



Adult CIRB – Late Phase Emphasis Meeting Agenda

Thursday, June 1, 2017
9:00 am – 11:30 am (Eastern)

I Initial Review

S1608, Randomized Phase II Trial in Early Relapsing or Refractory Follicular Lymphoma (Protocol Version Date 05/05/17)

II Response to Tabled (Initial 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 05/23/17)

III Amendment Review (Revision 3)

S1505, A Randomized Phase II Study of Perioperative mFOLFIRINOX versus Gemcitabine/NAB-Paclitaxel as Therapy for Resectable Pancreatic Adenocarcinoma (Protocol Version Date 05/09/17)

IV 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 11/14/16)

V 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 04/10/17)

VI Continuing Review

CALGB-80405, A Phase III Trial of Irinotecan/5-FU/Leucovorin or Oxaliplatin/5-FU/Leucovorin with Bevacizumab, or Cetuximab (C225), or with the Combination of Bevacizumab and Cetuximab for Patients with Untreated Metastatic Adenocarcinoma of the Colon or Rectum (Protocol Version Date 10/16/15)

VII 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 12/01/16)

VIII **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)
