

Adult CIRB - Late Phase Emphasis Meeting Agenda

June 1, 2023

I New Study - Initial Review

S1900I, A Phase II Study of Mobocertinib (TAK-788) with or without Ramucirumab in Participants with Previously Treated EGFR Exon 20 Insertion Non-Small-Cell Lung Cancer (LUNG-MAP SUB-STUDY) (Version Date 04/28/23)

II Continuing Review

A041702, A Randomized Phase III Study of Ibrutinib Plus Obinutuzumab Versus Ibrutinib plus Venetoclax and Obinutuzumab in Untreated Older Patients (≥ 65 Years of Age) with Chronic Lymphocytic Leukemia (CLL) (Version Date 04/18/22)

III Continuing Review

EA3163, Phase II randomized trial of neoadjuvant chemotherapy followed by surgery and post-operative radiation versus surgery and post-operative radiation for organ preservation of T3 and T4a (and selected T4b) nasal and paranasal sinus squamous cell carcinoma (NPNSCC) (Version Date 10/19/21)

IV Continuing Review

GOG-0262, A Phase III Trial of Every-3-Weeks Paclitaxel Versus Dose Dense Weekly Paclitaxel In Combination With Carboplatin With Or Without Concurrent and Consolidation Bevacizumab (NSC #704865, IND #113912) in the Treatment of Primary Stage II, III OR IV Epithelial Ovarian, Peritoneal or Fallopian Tube Cancer and ACRIN 6695: Perfusion CT Imaging To Evaluate Treatment Response in Patients Participating in GOG-0262 (Version Date 11/07/18)

V Continuing Review

NRG-LU002, Maintenance Systemic Therapy versus Local Consolidative Therapy (LCT) Plus Maintenance Systemic Therapy for Limited Metastatic Non-Small Cell Lung Cancer (NSCLC): A Randomized Phase II/III Trial (Version Date 02/22/23)

VI Continuing Review

EA9181, A Phase III Randomized Trial of Steroids + Tyrosine Kinase Inhibitor (TKI) Induction with Chemotherapy or Blinatumomab for Newly Diagnosed BCR-ABL-positive Acute Lymphoblastic Leukemia (ALL) in Adults (Version Date 01/23/23)

VII Continuing Review

EA9152, A Phase Ib/II Study of Venetoclax (ABT-199) in Combination with Liposomal Vincristine or Vincristine Sulfate in Patients with Relapsed or Refractory T-cell or B-cell Acute Lymphoblastic Leukemia (Version Date 07/20/22)

VIII Continuing Review

EA9161, A Randomized Phase III Study of the Addition of Venetoclax to Ibrutinib and Obinutuzumab versus Ibrutinib and Obinutuzumab in Untreated Younger Patients with Chronic Lymphocytic Leukemia (CLL) (Version Date 02/01/23)
