT-232 (AMG 232) Administered in Combination with Standard Induction Chemotherapy (Cytarabine and Idarubicin) in Newly Diagnosed Acute Myelogenous Leukemia (AML) (Protocol Version Date 12/21/21)

XII Amendment

10388, A Phase I Trial of Triapine and Lutetium Lu 177 Dotatate in Combination for Well-Differentiated Somatostatin Receptor-Positive Gastroenteropancreatic Neuroendocrine Tumors (GEP-NETs) (Protocol Version Date 12/07/21)

XIII Amendment

10440, A Phase 1/1a Study of Venetoclax, MLN9708 (ixazomib citrate) and Dexamethasone for Relapsed/Refractory Light Chain Amyloidosis (Protocol Version Date 12/02/21)
