

Adult CIRB - Early Phase Emphasis Meeting Agenda

August 4, 2020

I Continuing Review

10136, A Phase 2 Study Of AZD1775, A WEE1 Inhibitor, In Patients With CCNE1 Amplification (Protocol Version Date 06/02/20)

II Continuing Review

10186, A Phase I/II Study of Nivolumab plus or minus Ipilimumab in Combination with Multi-fraction Stereotactic Radiosurgery for Recurrent High-grade Radiation-relapsed Meningioma (Protocol Version Date 06/26/20)

III Continuing Review

10291, A Phase 1b Study of M6620 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 (Protocol Version Date 04/13/20)

IV Continuing Review

9782, A Phase 1 Study of Talazoparib (BMN 673) in Combination with Carboplatin and Paclitaxel in Patients with Advanced Solid Tumors (Protocol Version Date 07/16/19)

V Continuing Review

NRG-GY017, Anti PD-L1 (Atezolizumab) as an Immune Primer and Concurrently with Extended Field Chemoradiotherapy for Node Positive Locally Advanced Cervical Cancer (Protocol Version Date 11/08/18)

VI New Study - Initial Review

10404, A Phase 1 Trial of the ATR Inhibitor BAY 1895344 in Combination with Cisplatin and with Cisplatin Plus Gemcitabine in Advanced Solid Tumors with an Emphasis on Urothelial Carcinoma (Protocol Version Date 07/01/20)

VII Amendment

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 05/14/20)

VIII Amendment

EAY131-C1, MATCH Treatment Subprotocol C1: Crizotinib in Patients with Tumors with MET Amplification (Protocol Version Date 05/14/20)

IX Amendment

EAY131, Molecular Analysis for Therapy Choice (MATCH) (Protocol Version Date 05/14/20)

X Amendment

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 05/14/20)

XI Amendment

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



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Version Date 05/14/20)

XII Amendment

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 05/14/20)

XIII Amendment

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 05/14/20)

XIV Amendment

EAY131-L, MATCH Treatment Subprotocol L: Phase II Study of MLN0128 (TAK-228) in Patients with Tumors with mTOR Mutations (Protocol Version Date 05/14/20)

XV Amendment

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 05/14/20)

XVI Amendment

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 05/14/20)

XVII Amendment

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 05/14/20)

XVIII Amendment

EAY131-S1, MATCH Treatment Subprotocol S1: Phase II Study of Trametinib in Patients with Tumors with NF1 Mutations (Protocol Version Date 05/14/20)

XIX Amendment

EAY131-S2, MATCH Treatment Subprotocol S2: Phase II Study of Trametinib in Patients with Tumors with GNAQ or GNA11 Mutations (Protocol Version Date 05/14/20)

XX Amendment

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 05/14/20)

XXI Amendment

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 05/14/20)

XXII Amendment

EAY131-Z1E, MATCH Treatment Subprotocol Z1E: LOXO-101 in Patients with Tumors with NTRK Fusions (Protocol Version Date 05/14/20)

XXIII Amendment

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 05/14/20)

XXIV Amendment

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 05/14/20)

XXV Amendment

EAY131-Z1K, MATCH Treatment Subprotocol Z1K: Ipatasertib in Patients with Tumors with AKT Mutations (Protocol Version Date 05/14/20)

XXVI Amendment

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 05/14/20)
