

Adult CIRB - Early Phase Emphasis Meeting Agenda

October 6, 2020

I Amendment Prior to Activation

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 09/10/20)

II Continuing Review

10015, A Non-Randomized, Open-Label, Phase 2 Study of Trametinib in Patients with Unresectable or Metastatic Epithelioid Hemangioendothelioma (Protocol Version Date 06/23/20)

III Continuing Review

10296, Phase Ib/II trial of copanlisib in combination with trastuzumab and pertuzumab after induction treatment of HER2 positive (HER2+) metastatic breast cancer (MBC) with PIK3CA mutation or PTEN mutation (Protocol Version Date 06/30/20)

IV Continuing Review

9673, PART A: A Multi-Institutional Phase 2 Study of Nivolumab in Refractory Metastatic Squamous Cell Carcinoma of the Anal Canal PART B: A Multi-Institutional Phase 2 Study of Nivolumab or Nivolumab in Combination with Ipilimumab in Refractory Metastatic Squamous Cell Carcinoma of the Anal Canal (Protocol Version Date 08/27/20)

V Continuing Review

9825, A Phase 2 Study of Olaparib and Cediranib for the Treatment of Recurrent Ovarian Cancer (Protocol Version Date 05/24/19)

VI Continuing Review

9914, A Phase I Study of a Combination of MM-398 and Veliparib in Solid Tumors (Protocol Version Date 10/01/19)

VII Continuing Review

9924, A Phase I Trial of the Combination of Lenalidomide and Blinatumomab in Patients with Relapsed or Refractory Non-Hodgkins Lymphoma (NHL) (Protocol Version Date 08/25/20)

VIII Continuing Review

9948, Phase 1 Dose Escalation and Expansion Cohort of Carboplatin and Gemcitabine with or without M6620 (VX-970) in First or Second Recurrence Platinum-Sensitive Epithelial Ovarian, Peritoneal, and Fallopian Tube Cancer (Protocol Version Date 07/23/20)

IX Continuing Review

9952, Phase 1 Trial to Determine the Recommended Phase 2 Dose (RP2D) of M6620 (VX-970) When Combined with Whole Brain Radiotherapy (WBRT) in Patients with Brain Metastases from Lung Cancer (Protocol Version Date 07/07/20)

X Continuing Review

9979, Phase 1 and Pharmacology Study of Oral 5-iodo-2-pyrimidinone-2-deoxyribose (IPdR) as a Prodrug for IUdR-Mediated Tumor Radiosensitization in Brain Metastases (Protocol Version Date 09/04/20)

XI Continuing Review

A071401, Phase II Trial of SMO/AKT/NF2/CDK Inhibitors in Progressive Meningiomas with SMO/AKT/NF2/CDK Pathway Mutations (Protocol Version Date 05/27/20)

XII Continuing Review

EA2142, Randomized Phase II Study of Platinum and Etoposide versus Temozolomide and Capecitabine in Patients with Advanced G3 Non-Small Cell Gastroenteropancreatic Neuroendocrine Tumors including Poorly Differentiated Neuroendocrine Carcinomas and Well-Differentiated Neuroendocrine Neoplasms (Protocol Version Date 01/23/20)

XIII Continuing Review

NRG-LU004, Phase I Trial of Accelerated or Conventionally Fractionated Radiotherapy Combined With MEDI4736 (durvalumab) in PD-L1 High Locally Advanced Non-Small Cell Lung Cancer (NSCLC) (ARCHON-1) (Protocol Version Date 08/03/20)

XIV Continuing Review

S1318, A Phase II Study of Blinatumomab (NSC-765986) and POMP (Prednisone, Vincristine, Methotrexate 6-Mercaptopurine) for Patients ≥ 65 Years of Age with Newly Diagnosed Philadelphia-Chromosome Negative (Ph-) Acute Lymphoblastic Leukemia (ALL) and of Dasatinib (NSC-732517), Prednisone and Blinatumomab for Patients ≥ 65 Years of Age with Newly Diagnosed Philadelphia-Chromosome Positive (Ph+) ALL and Philadelphia-Chromosome-Like Signature (Ph-like) ALL (Newly Diagnosed or Relapsed/Refractory) With Known or Presumed Activating Dasatinib-Sensitive Mutations or Kinase Fusions (DSMKF) (Protocol Version Date 12/06/19)

XV New Study ReReview

NRG-HN008, Phase I Trial with Expansion Cohort of DNA-PK Inhibition and IMRT in Cisplatin-Ineligible Patients with Stage 3-4 Local-Regionally Advanced Head and Neck Squamous Cell Carcinoma (HNSCC) (Protocol Version Date 09/18/20)

XVI New Study - Initial Review

10285, Phase 1/2 Study of an EZH2 inhibitor (tazemetostat) in combination with dual BRAF/MEK inhibition in patients with BRAF- mutated metastatic melanoma who progressed on prior BRAF/MEK inhibitor therapy (Protocol Version Date 08/18/20)

XVII New Study - Initial Review

10371, A Pharmacodynamics-Driven Trial of Talazoparib, an Oral PARP Inhibitor, in Patients With Advanced Solid Tumors and Aberrations in Genes Involved in DNA Damage Response (Protocol Version Date 08/14/20)

XVIII Amendment

9930, A Phase I Trial of MEDI-570 in Patients with Peripheral T-Cell Lymphoma (PTCL) Follicular Variant and Angioimmunoblastic T-Cell Lymphoma (AITL) (Protocol Version Date 08/11/20)
