

Adult CIRB - Late Phase Emphasis Meeting Agenda

July 16, 2020

I Amendment Prior to Activation

EA5182, Randomized Phase III Study of Combination AZD9291 (osimertinib) and Bevacizumab versus AZD9291 (osimertinib) Alone as First-Line Treatment for Patients with Metastatic EGFR-Mutant Non-Small Cell Lung Cancer (NSCLC) (Protocol Version Date 06/19/20)

II Amendment Prior to Activation

S1905, A Phase I/II Study of AKR1C3-Activated Prodrug OBI-3424 (OBI-3424) in Patients with Relapsed/Refractory T-Cell Acute Lymphoblastic Leukemia (T-ALL)/T-Cell Lymphoblastic Lymphoma (T-LBL) (Protocol Version Date 06/05/20)

III Continuing Review

S1922, Randomized Phase II Selection Study of Ramucirumab and Paclitaxel Versus FOLFIRI In Refractory Small Bowel Adenocarcinoma (Protocol Version Date 02/19/20)

IV New Study - Initial Review

NRG-GU009, Parallel Phase III Randomized Trials for High Risk Prostate Cancer Evaluating De-Intensification for Lower Genomic Risk and Intensification of Concurrent Therapy for Higher Risk Genomic Risk with Radiation (PREDICT-RT) (Protocol Version Date 06/22/20)

V Amendment

EA2165, A Randomized Phase III Study of Nivolumab After Combined Modality Therapy (CMT) in High Risk Anal Cancer (Protocol Version Date 06/12/20)
