

Adult CIRB - Early Phase Emphasis Meeting Agenda

August 16, 2022

I Continuing Review

10402, BAY 1895344 Plus Topoisomerase-1 (Top1) Inhibitors in Patients with Advanced Solid Tumors, Phase I Studies with Expansion Cohorts in Small Cell Lung Carcinoma (SCLC), Poorly Differentiated Neuroendocrine Carcinoma (PD-NEC) and Pancreatic Adenocarcinoma (PDA) (Protocol Version Date 05/23/22)

II Continuing Review

10483, Phase Ib trial of Erdafitinib combined with Enfortumab Vedotin following platinum and PD1/L1 inhibitors for metastatic urothelial carcinoma with FGFR2/3 genetic alterations (Protocol Version Date 04/11/22)

III 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)

IV Continuing Review

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 05/25/22)

V 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 11/03/21)

VI Amendment

10388, A Phase I Trial of Triapine and Lutetium Lu 177 Dotatate in Combination for Well-Differentiated Somatostatin Receptor-Positive Gastroenteropancreatic Neuroendocrine Tumors (GEP-NETs) (Protocol Version Date 07/19/22)

VII Amendment

10466, A Phase 2 Study of Bevacizumab, Erlotinib and Atezolizumab in Subjects with Advanced Hereditary Leiomyomatosis and Renal Cell Cancer (HLRCC) Associated or Sporadic Papillary Renal Cell Cancer (Protocol Version Date 06/23/22)

VIII Amendment

ABTC-1801, Phase I/II Study of Pamiparib (BGB-290) with Temozolomide in Recurrent Gliomas with IDH1/2 Mutations (Protocol Version Date 07/07/22)

IX Patient Recruitment Material/Information Docs

10096, A Phase 1/2 Study of Combination Olaparib and Radium-223 in Men with Metastatic Castration-Resistant Prostate Cancer with Bone Metastases (COMRADE) (Protocol Version Date)

X Memos

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)
