

Adult CIRB - Early Phase Emphasis Meeting Agenda

January 21, 2025

I New Study - Initial Review

10699, A Phase I Trial Combining Triapine with Radiation Therapy for Recurrent Glioblastoma (or variants) (Version Date 12/09/24)

II Continuing Review

10495, Phase I Trial of DS-8201a (Trastuzumab Deruxtecan) in Combination with Neratinib in Solid Tumors with HER2 Alterations (Version Date 06/15/23)

III Amendment

10495, Phase I Trial of DS-8201a (Trastuzumab Deruxtecan) in Combination with Neratinib in Solid Tumors with HER2 Alterations (Version Date 12/09/24)

IV Continuing Review

10507, A Phase 1/2 Study of the Bromodomain Inhibitor ZEN003694 in Combination with Etoposide/Platinum in Patients with NUT Carcinoma (Version Date 10/03/24)

V Continuing Review

10509, A Phase 1 Study of BET Bromodomain Inhibitor ZEN003694 in Combination with the CDK4/6 Inhibitor Abemaciclib in Patients with NUT Carcinoma, Breast Cancer and Other Solid Tumors (Version Date 08/16/24)

VI Continuing Review

10508, A Phase 1 Study of Nivolumab in Combination with ASTX727 in B-cell lymphoma (NHL or HL) with an Expansion Cohort in Relapsed or Refractory Diffuse Large B-Cell Lymphoma (DLBCL) and Hodgkin lymphoma (HL) (Version Date 12/05/24)

VII Continuing Review

EAY131, Molecular Analysis for Therapy Choice (MATCH) (Version Date 10/16/24)

VIII Continuing Review

EAY131-H, MATCH Treatment Subprotocol H: Phase II Study of Dabrafenib and Trametinib in Patients with Tumors with BRAF V600E or V600K Mutations (Excluding Melanoma, Thyroid Cancer, Colorectal Adenocarcinoma, and Non-Small Cell Lung Cancer) (Version Date 03/18/24)

IX Continuing Review

EAY131-J, MATCH Treatment Subprotocol J: Trastuzumab and Pertuzumab (HP) in Patients with Non-Breast, Non-Gastric/GEJ, and Non-Colorectal Cancers with HER2 Amplification (Version Date 10/16/24)

X Continuing Review

EAY131-Z1D, MATCH Treatment Subprotocol Z1D: Nivolumab in Patients with Tumors with Mismatch Repair Deficiency (Version Date 08/11/23)

XI Continuing Review

EAY131-Z1E, MATCH Treatment Subprotocol Z1E: Larotrectinib (LOXO-101) in Patients with Tumors with NTRK Fusions (Version Date 11/10/22)

XII Continuing Review

EAY131-Z1F, MATCH Treatment Subprotocol Z1F: Phase II Study of Copanlisib in Patients with Tumors with PIK3CA Mutations (PTEN Loss Allowed) (Version Date 08/12/19)

XIII Continuing Review

EAY131-A, MATCH Treatment Subprotocol A: Phase II Trial of Afatinib in Patients with Solid Tumors (Other Than Small Cell and Non-Small Cell Lung Cancer) or Lymphomas, That Have Activating Mutations of EGFR and Have Progressed After Standard Treatment (Version Date 09/15/20)

XIV Continuing Review

EAY131-B, MATCH Treatment Subprotocol B: Phase II Study of Afatinib in Patients with Tumors with HER2 Activating Mutations (Version Date 07/10/19)

XV Continuing Review

EAY131-C1, MATCH Treatment Subprotocol C1: Crizotinib in Patients with Tumors with MET Amplification (Version Date 08/19/20)

XVI Continuing Review

EAY131-C2, MATCH Treatment Subprotocol C2: Crizotinib in Patients with Tumors with MET Exon 14 Deletion (Version Date 08/19/20)

XVII Continuing Review

EAY131-E, MATCH Treatment Subprotocol E: Osimertinib (AZD9291) in Patients with Tumors Having EGFR T790M Mutations (Except Non-Small Cell Lung Cancer) or Rare Activating Mutations of EGFR (Version Date 07/16/21)

XVIII Continuing Review

EAY131-F, MATCH Treatment Subprotocol F: Crizotinib in Patients with Tumors (Other Than Adenocarcinoma of Lung or ALCL) with ALK Rearrangements (Version Date 03/11/19)

XIX Continuing Review

EAY131-G, MATCH Treatment Subprotocol G: Phase II Study of Crizotinib in Patients with ROS1 Translocations (Other Than Patients with Non-Small Cell Lung Cancer) (Version Date 01/25/19)

XX Continuing Review

EAY131-I, MATCH Treatment Subprotocol I: GDC-0032 (taselisib) in Patients with Tumors (other than breast cancer) with PIK3CA Mutation but without KRAS Mutation or PTEN Loss (Version Date 11/10/22)

XXI Continuing Review

EAY131-K1, MATCH Treatment Subprotocol K1: Phase 2 Study of JNJ-42756493 (Erdafitinib) in Patients with Tumors with FGFR Amplifications (Version Date 03/11/19)

XXII Continuing Review

EAY131-K2, MATCH Treatment Subprotocol K2: Phase 2 Study of Erdafitinib (JNJ-42756493) in Patients with Tumors with FGFR Mutations or Fusions (Version Date 08/19/20)

XXIII Continuing Review

EAY131-L, MATCH Treatment Subprotocol L: Phase II Study of MLN0128 (TAK-228) in Patients with Tumors with mTOR Mutations (Version Date 08/19/20)

XXIV Continuing Review

EAY131-M, MATCH Treatment Subprotocol M: Phase II Study of MLN0128 (TAK-228) in Patients with Tumors with TSC1 or TSC2 Mutations (Version Date 08/19/20)

XXV Continuing Review

EAY131-N, MATCH Treatment Subprotocol N: Phase II Study of PI3K Beta Specific Inhibitor, GSK2636771, in Patients with Tumors with PTEN Mutation or Deletion, with PTEN Expression on IHC (Version Date 02/06/17)

XXVI Continuing Review

EAY131-P, MATCH Treatment Subprotocol P: Phase II Study of PI3K Beta Specific Inhibitor, GSK2636771, in Patients with Tumors with PTEN Loss by IHC (Version Date 02/06/17)

XXVII Continuing Review

EAY131-Q, MATCH Treatment Subprotocol Q: Ado-trastuzumab Emtansine in Patients with Tumors with HER2 Amplification (Except Breast and Gastric/Gastro-Esophageal Junction (GEJ) Adenocarcinomas) (Version Date 08/19/20)

XXVIII Continuing Review

EAY131-R, MATCH Treatment Subprotocol R: Phase II Study of Trametinib in Patients with BRAF Fusions, or with Non-V600E, Non-V600K BRAF Mutations (Version Date 11/10/22)

XXIX Continuing Review

EAY131-S1, MATCH Treatment Subprotocol S1: Phase II Study of Trametinib in Patients with Tumors with NF1 Mutations (Version Date 11/10/22)

XXX Continuing Review

EAY131-S2, MATCH Treatment Subprotocol S2: Phase II Study of Trametinib in Patients with Tumors with GNAQ or GNA11 Mutations (Version Date 08/19/20)

XXXI Continuing Review

EAY131-T, MATCH Treatment Subprotocol T: GDC-0449 (vismodegib) in Patients with Tumors (except basal cell skin carcinoma) with Smoothed (SMO) or Patched 1 (PTCH1) Mutations (Version Date 08/19/20)

XXXII Continuing Review

EAY131-U, MATCH Treatment Subprotocol U: VS-6063 (defactinib) in Patients with Tumors with NF2 Loss (Version Date 07/10/19)

XXXIII Continuing Review

EAY131-V, MATCH Treatment Subprotocol V: Phase II Study of Sunitinib in Patients with Tumors with cKIT Mutations (Excluding GIST, Renal Cell Carcinoma or Pancreatic Neuroendocrine Tumor) (Version Date 11/10/22)

XXXIV Continuing Review

EAY131-W, MATCH Treatment Subprotocol W: Phase II Study of AZD4547 in Patients with Tumors with Aberrations in the FGFR Pathway (Version Date 05/16/18)

XXXV Continuing Review

EAY131-X, MATCH Treatment Subprotocol X: Phase II Study of Dasatinib in Patients with Tumors with DDR2 Mutations (Version Date 02/06/17)

XXXVI Continuing Review

EAY131-Y, MATCH Treatment Subprotocol Y: AZD5363 in Patients with Tumors with AKT Mutations (Version Date 01/05/22)

XXXVII Continuing Review

EAY131-Z1A, MATCH Treatment Subprotocol Z1A: Binimetinib in Patients with Tumors (Other Than Melanoma) with NRAS Mutations (Version Date 05/16/18)

XXXVIII Continuing Review

EAY131-Z1B, MATCH Treatment Subprotocol Z1B: Phase II Study of Palbociclib (PD-0332991) in Patients with Tumors with CCND1, 2, 3 Amplification (Version Date 06/21/18)

XXXIX Continuing Review

EAY131-Z1C, MATCH Treatment Subprotocol Z1C: Phase II Study of Palbociclib (PD-0332991) in Patients with Tumors with CDK4 or CDK6 Amplification (Version Date 10/09/20)

XL Continuing Review

EAY131-Z1G, MATCH Treatment Subprotocol Z1G: Phase II Study of Copanlisib in Patients with Tumors with PTEN Loss by IHC and any PTEN Sequencing Result (Version Date 07/16/21)

XLI Continuing Review

EAY131-Z1H, MATCH Treatment Subprotocol Z1H: Phase II Study of Copanlisib in Patients with Tumors with Deleterious PTEN Sequencing Result and PTEN Expression by IHC (Version Date 08/19/20)

XLII Continuing Review

EAY131-Z1I, MATCH Treatment Subprotocol Z1I: Phase II Study of AZD1775 in Patients with Tumors Containing BRCA1 and BRCA2 Mutations (Version Date 11/10/22)

XLIII Continuing Review

EAY131-Z1K, MATCH Treatment Subprotocol Z1K: Ipatasertib in Patients with Tumors with AKT Mutations (Version Date 11/10/22)

XLIV Continuing Review

EAY131-Z1L, MATCH Treatment Subprotocol Z1L: BVD-523FB (Ulixertinib) in Patients with Tumors with BRAF Fusions, or with Non-V600E, Non-V600K BRAF Mutations (Version Date 08/19/20)

XLV Continuing Review

EAY131-Z1M, Phase 2 Study of Nivolumab and BMS-986016 (Relatlimab) in Patients with LAG-3+ Tumors with Mismatch Repair Deficiency (MMR-d) after Progression on Anti-PD-1/PD-L1 Therapy (Version Date 01/05/22)
