

Adult CIRB - Early Phase Emphasis Meeting Agenda

July 7, 2020

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 08/05/19)

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)

III Continuing Review

EAY131-ADON'T USE****, 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 07/10/19)

IV Continuing Review

EAY131-BDON'T USE****, MATCH Treatment Subprotocol B: Phase II Study of Afatinib in Patients with Tumors with HER2 Activating Mutations (Protocol Version Date 07/10/19)

V Continuing Review

EAY131-C1DON'T USE****, MATCH Treatment Subprotocol C1: Crizotinib in Patients with Tumors with MET Amplification (Protocol Version Date 02/28/20)

VI Continuing Review

EAY131-C2DON'T USE****, MATCH Treatment Subprotocol C2: Crizotinib in Patients with Tumors with MET Exon 14 Deletion (Protocol Version Date 02/28/20)

VII Continuing Review

EAY131-EDON'T USE****, 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 10/03/19)

VIII Continuing Review

EAY131, Molecular Analysis for Therapy Choice (MATCH) (Protocol Version Date 02/28/2020)

IX Continuing Review

EAY131-FDON'T USE****, 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)

X Continuing Review

EAY131-GDON'T USE****, 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)

XI Continuing Review

EAY131-HDON'T USE****, 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 07/10/19)



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XII Continuing Review

EAY131-IDON'T USE****, 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)

XIII Continuing Review

EAY131-JDON'T USE****, 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 08/12/19)

XIV Continuing Review

EAY131-K1DON'T USE****, MATCH Treatment Subprotocol K1: Phase 2 Study of JNJ-42756493 (Erdafitinib) in Patients with Tumors with FGFR Amplifications (Protocol Version Date 03/11/19)

XV Continuing Review

EAY131-K2DON'T USE****, MATCH Treatment Subprotocol K2: Phase 2 Study of JNJ-42756493 (erdafitinib) in Patients with Tumors with FGFR Mutations or Fusions (Protocol Version Date 03/11/19)

XVI Continuing Review

EAY131-LDON'T USE****, MATCH Treatment Subprotocol L: Phase II Study of MLN0128 (TAK-228) in Patients with Tumors with mTOR Mutations (Protocol Version Date 10/03/19)

XVII Continuing Review

EAY131-MDON'T USE****, MATCH Treatment Subprotocol M: Phase II Study of MLN0128 (TAK-228) in Patients with Tumors with TSC1 or TSC2 Mutations (Protocol Version Date 02/28/20)

XVIII Continuing Review

EAY131-NDON'T USE****, 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)

XIX Continuing Review

EAY131-PDON'T USE****, 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)

XX Continuing Review

EAY131-QDON'T USE****, 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 02/28/20)

XXI Continuing Review

EAY131-RDON'T USE****, 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 03/11/19)

XXII Continuing Review

EAY131-S1DON'T USE****, MATCH Treatment Subprotocol S1: Phase II Study of Trametinib in Patients with Tumors with NF1 Mutations (Protocol Version Date 03/11/19)

XXIII Continuing Review

EAY131-S2DON'T USE****, MATCH Treatment Subprotocol S2: Phase II Study of Trametinib in Patients with Tumors with GNAQ or GNAI1 Mutations (Protocol Version Date 03/11/19)



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XXIV Continuing Review

EAY131-TDON'T USE****, 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 07/10/19)

XXV Continuing Review

EAY131-UDON'T USE****, MATCH Treatment Subprotocol U: VS-6063 (defactinib) in Patients with Tumors with NF2 Loss (Protocol Version Date 07/10/19)

XXVI Continuing Review

EAY131-VDON'T USE****, 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 07/10/19)

XXVII Continuing Review

EAY131-WDON'T USE****, 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)

XXVIII Continuing Review

EAY131-XDON'T USE****, MATCH Treatment Subprotocol X: Phase II Study of Dasatinib in Patients with Tumors with DDR2 Mutations (Protocol Version Date 02/06/17)

XXIX Continuing Review

EAY131-YDON'T USE****, MATCH Treatment Subprotocol Y: AZD5363 in Patients with Tumors with AKT Mutations (Protocol Version Date 07/10/19)



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XXX Continuing Review

EAY131-Z1ADON'T USE****, MATCH Treatment Subprotocol Z1A: Binimetinib in Patients with Tumors (Other Than Melanoma) with NRAS Mutations (Protocol Version Date 05/16/18)

XXXI Continuing Review

EAY131-Z1BDON'T USE****, 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)

XXXII Continuing Review

EAY131-Z1CDON'T USE****, MATCH Treatment Subprotocol Z1C: Phase II Study of Palbociclib (PD-0332991) in Patients with Tumors with CDK4 or CDK6 Amplification (Protocol Version Date 02/28/20)

XXXIII Continuing Review

EAY131-Z1DDON'T USE****, MATCH Treatment Subprotocol Z1D: Nivolumab in Patients with Tumors with Mismatch Repair Deficiency (Protocol Version Date 12/11/18)

XXXIV Continuing Review

EAY131-Z1EDON'T USE****, MATCH Treatment Subprotocol Z1E: LOXO-101 in Patients with Tumors with NTRK Fusions (Protocol Version Date 10/03/19)

XXXV Continuing Review

EAY131-Z1FDON'T USE****, 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-Z1GDON'T USE****, 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 08/12/19)

XXXVII Continuing Review

EAY131-Z1HDON'T USE****, 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 08/12/19)

XXXVIII Continuing Review

EAY131-Z1IDON'T USE****, MATCH Treatment Subprotocol Z1I: Phase II Study of AZD1775 in Patients with Tumors Containing BRCA1 and BRCA2 Mutations (Protocol Version Date 07/10/19)

XXXIX Continuing Review

EAY131-Z1KDON'T USE****, MATCH Treatment Subprotocol Z1K: Ipatasertib in Patients with Tumors with AKT Mutations (Protocol Version Date 05/14/19)

XL Continuing Review

EAY131-Z1LDON'T USE****, 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 05/14/19)

XLI New Study - Initial Review

10398, A Phase 2 Study of Anti-PD-L1 Antibody (Atezolizumab) in Chondrosarcoma and Clear Cell Sarcoma (Protocol Version Date 05/22/20)
