

Adult CIRB - Late Phase Emphasis Meeting Agenda

March 5, 2020

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 09/18/18)

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 11/11/19)

III 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)

IV 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)

V Continuing Review



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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 03/23/18)

VI Continuing Review

GOG-0281, A Randomized Phase II/III Study To Assess The Efficacy of Trametinib (GSK 1120212) In Patients With Recurrent Or Progressive Low-Grade Serous Ovarian Cancer Or Peritoneal Cancer. NCT # NCT02101788 (Protocol Version Date 12/11/19)

VII 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)

VIII Continuing Review

NRG-LU005, Limited Stage Small Cell Lung Cancer (LS-SCLC): A Phase II/III Randomized Study of Chemoradiation Versus Chemoradiation Plus Atezolizumab (Protocol Version Date 11/26/19)

IX Continuing Review

NSABP-B-42, A Clinical Trial to Determine the Efficacy of Five Years of Letrozole Compared to Placebo in Patients Completing Five Years of Hormonal Therapy Consisting of an Aromatase Inhibitor (AI) or Tamoxifen Followed by an AI in Prolonging Disease-Free Survival in Postmenopausal Women with Hormone Receptor Positive Breast Cancer (Protocol Version Date 04/16/14)

X Continuing Review

S1607, A Phase II Study of Combining Talimogene Laherparepvec (T-VEC) (NSC-785349) and MK-3475 (Pembrolizumab) (NSC-776864) in Patients with Advanced Melanoma who have Progressed on ANTI-PD1/L1 Based Therapy (Protocol Version Date 11/12/19)



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XI Continuing Review

S1608, Randomized Phase II Trial in Early Relapsing or Refractory Follicular Lymphoma (Protocol Version Date 10/16/19)

XII New Study - Initial Review

S1925, Randomized, Phase II 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 12/03/19)
