

Adult CIRB - Late Phase Emphasis Meeting Agenda

January 6, 2022

I Continuing Review

A011202, A Randomized Phase III Trial Comparing Axillary Lymph Node Dissection to Axillary Radiation in Breast Cancer Patients (cT1-3 N1) Who Have Positive Sentinel Lymph Node Disease After Neoadjuvant Chemotherapy (Protocol Version Date 07/12/21)

II Continuing Review

A031102, A Randomized Phase III Trial Comparing Conventional-Dose Chemotherapy Using Paclitaxel, Ifosfamide, and Cisplatin (TIP) with High-Dose Chemotherapy Using Mobilizing Paclitaxel Plus Ifosfamide followed by High-Dose Carboplatin and Etoposide (TI-CE) as First Salvage Treatment in Relapsed or Refractory Germ Cell Tumors (Protocol Version Date 07/23/21)

III Continuing Review

A041202, A Randomized Phase III Study of Bendamustine Plus Rituximab Versus Ibrutinib Plus Rituximab Versus Ibrutinib Alone in Untreated Older Patients (\geq 65 Years of Age) with Chronic Lymphocytic Leukemia (CLL) (Protocol Version Date 03/20/19)

IV Continuing Review

A081801, Integration of Immunotherapy into Adjuvant Therapy for Resected NSCLC: ALCHEMIST Chemo-IO (ACCIO) (Protocol Version Date 10/25/21)

V Continuing Review

E1912, A Randomized Phase III Study of Ibrutinib (PCI- 32765)-based Therapy vs Standard Fludarabine, Cyclophosphamide, and Rituximab (FCR) Chemoimmunotherapy in Untreated Younger Patients with Chronic Lymphocytic Leukemia (CLL) (Protocol Version Date 05/25/18)

VI Continuing Review

GOG-0213, A Phase III Randomized Controlled Clinical Trial of Carboplatin and Paclitaxel (Or Gemcitabine) Alone or in Combination with Bevacizumab (NSC #704865, IND #113912) followed by Bevacizumab and Secondary Cytoreductive Surgery in Platinum-Sensitive,

Recurrent Ovarian, Peritoneal Primary and Fallopian Tube Cancer. NCI-Supplied Agents: Bevacizumab (NSC #704865, IND #113912)(12/19/2011) (10/01/12) NCT# 00565851 (Protocol Version Date 11/16/18)

VII Continuing Review

GOG-0263, Randomized Phase III Clinical Trial of Adjuvant Radiation Versus Chemoradiation in Intermediate Risk, Stage I/IIA Cervical Cancer Treated with Initial Radical Hysterectomy and Pelvic Lymphadenectomy (Protocol Version Date 05/12/20)

VIII Continuing Review

NRG-GY012, A Randomized Phase II Study Comparing Single-Agent Olaparib, Single Agent Cediranib, and the Combinations of Cediranib/Olaparib, Olaparib/Durvalumab (MEDI4736), Cediranib/Durvalumab (MEDI4736), Olaparib/AZD5363 (Capivasertib) in Women with Recurrent, Persistent or Metastatic Endometrial Cancer. A Multi-Arm Trial for Women with Recurrent or Persistent Endometrial Cancer (Protocol Version Date 11/08/21)

IX Continuing Review

NRG-GY019, A Randomized Phase III, Two-Arm Trial of Paclitaxel/Carboplatin/Maintenance Letrozole Versus Letrozole Monotherapy in Patients with Stage II-IV, Primary Low-Grade Serous Carcinoma of the Ovary or Peritoneum (Protocol Version Date 12/10/19)

X Continuing Review

NRG-LU005, Limited Stage Small Cell Lung Cancer (LS-SCLC): A Phase III Randomized Study of Chemoradiation Versus Chemoradiation Plus Atezolizumab (Protocol Version Date 10/26/21)

XI Continuing Review

S1403, A Randomized Phase II Trial of Afatinib Plus Cetuximab Versus Afatinib Alone in Treatment-Naive Patients with Advanced, EGFR Mutation Positive Non-Small Cell Lung Cancer (NSCLC) (BI 1200.124) (Protocol Version Date 07/29/20)

XII Continuing Review

S1607, A Phase II Study of Combining Talimogene Laherparepvec (T-VEC) (NSC-785349) and Pembrolizumab (MK-3475) (NSC-776864) in Patients with Advanced Melanoma who have Progressed on ANTI-PD1/L1 Based Therapy (Protocol Version Date 10/15/21)

XIII Continuing Review

S1608, Randomized Phase II Trial in Early Relapsing or Refractory Follicular Lymphoma (Protocol Version Date 07/02/21)

XIV Continuing Review

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 07/28/21)

XV Continuing Review

S1925, Randomized, Phase III Study of Early Intervention with Venetoclax and Obinutuzumab versus Delayed Therapy with Venetoclax and Obinutuzumab in Newly Diagnosed Asymptomatic High-Risk Patients with Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma (CLL/SLL): EVOLVE CLL/SLL Study (Protocol Version Date 08/06/21)

XVI Continuing Review

S1929, Phase II Randomized Study of Maintenance Atezolizumab Versus Atezolizumab in Combination with Talazoparib in Patients with SLFN11 Positive Extensive Stage Small Cell Lung Cancer (ES-SCLC) (Protocol Version Date 11/12/21)

XVII Continuing Review

S1933, A Pilot Study of Hypofractionated Radiotherapy Followed by Atezolizumab Consolidation in Stage II or III NSCLC Patients with Borderline Performance Status (Protocol Version Date 06/01/21)

XVIII New Study - Initial Review

A032101, A Phase 2 Trial of ADT Interruption in Patients Responding Exceptionally to AR-Pathway Inhibitor in Metastatic Hormone-Sensitive Prostate Cancer (MHSPC): A-DREAM (Protocol Version Date 11/23/21)

XIX New Study - Initial Review

EA9213, A Phase II Study of Daratumumab-Hyaluronidase for Chemotherapy-Relapsed/Refractory Minimal Residual Disease (MRD) in T Cell Acute Lymphoblastic Leukemia (T-ALL) (Protocol Version Date 12/02/21)

XX Amendment

EA6134, DREAMseq (Doublet, Randomized Evaluation in Advanced Melanoma Sequencing) A Phase III Trial (Protocol Version Date 11/19/21)

XXI Amendment

S1803, Phase III Study of Daratumumab/rHuPH20 (NSC-810307) + Lenalidomide or Lenalidomide as Post-Autologous Stem Cell Transplant Maintenance Therapy in Patients with Multiple Myeloma (MM) using Minimal Residual Disease to Direct Therapy Duration (DRAMMATIC STUDY) (Protocol Version Date 11/16/21)
