

**Adult CIRB - Early Phase Emphasis Meeting Agenda**

**June 1, 2021**

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**I Continuing Review**

**10193**, Phase 2 Study of Copanlisib in Combination with Nivolumab in Subjects with Relapsed/Refractory Diffuse Large B-cell Lymphoma and Primary Mediastinal Large B-cell Lymphoma (Protocol Version Date 02/16/21)

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**II Continuing Review**

**CITN-14**, A Randomized Phase II Study of Atezolizumab (MPDL3280A) plus Recombinant Human IL-7 (CYT107) in patients with locally advanced or metastatic urothelial carcinoma (Protocol Version Date 10/11/19)

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**III 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 (Protocol Version Date 09/15/20)

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**IV Continuing Review**

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

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**V Continuing Review**

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

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**VI Continuing Review**

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

**VII Continuing Review**

**EAY131**, Molecular Analysis for Therapy Choice (MATCH) (Protocol Version Date 05/06/21)

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**VIII Continuing Review**

**EAY131-E**, MATCH Treatment Subprotocol E: AZD9291 in Patients with Tumors Having EGFR T790M Mutations (Except Non-Small Cell Lung Cancer) or Rare Activating Mutations of EGFR (Protocol Version Date 02/23/21)

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**IX Continuing Review**

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

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**X 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) (Protocol Version Date 01/25/19)

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**XI 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) (Protocol Version Date 08/19/20)

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**XII 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 (Protocol Version Date 01/25/19)

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### **XIII 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 (Protocol Version Date 08/19/20)

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### **XIV Continuing Review**

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

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### **XV Continuing Review**

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

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### **XVI Continuing Review**

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

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### **XVII Continuing Review**

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

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### **XVIII 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 (Protocol Version Date 02/06/17)

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### **XIX 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 (Protocol Version Date 02/06/17)

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**XX 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) (Protocol Version Date 08/19/20)

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**XXI 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 (Protocol Version Date 08/19/20)

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**XXII Continuing Review**

**EAY131-S1**, MATCH Treatment Subprotocol S1: Phase II Study of Trametinib in Patients with Tumors with NF1 Mutations (Protocol Version Date 08/19/20)

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**XXIII Continuing Review**

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

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**XXIV Continuing Review**

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

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**XXV Continuing Review**

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

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**XXVI 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) (Protocol Version Date 08/19/20)

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**XXVII Continuing Review**

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

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**XXVIII Continuing Review**

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

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**XXIX Continuing Review**

**EAY131-Y**, MATCH Treatment Subprotocol Y: AZD5363 in Patients with Tumors with AKT Mutations (Protocol Version Date 05/06/21)

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**XXX Continuing Review**

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

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**XXXI Continuing Review**

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

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**XXXII Continuing Review**

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

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**XXXIII Continuing Review**

**EAY131-Z1D**, MATCH Treatment Subprotocol Z1D: Nivolumab in Patients with Tumors with Mismatch Repair Deficiency (Protocol Version Date 02/23/21)

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**XXXIV Continuing Review**

**EAY131-Z1E**, MATCH Treatment Subprotocol Z1E: Larotrectinib (LOXO-101) in Patients with Tumors with NTRK Fusions (Protocol Version Date 08/19/20)

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**XXXV Continuing Review**

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

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**XXXVI 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 (Protocol Version Date 08/19/20)

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**XXXVII 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 (Protocol Version Date 08/19/20)

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**XXXVIII Continuing Review**

**EAY131-Z1I**, MATCH Treatment Subprotocol Z1I: Phase II Study of AZD1775 in Patients with Tumors Containing BRCA1 and BRCA2 Mutations (Protocol Version Date 07/10/19)

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**XXXIX Continuing Review**

**EAY131-Z1K**, MATCH Treatment Subprotocol Z1K: Ipatasertib in Patients with Tumors with AKT Mutations (Protocol Version Date 08/19/20)

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**XL 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 (Protocol Version Date 08/19/20)

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**XLI 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 (Protocol Version Date 02/23/21)

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**XLII Amendment**

**10058**, A Phase I Study of talimogene laheparepvec (TALIMOGENE LAHERPAREPVEC) with Neoadjuvant Chemotherapy and Radiation in Adenocarcinoma of the Rectum (Protocol Version Date 04/08/21)

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**XLIII Amendment**

**10358**, Phase 1/1B study of DS-8201a in combination with ATR Inhibition (AZD6738) in advanced solid tumors with HER2 expression (DASH Trial) (Protocol Version Date 04/26/21)

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